Health Care Cost Containment and Medical Technology: A Critique of Waste Theory

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The high cost of health care has led to proposals to reduce wasteful medical technology under Medicare and other payment systems. Professor Mehlman warns that achieving this objective, while laudable in theory, is problematic because of the difficulties of defining, detecting and eliminating technology waste.

A particular danger is that, in an effort to reduce waste, patients will be denied not only technologies that are wasteful from the patient's own perspective but technologies that yield net patient benefit. This risk is exacerbated by the Medicare prospective payment system, which rewards hospitals financially in inverse proportion to the amount of care they furnish patients. Professor Mehlman describes legal methods to reduce this risk, and recommends significant changes in the Medicare administrative process.

INTRODUCTION

THE NEED TO control health care costs in the United State has been widely recognized.1 Much of the blame for rising costs has been focused on health care technologies—in particular, expensive,

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"big ticket" items and services. This Article explores the ways in which health care technology is affected by regulatory efforts to control health care costs, especially those programs adopted for the Medicare system. The legal implications of these regulatory efforts will also be investigated.

In this Article, the term "medical technology" will connote a drug, device, or medical or surgical procedure used in medical care. This definition is admittedly broad, including all aspects of the detection, prevention and treatment of disease, but excluding health care delivery organizations. Focusing on technology per-


2. See generally MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS (S. Altman & R. Blendon eds. 1979). "Big ticket" technologies are expensive on a per unit or per treatment basis. They may not, however, be solely responsible for the cost crisis. See Moloney & Rogers, Medical Technology—A Different View of the Contentious Debate Over Costs, 301 NEW ENGL. J. MED. 1413 (1979) (blaming low unit-cost technologies such as laboratory tests for increased health care costs). Unfortunately, segregating technology-related cost increases from increases due to other factors is difficult. See generally OFFICE OF TECHNOLOGY ASSESSMENT, MEDICAL TECHNOLOGY AND COSTS OF THE MEDICARE PROGRAM 45-61 (1984) [hereinafter cited as OTA MEDICARE]. Nevertheless, for purposes of this Article, it is assumed that technology has played a substantial role in the increase in health care costs over the last fifteen years.


4. This is the definition formerly used by the Congressional Office of Technology Assessment. See OFFICE OF TECHNOLOGY ASSESSMENT, STRATEGIES FOR MEDICAL TECHNOLOGY ASSESSMENT 3 (1982) [hereinafter cited as OTA STRATEGIES]. It resembles the one favored by economists. See Warner, Effects of Hospital Cost Containment on the Development and Use of Medical Technology, 56 MILBANK MEMORIAL FUND Q. 187, 191 (1978) (describing economists' general definition of technology as a "defined configuration of all inputs, both human and nonhuman, used in a specific production process"). Some commentators, including Warner, exclude labor inputs from the meaning of the term, defining it primarily as medical hardware. See id. at 191. See also Fineberg, Technology Assessment: Motivation, Capability, and Future Directions, 23 MED. CARE 663, 663 (1985) (defining technology as "knowledge applied to a purpose").

5. Health care delivery organizations, such as hospitals, physicians, and health maintenance organizations, are the entities that provide health care. The OTA has recently broad-
mits discussion of relatively discrete drugs, devices, and surgical and medical procedures that can be evaluated and regulated, more or less, as units.

Classic examples of discrete medical technologies include drugs, such as aspirin and penicillin, and medical devices, such as scalpels and respirators. Although both drugs and medical devices are often used in conjunction with other medical inputs, they can to some extent be treated as separate entities, and indeed are regulated largely as such by the federal government. Surgical and medical technologies are less often thought of as discrete entities, but are somewhat amenable to being so treated. Nevertheless, the utility of this heuristic approach must not be overestimated. As will be explained, it is often extremely difficult to isolate a particular technology from the medical context in which it is used. It is even more difficult to manipulate its development, diffusion and use.

6. The term “technology” in this Article refers to medical technology unless otherwise indicated.


8. Surgical and medical procedures, however, are more difficult to deal with in this fashion than drugs and devices. See infra notes 190-91 and accompanying text.

9. See infra notes 98-100 and accompanying text.

10. Different medical technologies can be categorized in terms of their respective functions. One taxonomy might distinguish between information-gathering technologies such as diagnostic tests and patient monitoring devices, information-processing technologies such as computerized diagnostics and computerized recordkeeping, and treatment technologies. See Anbar, Penetrating the Black Box: Physical Principles Behind Health Care Technology, in THE MACHINE AT THE BEDSIDE: STRATEGIES FOR USING TECHNOLOGY IN PATIENT CARE 23, 32 (S. Reiser & M. Anbar eds. 1984) [this collection of essays will hereinafter be cited as MACHINE AT THE BEDSIDE]; see also Smits, The Clinical Context of Technology Assessment, J. HEALTH POL., POL'Y & L. 31, 35 (1984) (distinguishing between diagnostic and therapeutic technologies, with preventive technologies as a subset of the latter). Another approach is to classify technologies according to usefulness. Technologies that provide new information or patient outcomes might be distinguished from technologies that yield marginally greater information or better outcomes. Technologies that produce the same information or outcome as another technology might be distinguished on the basis of relative cost or ease of use. See id. at 35-37.

A classic division within therapeutic technologies is Lewis Thomas’ breakdown of “decisive” and “half-way” technologies. The former, epitomized by antibiotics, are preventive or curative, and result from genuine understanding of disease mechanisms. Half-way technologies, exemplified by kidney dialysis, “make up for” a disease or postpone disease-related death. L. THOMAS, THE LIVES OF A CELL: NOTES OF A BIOLOGY WATCHER 5-42 (1974). Smits, however, cautions against singling out half-way technologies for scrutiny and criticism, pointing out that, although they are in need of eventual replacement with definitive technologies, they are not “half-way” in terms of current value. See Smits, supra, at 33-34.
Prior to the recent profound changes in the health care system, a particular set of perverse incentives affected medical technology. Medicare, for example, paid health care providers for each technology employed each time they employed it. Consequently, providers were motivated to apply as much technology as possible, regardless of cost.

The providers' desire to do everything possible to help patients, the attraction of using state-of-the-art techniques, combined with the aforementioned incentives, are said to have created a "technological imperative" that led to inappropriate and excessive development, acquisition, and use of technology. In particular,

11. See infra notes 260-67 and accompanying text.
13. See Anderson & Steinberg, To Buy or Not to Buy: Technology Acquisition Under Prospective Payment, 311 NEW ENG. J. MED. 182, 183 (1984). Hellerstein emphasizes the desire of physicians to appear able to benefit their patients even when they may not be able to do so. Technology, he states, serves to distract providers from the "woeful inadequacy" of medicine. Hellerstein, Overdosing on Medical Technology, 86 TECH. REV. 13, 15 (1983). Indeed, "[t]echnology often serves the purposes that religious ritual once did. Better than prayers or candles, technology brings hope." Id. Warner agrees that "technological sophistication is viewed by many—patients, physicians, and administrators—as a surrogate for high quality care." Warner, supra note 4, at 193.

14. The replacement of the scalpel by the laser in surgery is one example of the switch to state-of-the-art technology. See Anbar, supra note 10, at 32.

15. A classic example of the operation of this imperative is the development of the intensive care unit (ICU). The ICU first appeared during World War II as a recovery area for post-operative patients. See L. RUSSELL, TECHNOLOGY IN HOSPITALS: MEDICAL ADVANCES AND THEIR DIFFUSION 41 (1979). By the mid-1950's, "mixed" ICU's were developed in which both post-operative and critically-ill patients were treated. Id. at 42-43. This led to specialized ICU's such as coronary care units, neonatal intensive care units, and burn units. Id. at 43. This proliferation occurred despite data indicating that ICU benefits were marginal. Id. at 70. Hellerstein comments that "[i]ntensive care' sounds like love, so the dying patient is surrounded by monitors and catheters and respirators." Hellerstein, supra note 13, at 15. Another example of the technological imperative is the CT scanner. See Iglehart, The Cost and Regulation of Medical Technology: Future Policy Directions, 55 MILBANK MEMORIAL FUND Q. 25, 30-35 (1977).

16. Besides the desire to help patients and to use the newest and best techniques, the technological imperative is fueled by a number of other factors, including: (1) increased specialization by physicians, see Banta, Embracing or Rejecting Innovations: Clinical Diffusion of Health Care Technology, in MACHINE AT THE BEDSIDE, supra note 10, at 82; Schroeder, Curbing the High Costs of Medical Advances, 1 BUS. & HEALTH 7, 10 (1984) (noting the higher incomes of high-technology specialists); (2) increased numbers of doctors competing with one another for patients, relying on more intensive use of expensive technology to make up for fewer patient visits, see id. at 9-10 (noting predictions of a surplus of 70,000 doctors by 1990 and 150,000 by the year 2000); (3) the increase in patients whose care is paid for by third parties, see Banta, supra, at 83; Schroeder, supra, at 9; (4) increases in malpractice liability and insurance costs, see Banta, supra, at 82; Schroeder, supra, at 9; (5) competition among hospitals for patients and referring physicians, see Health Services Research and Health Statistics Amendments of 1978: Hearings on H.R. 4869, 10389, 11762, and 12166 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and
the old system is said to have permitted, indeed fostered, "waste" in technology. By eliminating this waste through cost-containment efforts, the quality of care could arguably be maintained and even enhanced while costs could be stabilized or reduced.

The leading exponent of this viewpoint is Dr. Arnold S. Relman, editor of the prestigious New England Journal of Medicine, who states: "The cost culprit is not technology per se, but only technology that is ineffective, superfluous, or unsafe."17 Echoing Relman are the new Prospective Payment Commission (PROPAC), the group of experts charged with overseeing and guiding Medicare cost control programs,18 and the Health Care Finance Administration (HCFA), the agency within the United States Department of Health and Human Services (DHHS) charged with administering Medicare.19

Foreign Commerce, 95th Cong., 2d. Sess. 88-89 (1978) [hereinafter cited as Hearings on H.R. 4869] (testimony of Dr. Steven A. Schroeder); and (6) the lack of adequate incentive to be first to abandon, as apposed to adopt, a new technology, see Hawkins, Evaluating the Benefit of Clinical Trials to Future Patients, 5 CONTROLLED CLINICAL TRIALS 13, 14 (1984).


18. PROPAC states that "[i]ncreases in payments for hospital care can be limited while maintaining a high level of quality when productivity is improved. Productivity is improved when fewer or less costly resources are used to yield a product of given quality . . . ." PROPAC 1985, supra note 1, at 24,464. PROPAC was established by the Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65. As amended by the Medicare and Medicaid Budget Reconciliation Amendments of 1984, Pub. L. No. 98-369, 98 Stat. 1061, this legislation authorizes the Director of the Congressional Office of Technology Assessment to appoint a 15-member commission to collect and assess information on health care, particularly on the need to make adjustments in the prospective payment system, and to make recommendations to the Secretary of the U.S. Department of Health and Human Services and Congress. See 42 U.S.C. §§ 1395 ww(d)-(e) (Supp. 1984). PROPAC is specifically authorized to assess the safety, efficacy and cost effectiveness of care. See id. at § 1395ww(e)(6)(E) (Supp. 1984). PROPAC 1985, supra note 1, issued in June, 1985, was its first report.

19. See DEP'T OF HEALTH AND HUMAN SERVICES, STATEMENT OF ORGANIZATION, FUNCTIONS, AND DELEGATIONS OF AUTHORITY, 49 Fed. Reg. 35,247-49 (1984). HCFA states that "[b]y reallocating inputs and outputs toward more cost-effective practice patterns, cost per discharge can decrease in real terms, while quality of care can be potentially improved." 50 Fed. Reg. 24,443 (1985). See also Relman, Assessment of Medical Practices: A Simple Proposal, 303 NEW ENG. J. MED. 153 (1980). Bunker argues that eliminating waste is necessary to provide effective care, stating that "[p]urchase of care that is ineffective or of undocumented efficacy for some patients will almost certainly result in a failure to provide effective care to other patients." Bunker, Evaluation of Medical-Technology Strategies: Proposal for an Institute for Health-Care Evaluation, 308 NEW ENG. J. MED. 687, 691 (1982). Yet, he does not explain why he conceives of health care decisionmaking as such a zero-sum proposition. The purchase of wasteful technology need not preclude proper care for others, although it may prevent the purchase of other non-health care goods, or increase the national
Eliminating wasteful technology appears a desirable and simply attainable objective for cost containment: merely identify and eliminate wasteful technologies or uses of technology. This will save money without compromising the quality of care. Indeed, it may save enough money so that more extreme cost controls, such as technology rationing20 or preventing the development or use of nonwasteful technologies,21 would be unnecessary.

Unfortunately these directives are extremely difficult to achieve. First, the definition of “wasteful” technology is by no means clear. A technology may be wasteful in one sense but not in another. For instance, a technology may not provide a great deal of health care compared to its cost, but may provide more benefit than any alternative technology. Moreover, a technology that is wasteful when viewed from one perspective—say, that of a group insurance plan concerned with holding down its premiums—may not be wasteful when viewed from another perspective—such as that of an individual beneficiary who wants the best technology and is relatively indifferent to the effect of its cost on premium levels. The first task, then, is to define what is meant by “waste,” and to decide the perspective from which technology should be evaluated, since this will
debt. See Moore, Surgical Streams in the Flow of Health Care Financing: The Role of Surgery in National Expenditures: What Costs are Controllable?, 201 ANNALS ON SURGERY 132 (1985) (“The United States’ expenditure for medical care is not a ‘budget’ voted by any responsible body or enacted by some state health system. It is instead a flow of funds from many sources, expended for various aspects of the health care system.”).

20. Technology rationing refers to the denial of technology to some needy patients due to the high cost of providing the technology to all. See generally H. AARON & W. SCHWARTZ, THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE (1984); EMPLOYEE BENEFIT RESEARCH INST., RATIONING HIGH-COST HEALTH CARE: THE CASE OF ORGAN TRANSPLANTS (Issue Brief #31, 1984); Platt, Sounding Board: Cost Containment—Another View, 309 NEW ENG. J. MED. 726, 729 (1983); INST. OF MED., NATIONAL ACADEMY OF SCIENCES, DISEASE BY DISEASE TOWARD NATIONAL HEALTH INSURANCE? (1973). Another type of rationing is denying certain population segments, such as the poor, adequate health care. See, e.g., Blendon & Altman, The Hidden Cost of “Little Ticket” Advances, 1 BUS. & HEALTH 12, 16 (1984).

21. Some commentators argue that elimination of wasteful technology will be insufficient to curb health care costs. Schwartz and Jaskow, for example, state that attributing the health care cost problem to “unnecessary” technologies or to those provided at “avoidably high cost”—arguably examples of waste—is an oversimplification, since they count at most for only a small fraction of rising health care costs. Schwartz & Jaskow, Medical Efficacy Versus Economic Efficiency: A Conflict in Values, 299 NEW ENG. J. MED. 1462, 1464 (1978). To the extent that wasteful technology is interpreted as technology that does not confer any benefit on patients, the Congressional Office of Technology Assessment agrees, stating: “Unfortunately, the rapid rate of growth of Medicare expenditures cannot be stemmed simply by eliminating technologies that do not provide any benefit, because most technologies do provide some benefit, however small or costly the benefit may be.” OTA MEDICARE, supra note 2, at 4.
determine which technologies are targeted in the cost-containment effort.

Assuming agreement can be reached on how waste should be defined, however, major obstacles confront attempts to identify specific wasteful technologies (or their wasteful use). Costs, risks and benefits must be compared, often involving complicated measurements and valuations. These assessments are particularly difficult when a comparison must be made between different intangible benefits, such as additional years of life or relief from pain.

Finally, once "waste" is defined and wasteful technologies are identified, their elimination may be problematic. Deciding what action to take against wasteful technologies raises profound issues concerning the proper relationship between government and the private health care sector. Moreover, there is a serious risk, especially within the Medicare system, that cost control incentives may deny access to nonwasteful as well as to wasteful technologies. The absence of an adequate statutory or regulatory statement of the technologies to which beneficiaries are entitled will further exacerbate efforts to implement a sound anti-waste policy for Medicare.

I. WHAT IS WASTE?

While there may be general agreement that eliminating waste is desirable, there is little consensus on how the term should be defined. Nevertheless, an attempt to define waste might yield the following general categories, which will be discussed in turn: (1) unsafe and or ineffective technologies (or their unsafe or ineffective use), (2) non-cost-effective technologies (or their non-cost-effective use), and (3) technologies that do not yield adequate net benefits.

22. Commentators have described wasteful technology as: (1) ineffective technology, see Bunker, supra note 19, at 691 (1982); Relman, supra note 17, at 669 (1982); (2) care of undocumented efficacy, see Bunker, supra note 19, at 691; (3) useless technology, see H.R. Rep. No. 818, 98 Cong., 2d Sess. 4 (1984); (4) redundant technology, see id.; (5) unsafe or dangerous technology, see Relman, supra note 17, at 669 (1982); Morreim, supra note 17, at 31 (defining wasteful technology as interventions leading directly or indirectly to iatrogenic injury —that is, injury inadvertently caused by the physician or other health care provider); H.R. Rep. No. 818, supra, at 4; (6) superfluous technology, see Relman, supra note 17, at 669; (7) use of more or more costly resources than necessary to yield a given product, see PROPAC 1985, supra note 1, at 24642; (8) unnecessary technology, see Moore, supra note 19, at 135 (discussing unnecessary surgery); (9) poor quality technology, see id. (discussing incapable surgeons); (10) technology that is marginally beneficial at best, see Lack of Data Causes Medical Procedure Waste, 58 Hosp. 28 (1984); and (11) technology that inflates costs without significantly increasing the quality of care, see Smits, supra note 10, at 32).
A. Unsafe and or Ineffective Technologies

A technology or its particular use is considered unsafe, and therefore perhaps wasteful, when its risks exceed the benefits to the patient. Risk of harm is defined in terms of the probability and severity of harm. Therefore, if the probability and the severity of harm from a technology are greater than the probability and the magnitude of the benefits it purports to provide, the technology is unsafe. A surgical procedure would clearly be unsafe, for example, if it had a 50% probability of killing the patient but only a 10% chance of correcting a condition that created a 25% probability of the patient's death.

Safety is a relative concept. A safe technology has a low risk (probability times severity of harm) compared with its potential benefits (probability times magnitude). As a result, the greater the potential benefits of a technology, the greater the risk that might be acceptable for the technology to be deemed safe.

A technology is ineffective if it produces no discernible benefit to the patient. For example, a technology that either produces no positive change in a patient's condition, or that produces a positive

23. The Congressional Office of Technology Assessment defines “safety” as a “judgment of the acceptability of risk (i.e., the probability and severity of an adverse effect) associated with the use of a technology.” OTA STRATEGIES, supra note 4, at 23.

24. See id.; H.D. BANTA, C. BEHNEY & J. WILLEMS, TOWARD RATIONAL TECHNOLOGY AND MEDICINE 98 (1981) (defining “risk of harm” as “the probability of an adverse or untoward outcome’s occurring and the severity of the resultant harm to health of individuals in a defined population, associated with use of a medical technology, applied for a given medical problem under specified conditions of use”). This definition is reminiscent of Learned Hand’s classic expression of the basic standard for determining if an actor exercised reasonable care so as not to have acted negligently: “[I]f the probability be called P; the injury, L; and the burden [of adequate precautions], B; liability depends upon whether B is less than L multiplied by P . . . .” United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).


26. The issue becomes more complicated if the harm and the benefit are different health outcomes. For example, suppose a surgical procedure had a 50% probability of killing the patient, but if it did not cause this outcome it had a 100% probability of eliminating severe pain that the patient would otherwise experience for the rest of his life. In this case, it would be necessary to compare the risk of death with the potential relief from pain; the technology would only be unsafe if the former could be said to outweigh the latter. This conclusion might vary, furthermore, from patient to patient and from time to time.

27. See OTA STRATEGIES, supra note 4, at 23.

28. Banta defines “effectiveness” as “[t]he probability of benefit to individuals in a defined population from medical technology applied for a given medical problem under average conditions of use.” H.D. BANTA, C. BEHNEY & J. WILLEMS, supra note 24, at 98. It is important to distinguish “effectiveness” from “efficacy.” The latter refers to the probability of benefit under ideal rather than average conditions. See id.; OTA STRATEGIES, supra note 4, at 10, 23. Ideal conditions include those that obtain in a carefully conducted clinical test.
change no more frequently or of no greater magnitude than would occur without applying the technology,\textsuperscript{29} would be ineffective. Arguably, providing this technology to patients would be wasteful.

Medical history reveals a number of technologies that flourished for a time but that were eventually determined to be ineffective. One example was the tying off of an artery in the chest in order to treat angina pectoris, a painful symptom of coronary artery disease.\textsuperscript{30} This technology was discarded after several studies in the late 1950's failed to show that the technology produced any positive results.\textsuperscript{31} An example of an ineffective diagnostic technology is the Wasserman test for syphilis, which was used for forty years before it was discovered to identify uninfected people as carriers fifty percent of the time.\textsuperscript{32} Ineffective technologies are by no means rare; expert panels established by the U.S. Food and Drug Administration (FDA) concluded that approximately one-third of the drugs marketed in 1962 lacked sufficient evidence of efficacy to justify their use.\textsuperscript{33}

\textsuperscript{29} This distinction is necessary because a technology may appear to produce a positive change in some patients, but the same changes may appear with the same frequency as a matter of chance in a group of patients with the same disease who are not given the technology. For example, administration of a drug may be associated with the alleviation of disease symptoms in 20% of a group of patients, and the drug therefore might be thought effective. However, the symptoms might disappear in 20% of another, equivalent group of patients who are merely left alone. The comparison of a group of patients receiving a technology with an equivalent group that does not receive it is known as a "controlled" experiment, and is discussed infra at notes 192-202 and accompanying text.


\textsuperscript{31} See Fineberg & Hiatt, \textit{supra} note 30, at 1088.

\textsuperscript{32} See H.D. BANTA, C. BEHNEY & J. WILLEMS, \textit{supra} note 24, at 121. In contrast to the Wasserman test's 50% false positive rate, the ELISA test for detecting the presence in blood of the antibody to LAV/HTLV-III, the virus associated with acquired immune deficiency syndrome (AIDS), and thus whether the person has been infected with the virus, is reported to have a false-positive rate of 1.7%. See McDougal, \textit{Screening Tests for Blood Donors Presumed to Have Transmitted the Acquired Immunodeficiency Syndrome}, 65 BLOOD 772, 772-74 (1985). One commentator lists as ineffective technologies, along with internal mammary ligation, colectomy (removal of the colon) for treatment of epilepsy, hypogastric artery ligation (tying off the hypogastric artery) to treat pelvic hemorrhage, sympathectomy (surgical removal of nerves) for treatment of asthma, adrenalectomy (removal of the adrenal glands) to treat essential hypertension and "wiring" to treat aortic aneurysm, or a bulge in the wall of the aorta. See Evans, \textit{supra} note 30, at 2049.

\textsuperscript{33} See Moses & Brown, \textit{Experiences with Evaluating the Safety and Efficacy of Medical Technologies}, 5 ANN. REV. PUB. HEALTH 267, 288 (1984). These panels were known as the Drug Efficacy Study Implementation, or "DESI," panels. They reviewed the efficacy of virtually all drugs on the market in 1962 which, by virtue of the 1962 New Drug Amendments to the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 87-781, 76 Stat. 780 (1962), were
Some wasteful technologies are both unsafe and ineffective, posing risks but no benefits to patients. A classic example of such a technology is gastric freezing, which was developed in the mid-1950's to treat peptic ulcers. The technique involved swallowing a balloon connected to a nasogastric tube through which alcohol cooled to minus 15 degrees Centigrade was circulated for one hour. Initial reports in 1962 of results in dogs and in twelve human patients were said to show relief from ulcer symptoms, healing and no serious side effects. By the end of 1963, over 15,000 gastric freezing procedures had been performed, and over 1000 machines to chill and pump the alcohol had been sold. In 1964, however, published reports of experiments with the technology revealed that it had no real effectiveness but that it did create a risk of serious side effects. By 1966, use of the technology was rare.

Even if they produced no direct adverse effects on patients, ineffective technologies might be deemed to be prima facie unsafe since they might cause patients to forego treatment with effective alternatives. This was part of the Supreme Court's rationale in upholding the FDA's prohibition on terminal cancer patients obtaining laetrile.

Another type of wasteful technology might be one that was less safe or less effective than another technology. The FDA, which

required for the first time to be efficacious as well as safe in order lawfully to be marketed in interstate commerce.

34. Gastric freezing was developed by Owen Wangensteen, a well-known surgeon at the University of Minnesota Medical School, in conjunction with a small, private refrigeration company, Swenko. See OTA STRATEGIES, supra note 4, at 4; Id., at 167 app. E; Banta & Behney, Efficacy, Safety, and Health Care Policy, 44 CONN. MED. 377, 377-88 (1980).

35. See OTA STRATEGIES, supra note 4, at 4; Miao, Gastric Freezing: An Example of the Evaluation of Medical Therapy by Randomized Clinical Trials, in COSTS, RISKS, AND BENEFITS OF SURGERY 198 (J. Bunker, B. Barnes & F. Mosteller eds. 1977) [this collection hereinafter cited as COSTS, RISKS, AND BENEFITS OF SURGERY].

36. These reported results included a reduction in stomach acid, immediate relief of ulcer pain, and x-ray evidence of ulcer healing. See OTA STRATEGIES, supra note 4, at 4.

37. See OTA STRATEGIES, supra note 4, at 4. The technology was sufficiently accepted that Blue Cross reimbursed providers for performing it on Blue Cross subscribers. See Moses & Brown, supra note 33, at 270.

38. See OTA STRATEGIES, supra note 4, at 4.

39. See id. See generally Greer, Medical Technology: Assessment, Adoption, and Utilization, 5 J. MED. SYSTEMS 129, 139-40 (1981) (describing the gastric freezing episode as a "medical and financial fiasco"). Greer notes that, in 1963, the technology was evaluated and condemned by the American Gastroenterological Association, and laments that no regulatory restraints were placed on the procedure on the basis of this evaluation. Id. at 140.


41. More precisely, relatively unsafe and/or ineffective technologies are those that are less safe than other technologies expected to produce the same benefit; or less effective than other technologies available to treat or to diagnose the same condition, and that present the
must approve the safety and efficacy of drugs and medical devices before they may be marketed lawfully in interstate commerce, has occasionally, albeit rarely, denied approval to market a drug on the basis that it was less safe or less effective than an alternative already on the market.

B. Non-Cost-Effective Technologies

Thus far, the effort to define waste has not considered cost.

same risks; or that are more effective but so much less safe than other technologies available to treat or to diagnose the same condition, or that are safer but so much less effective than alternate technologies, that, on balance, they could be regarded as providing fewer net benefits (benefits minus risks) than the alternatives.

42. The term "drug" is defined in Federal Food, Drug, and Cosmetic Act as any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or any article (other than food) intended to affect the structure or any function of the body, or any article intended for use as a component of such an article. 21 U.S.C. § 321(g) (1982).

43. The term "device" is defined in the Federal Food, Drug, and Cosmetic Act to mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which has the same intended uses as a drug but which does not achieve any of its principal intended purposes through chemical action within the body. 21 U.S.C. § 321(h) (1982). The category of devices is broad, ranging "from surgeon's gloves to jelly-filled teething rings, cardiac pacemakers, hypodermic needles, oxygen units, kidney dialysis machines, surgical sponges, prophylactics, air purifiers, crutches, and tongue depressors." Iglehart, supra note 15, at 43-44 (1977).

44. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351-60 (1982), the FDA regulates the introduction of "new" drugs and medical devices into interstate commerce. "New" denotes not only technologies being introduced for the first time but also technologies that, on the basis of scientific evidence, are not generally recognized as safe and effective by medical experts. See 21 U.S.C. § 321(p) (definition of "new drug"). The Act does not explicitly refer to "new" devices, but employs a combined classification and premarket approval grandfathering system to distinguish between "old" and "new" devices. See 21 U.S.C. §§ 360(c)-(e). Under the Act, the FDA must approve the new drug or device before it may be marketed in interstate commerce. See 21 U.S.C. §§ 331(a), 331(d), 351(f), 355. For a general description of the drug and device provisions of the Act, see OTA STRATEGIES, supra note 4, at 159-60 app. D; Cole, History of Premarket Approval Provisions of the Device Amendments, 35 FOOD DRUG COSM. L.J. 568 (1980); Sauberman, Impact of FDA Regulations on the Cochlear Implant Field, 405 ANN. N.Y. ACAD. SCI. 451, 451-52 (1983). For a history of the medical device provisions, see Iglehart, supra note 15 at 43-47.

45. Conversation with William Vodra, former Associate Chief Counsel for Drugs, Food and Drug Administration (Sept. 16, 1985). The FDA has denied approval of the less effective drug on the basis that it was unsafe, since it would yield less benefit to the patient but with the same degree of risk. Id. It is questionable that the agency has the statutory authority to refuse to approve the marketing of a drug or a device on the basis that it is less effective than an existing alternative.

46. "Cost" refers to the opportunity cost of the technology, i.e., the value of foregone benefits and additional risks associated with a particular technology. Thus, the discussion of waste in terms of unsafe and ineffective technologies might be regarded in part as a discussion of cost. However, to simplify the analysis, the term cost will be used in its narrow, monetary sense unless otherwise indicated.
An unsafe or ineffective technology would be regarded as wasteful even if, so to speak, it grew on trees. Merely determining that a technology is safe, effective, or relatively safe and effective, however, does not establish that technology as a wise use of resources. A technology might also be regarded as wasteful if it is expected to yield the same net benefit as another technology but at a greater cost—that is, if it is not the most efficient,\(^47\) cost-effective technology to treat or to diagnose the patient's condition.\(^48\)

This point is illustrated by comparing several technologies capable of preventing death from end-stage renal disease (ESRD),\(^49\) including kidney transplantation, dialysis at home, dialysis in a special dialysis center, and a technique called continuous ambulatory peritoneal dialysis.\(^50\) The analysis of the relative cost-effectiveness of each technology requires selection of a health outcome as a benefit endpoint.\(^51\) Examples of benefit endpoints include years of

\(^47\) See Weinstein, Economic Assessments of Medical Practices and Technologies, 1 MED. DECISION MAKING 309, 310 (1981) (purpose of cost-effectiveness analysis is "... to assess the efficiency with which limited resources are being allocated to achieve the desired benefits"); K. WARNER & B. LUCE, supra note 1, at 59 (goal of cost-effectiveness analysis is "efficiency," defined as the "attainment of the greatest social good [however defined] permitted by the limits on resources") (bracketed material in original). Warner and Luce's approach assumes an identifiable limit on resources, which may be problematic. A variant on the "efficiency" objective of cost-effectiveness analysis is a "business" orientation. See Kristein, Using Cost-Effectiveness and Cost/Benefit Analysis for Health Care Policy Making, ADV. HEALTH ECON. HEALTH SERVICES RESEARCH 199, 211 (1983) ("One may regard the application of [cost-effectiveness analysis] as an attempt to introduce in the nonbusiness sector the point of view of the business sector").

48. A technology also might be regarded as wasteful if it yielded less net benefit at the same cost as another technology, but this more properly might be deemed a case of relative ineffectiveness. Note that the issue of the cost of a technology—in terms of its opportunity cost—arises only in comparison with the cost of other goods, such as alternate technologies to treat or to diagnose the same condition. Absent other uses for these resources there would be no issue of cost. It is therefore incorrect to ask "how cost-effective is technology X?" The correct question is "how much more cost-effective is technology X than technology Y?" See K. WARNER & B. LUCE, supra note 1, at 43-44. In this Article, however, "non-cost-effective" denotes a technology that is not the most cost-effective alternative available.

49. End-stage renal disease results in the inability to remove impurities from the blood. Toxic substances build up and eventually cause death. The blood of victims of this disease can be artificially cleansed by means of a technique called dialysis, and in some cases a donor kidney can be successfully transplanted. See Delmez, Pathophysiological Principles in Treatment of Patients with Renal Failure, in THE KIDNEY AND BODY FLUIDS IN HEALTH AND DISEASE 492-93, 499 (S. Klahr ed. 1983).

50. See Evans, Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions (pt. 2), 249 J. A.M.A. 2208, 2209 (1983). As other examples of cost-effectiveness technology comparisons, Evans cites a comparison between transplantation and traditional medical and surgical management for end-stage cardiac disease as well as a comparison between coronary artery bypass surgery and percutaneous transluminal coronary angioplasty as treatments for atherosclerosis. Id.

51. A "unifactorial" analysis employs only one health outcome as the benefit endpoint.
life saved by the technology, days without pain, the patient's ability to resume his or her career, or a combination of these. Once the benefit endpoint is identified, the relative ability of each technology to achieve the greatest amount of the endpoint is measured. The technology that achieves the greatest amount of the benefit for the lowest cost is deemed the most cost-effective. All less cost-effective technologies would be regarded as wasteful.

In practice, cost-effectiveness analysis is much more complicated. Alternate technologies are likely to yield varying degrees of different benefits accompanied by different types and amounts of risk. For instance, dialysis and transplantation may yield the same number of additional years of life to a patient with end-stage renal disease. However, while transplantation may afford a better quality of life, dialysis may have a greater likelihood of producing its admittedly more limited benefit, since transplants have a higher rate of failure. In order to perform cost-effectiveness analysis, these variables must all be reduced to a net benefit expressed in terms of the same health outcomes.

The cost of a technology only becomes a factor in defining waste in the case of a safe and effective technology. Only if the benefits of

If more than one outcome is used, the analysis is called "multifactorial." See Butt & Neuhauser, The Machine and the Marketplace: Economic Considerations in Applying Health Care Technology, in MACHINE AT THE BEDSIDE, supra note 4, 140.

52. This would be a function of the probability that the technology would achieve the endpoint.


54. See infra notes 56-65 and accompanying text. Weinstein offers another approach to defining waste in cost-effectiveness terms. Three categories of technologies are distinguished: those that produce a positive expected net health benefit (net referring to benefits minus risks) and a negative expected net cost (net referring to costs minus savings, such as savings from avoidance of future illness); those that produce a negative expected net benefit (i.e., unsafe, ineffective or both); and those that produce positive expected net benefits and positive expected net costs.

By virtue of reducing costs as well as providing benefits, the first category of technologies—called cost-saving technologies—should be fostered in an effort to combat waste. The second category would be attacked as clear cases of waste. The third category—comprised of cost-increasing technologies that confer net benefits—could be ranked in order of the increasing ratio of costs to benefits. If there were a fixed budget for how much could be spent on technology, cost-increasing technologies could be considered non-wasteful descending from the top of the list until the budget limit were reached. See Weinstein, supra note 47, at 311. Alternatively, technologies on the list could be considered wasteful if their cost of achieving a health outcome exceeded a preset amount. See Neuhauser, Cost-Effective Clinical Decision-Making: Implications for the Delivery of Health Services, in COSTS, RISKS, AND BENEFITS OF SURGERY, supra note 35, 30-34. For example, technologies that cost more than $X per additional year of life might be regarded as wasteful.
the technology exceed its risks—i.e., if it is expected to yield net benefit to the patient—does the question of whether the technology yields the most net benefit given its relative cost arise. This suggests that, in principle, the assessment of the cost-effectiveness of a technology in order to determine if it is wasteful should be performed only after the technology is demonstrated to be safe and effective.\textsuperscript{55}

C. Technologies That Yield Inadequate Net Benefits

In comparing technologies to determine which yields the greatest net benefit for the lowest cost, benefit has been considered in terms of health outcomes, such as additional years of life or days without pain. While this facilitates comparing technologies that are expected to yield the same health outcomes, it does not allow a very precise comparison of technologies that are expected to yield different health outcomes, or different mixes of health outcomes. How is a treatment that is expected to provide a patient with additional years of life, for example, to be compared to a technology that only reduces pain? Or how should a technology that is expected to yield five additional years of life and increased mobility, but with little pain relief, be compared with a technology that is expected to yield only three additional years of life, no increased mobility, but substantial pain reduction?

One approach is simply to delineate these different benefits, along with the costs of each technology, and to allow the decision-maker—the patient, for example—to select the technology that offers what seems like the best benefit package for the money. This entails an assessment of the relative utility of the various expected benefits, which will be contingent on each individual decisionmaker’s benefit preferences.

An alternative approach to the problem of different expected benefits is to convert the benefits into common units. This is often referred to as “cost-benefit analysis,” in contrast to cost-effectiveness analysis, described above.\textsuperscript{56} One such common unit is a “quality-adjusted life year” or QALY.\textsuperscript{57} To compare technologies in this

\textsuperscript{55} See Ball, Prospective Payment: Implications for Medical Technology, 100 ANNALS INTERNAL MED. 606, 606-07 (1984) (cost-effectiveness analysis is complementary to safety and effectiveness evaluation of technologies).

\textsuperscript{56} See infra notes 48-55 and accompanying text.

\textsuperscript{57} The term was coined by Bush, Chen & Patrick, Health Status Index in Cost Effectiveness: Analysis of PKU Screening Program, in HEALTH STATUS INDEXES: PROCEEDINGS OF A CONFERENCE (R. Berg ed. 1973). See also K. WARNER & B. LUCE, supra note 1, at 148.
manner, all health benefits are converted into additional years of life, adjusted for non-life benefits such as days without pain or increased mobility. 58 Theoretically, once their benefits are converted to common terms, technologies can be compared, and those that yield fewer QALY's at the same cost, or the same QALY's at greater cost, can be deemed wasteful.

Technology benefits might also be converted into a common denominator of dollars and compared in terms of how many dollars of benefit result from a given dollar cost. Technologies that are expected to yield fewer dollars of benefit per dollar of cost than other technologies can be regarded as wasteful. For example, if the value of an additional year of life is $100,000, a technology that was expected to yield an additional year of life to a patient at a cost of $75,000, or a net benefit of $25,000, would be preferable to a technology that was also expected to yield an additional year of life to the patient, but at a cost of $85,000. Providing the latter rather than the former would be regarded as wasteful. If various health benefits can be assigned dollar values, technologies that produce different benefits can be compared directly. 59

In the discussion so far, converting benefits to dollars would fulfill the same function as converting benefits to QALY's; the only difference is the common unit employed. One advantage of converting benefits to dollars, however, is that technologies can be evaluated in terms of whether or not they provide a net benefit in

58. See Hellinger, Controlling Costs by Adjusting Payment for Medical Technologies, 19 Inquiry 34, 40 (1982).

59. "Cost effectiveness analysis" is often used to refer to evaluations that compare technologies according to how much they cost to yield a unit of the same health outcome, such as additional years of life. See, e.g., Weinstein, supra note 47, at 310-11. In contrast, evaluations that compare technologies that produce different health outcomes are often referred to as "cost-benefit" analyses. See Fuchs, What is CBA/CEA, and Why are They Doing This To Us?, 303 New Eng. J. Med. 937, 937-938 (1980). In this sense, a comparison of technologies on the basis of QALY's might be regarded as cost-benefit rather than cost-effectiveness analysis. See Hellinger, supra note 58, at 40; K. WARNER & B. LUCE, supra note 1, at 48-49.

Another distinction that is often made between cost-effectiveness and cost-benefit analysis, however, is that only the latter typically measures benefits as well as costs in dollars. See, e.g., Butt & Neuhauser, supra note 51, at 139-40. According to this distinction, QALY comparisons would constitute cost-effectiveness rather than cost-benefit analyses. Nevertheless, cost-effectiveness analysis can be performed so long as benefit is measured in common units for all technologies under consideration, and this can be in dollars. See Weinstein, supra note 47, at 311. Moreover, cost-benefit analysis need not measure benefits in monetary terms. See id. at 312.

In this Article, cost-effectiveness analysis will refer to evaluations and comparisons aimed at determining which technology produces the greatest amount of a given health outcome at the least cost. Cost-benefit analysis will refer to evaluations and comparisons of technologies where the benefits are converted into common units, such as QALY's or dollars.
dollars. For example, if an additional year of life were valued at $50,000, a technology that was expected to yield one additional year of life at a cost of $100,000 would be wasteful.

This in turn compels an evaluation of whether a cost-effective technology to achieve a given health outcome is worth it. Cost-effectiveness analysis merely aims at pinpointing which technology is the cheapest to achieve a given health outcome; cost-benefit analysis aims to determine if achieving the health outcome in the most cost-effective fashion is desirable or if it is an efficient use of resources.

To illustrate, cost-effectiveness analysis may disclose that technology A can save a patient one year of life for $100,000 while technology B could save a year of life for only $90,000; this presumably would lead to a preference for technology B, and under these circumstances technology A might be regarded as wasteful. But no information has been provided on whether a year of life is worth $90,000—that is, whether technology B is also wasteful. Nor can cost-effectiveness analysis determine if technology C, which relieves a patient’s pain for one week for $9,000, is preferable to technology D, which relieves the pain for two weeks for $15,000. Even QALY-based cost-benefit analysis cannot answer these questions; it can reveal which technology alternative is expected to yield the greatest amount of QALY’s per unit of cost, but not whether the purchase of this quantity of health outcome is a wise use of resources. Converting benefits into dollars, however, in theory permits these comparisons to be made. If a pain-free week is valued at $25,000, then technology C is cost-beneficial and not wasteful; if each additional week is also worth $25,000, then technology D is preferable to technology C.

60. Unless benefits are converted to units such as dollars, assessing net benefit must be restricted to the non-cost-related question of whether the benefits from the technology are greater than the risks. See supra notes 23-45 and accompanying text.

61. See Butt & Neuhauser, supra note 51, at 140.

62. See Weinstein, supra note 47, at 311-12 (“Because it avoids the problem of assigning economic value to health benefits, [non-monetary] cost-effectiveness analysis does not provide an unambiguous basis for concluding that a technology is or is not ‘cost-effective.’ Such a determination would have to depend on the judgment as to whether the calculated cost-effectiveness ratio exceeds an appropriate cut-off level.”).

63. This approach is fraught with practical difficulties, however. See infra notes 213-29 and accompanying text.

64. It would be incorrect to describe technology D as “cost-beneficial” compared to technology C. Instead, technology D yields a greater expected net benefit than C. See K. WARNER & B. LUCE, supra note 1, at 106-07. It is also preferable to express cost-benefit comparisons between technologies in terms of relative net benefit rather than ratios of costs to benefits. Cost-benefit ratios are sensitive to whether a positive technology effect is considered
Once benefits are converted into dollars, health care technologies can be compared to non-health care technologies and to other competing potential purchases. For example, if the net benefit of a life-extending technology were $100,000 per patient and the net benefit of providing adequate housing were $200,000 per person, the former could be regarded as a less efficient use of resources—wasteful, perhaps—in comparison with the latter.65

D. The Problem of Perspective

The three approaches to defining waste described above differ according to the parameters they evaluate: risk versus benefit for safety and effectiveness assessment, cost versus health outcome for cost-effectiveness analysis, and cost versus benefit for cost-benefit analysis. These are not merely alternate ways of saying that a particular technology is wasteful. The technologies that would be regarded as wasteful change depending on the definition that is adopted. A technology that is safe and effective, and therefore not wasteful on that account, nevertheless might be wasteful by virtue of not being cost-effective, and a cost-effective technology might be wasteful by virtue of providing inadequate net benefit.66

Different technologies may be classified as wasteful not only because different definitions of waste may be employed, but also by virtue of the choice of perspective, the standpoint from which the risks, costs, and benefits of technology are assessed. A number of perspectives are possible, reflecting the fact that evaluation of technologies occurs at a number of levels in the health care system. At the microlevel, there is first the perspective of the individual patient. This in turn can differ depending on the patient’s circumstances. For example, a patient in need of a technology, insured either by a government program such as Medicare or by private health insurance, would be likely to have a different perspective than a patient who is not insured and who therefore must pay directly for the technology.67 Furthermore, a patient in need of a technology in order to be a benefit or a negative cost factor, although such a distinction actually should be inconsequential. See id.

65. See id.

66. These three principle parameters can be grouped in order of priority. Generally speaking, a technology that would be deemed wasteful because it is unsafe would not need to be evaluated for cost-effectiveness, and a technology that is not cost-effective would not need to be assessed for its net benefits.

67. Some commentators believe that waste can best be curbed by making health care consumers (i.e., patients) and payors the same. This view has led to proposals to increase the degree to which patients resemble consumers in a market—proposals characterized both by
to save his life might have a different reaction to the risks, benefits, and costs of a technology than a potential patient contemplating what type of health insurance package to purchase.68

Similarly, a potential patient deciding which health insurance to buy views his need for health care from a different perspective than the insurance company itself. The insurance company is presumably interested in maximizing its net income, the combined premiums of all of its policyholders less administrative costs and the payments the insurance company must make for their health care. The potential patient, in contrast, presumably is interested in maximizing his own individual utility, which would be affected by the total group of policyholders only to the extent that fluctuations in their premiums or in the company's payments for their care affected his premiums or the type of care for which the company would reimburse.69 The perspective of a government third-party payment program, such as Medicare, also differs from that of a private insurer; the objective of the government program is unlikely to be the maximization of net revenue, but instead the achievement of social or political goals.

making patients pay for care and by making the health care system as much of a free market system as possible. See, e.g., OFFICE OF TECHNOLOGY ASSESSMENT, MEDICAL TECHNOLOGY UNDER PROPOSALS TO INCREASE COMPETITION IN HEALTH CARE 58 (1982) [hereinafter cited as OTA COMPETITION] ("Procompetitive proposals attempt to align (sic) individual preferences and costs more closely with social preferences and costs. Almost by definition, such convergence is professed to assure and improve quality."). A key feature of this approach is prepaid health care. Its proponents recognize that "the sick or worried patient is in a poor position to make an economic analysis of treatment alternatives." A. ENTHOVEN, HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE (1980), quoted in OTA COMPETITION, supra.

The viability of this "consumer-competitive" approach is questionable; because they lack knowledge and expertise, patients are unlikely to behave like rational consumers in a true market. See infra notes 257, 386-87 and accompanying text. Nevertheless, it cannot be denied that the third-party payment system, by divorcing the purchaser of health care from the beneficiary, creates incentives for waste. See supra notes 12-16 and accompanying text.

68. One commentator advocates the insurance purchaser viewpoint as the appropriate one from which to determine how to maximize utility, considering that the cost of a technology will be borne largely by those who never use it. Goddeeris, Medical Insurance, Technological Change, and Welfare, 22 Econ. Inquiry 56, 58 (1984). Goddeeris does not, however, consider the impact of intangible costs and benefits in his utility assessment. See infra notes 213-29 and accompanying text. Moreover, Goddeeris ignores the distinctly different risk aversiveness—hence different willingness to pay—of a sick patient contemplating a health insurance purchase, on the one hand, and a well patient, on the other. See infra note 229 and accompanying text.

Health care providers, moreover, possess perspectives that may differ greatly from those of patients and third-party payors. The perspective of the physician caring for the patient differs from those of his professional colleagues, and their perspective in turn differs from that of hospitals and other health care provider organizations. 70

Finally, there is the somewhat elusive perspective often referred to as that of "society." 71 This perspective is most often contrasted with that of the individual patient. 72 The clearest illustration of the divergence between the perspective of an individual patient and that of society arises in a choice between a preventive and a therapeutic technology for the same disease. From a societal standpoint, the net benefit to be expected from the preventive technology may be greater than the net benefit from the therapeutic technology, since preventing the disease may avoid substantial future health care expenditures. From the standpoint of a patient with the disease, however, the preventive technology would offer virtually no benefit at all. 73

70. Smits discusses how the various perspectives affect the selection of diagnostic technologies. The physician's perspective focuses on which test provides the best information about the patient. The insurer does not care which test is used so long as it does not cost more than the alternatives and so long as only one test is used. The hospital administrator is most concerned about expensive tests that disproportionately affect his budget. Finally, the manager of a hospital floor views diagnostic technologies in terms of the "relative value of items that have low unit costs but are used frequently." Smits, supra note 10, at 32-33.

71. "Society" presumably refers to the United States, not the entire world.

72. See, e.g., Weinstein, Pliskin & Stason, Coronary Artery Bypass Surgery: Decision and Policy Analysis, in COSTS, RISKS, AND BENEFITS OF SURGERY, supra note 35, at 363 ("What is optimal medical care for the individual patient may not be optimal where we, as society collectively, consider what it is costing us."). The paper discusses a study of coronary bypass surgery in which the authors conclude that the operation is more effective than nonsurgical treatments for most patients, but that it is more expensive than nonsurgical treatments in terms of the cost per additional QALY (quality-adjusted life year). Id. QALY's are discussed supra at notes 57-58 and accompanying text. In other words, from an individual patient's standpoint, bypass surgery yields a greater net benefit than alternative treatments, while from a broader, societal perspective aimed at obtaining the most additional QALY's at the least cost, the technology is not the most cost-effective. Other commentators distinguish between the perspectives of providers, consumers and society, see OTA COMPETITION, supra note 67, and between the perspectives of physicians, patients and society. See Tancredi, Social and Ethical Implications in Technology Assessment, in CRITICAL ISSUES IN MEDICAL TECHNOLOGY 93-99 (B. McNeil & E. Cravalho eds. 1982) [this collection hereinafter cited as CRITICAL ISSUES IN MEDICAL TECHNOLOGY].

73. The divergence between societal and patient perspective is widely recognized. See Dunlop, Our Emerging Technology—How Much is Enough?, 28 MD. STATE MED. J 42, 42-44 (1979) (statement of the past president of the American College of Surgeons that "[w]hat is the optimal medical care for the individual patient may not be optimal when society collectively considers what it is costing"). Often the dichotomy is portrayed from the standpoint of the patient's physician versus society. See Fineberg & Hiatt, supra note 30, at 1090 (physi-
Differences in perspective are reflected in the different approaches to defining wasteful technology. Safety and effectiveness,
for example, are invariably assessed from a patient perspective; a
technology that is unsafe for a patient or that has no demonstrable
therapeutic effect cannot be safe or effective in any other sense.\textsuperscript{74} Cost-effectiveness assessments, however, may be made from a
number of perspectives. For example, a technology may be evaluated in terms of whether or not it is the most cost-effective method:
(1) of achieving a desired health outcome in a particular individual
(patient perspective); (2) of maximizing a desired health outcome in
a group such as a pool of insureds (insurance perspective); or (3) of
maximizing total utility in an economic sense (societal perspective).\textsuperscript{75}

The choice of perspective will dictate which technologies are
wasteful by virtue of not being cost-effective. A technology might
be the cheapest way of prolonging a particular patient's life, but
may not be the cheapest way of prolonging lives generally. For ex-
ample, a vaccine may save lives far more cheaply than heart trans-
plants. From the lifesaving perspective of society, therefore, heart
transplants may seem wasteful because they are not as cost-effective
a means of achieving the desired health effect of saving lives as the
vaccine. However, the transplant may well be cost-effective from
the point of view of the patient. Furthermore, different perspectives
yield different waste targets when technology is evaluated by cost-
benefit analysis.\textsuperscript{76}

In short, the definition of waste in technology is dependent not
only on which criteria of waste are adopted but also on the perspec-
tive from which the technology is assessed. A waste control pro-
gram must make a choice between the foregoing alternatives, if only
to say that waste according to any perspective is a legitimate cost
control target. Before discussing which definition and perspective

\textsuperscript{74} Conceivably in an experiment, a patient might be exposed to risks or denied benefits
from a technology in order to generate information that might lead to benefits for others.
Although the technology might be deemed unsafe or ineffective from that patient's stand-
point, it would not be considered wasteful from a broader societal perspective. Such an ex-
periment, however, raises serious ethical and legal objections. See infra notes 196-98 and
accompanying text.

\textsuperscript{75} See Weinstein, supra note 47, at 310 (cost-effectiveness analysis is only appropriate,
even from the patient's viewpoint, when it is conducted "in the context of explicitly limited
resources"); K. WARNER & B. LUCE, supra note 1, at 43, 60 ("[w]e assume a societal perspec-
tive on costs and benefits, the traditional perspective of CBA-CEA [cost-benefit and cost-
effectiveness analysis].").

\textsuperscript{76} See Weinstein, supra note 47, at 310; Kristein, supra note 47, at 222; Schwartz &
Jaskow, supra note 21, at 1462. Kristein defines "uneconomical spending" for health care as
an instance "where (a) the marginal cost to the individual is less than the marginal cost to
society, and (b) where the marginal benefit to the individual is greater than the marginal
benefit to society." Kristein, supra note 47, at 220.
should be selected, however, the problems in attempting to identify specific wasteful technologies will be explored.

II. PROBLEMS OF IDENTIFICATION

Once wasteful technology is properly defined, the next step is to identify specific technologies that fall within the definition. The process of defining and identifying wasteful technologies is known as "technology assessment." The Congressional Office of Technology Assessment defines technology assessment as "[a] comprehensive form of policy research that examines the technical, economic, and social consequences of technological applications." As formally defined, technology assessment is a comprehensive process that produces the information that should form the basis of health care decisionmaking by physicians, patients, hospitals, health planners, insurers, and public program managers. These decision-makers must make choices between alternate technologies on the best available information, which is often far from ideal in quality and quantity. A less rigorous process of evaluation also occurs as a form of technology assessment, and will be included within the meaning of the term in the following discussion.

The task of identifying wasteful technologies raises difficulties apart from those encountered in the effort to define the term waste. Some of these problems are inherent in any effort to assess technology, while others arise in the context of specific technologies being assessed or specific assessment methods being employed.

A. General Problems of Waste Identification

1. Selection of Technologies for Assessment

The process of selecting technologies to be assessed raises an initial set of problems, particularly when undertaking the more comprehensive form of technology assessment envisioned by the Office of Technology Assessment. A technology assessment system designed to control costs should focus on costly technologies, in-

77. See OTA STRATEGIES, supra note 4, at 201-02.
78. See Banta & Behney, Policy Formulation and Technology Assessment, 59 MILBANK MEMORIAL FUND Q. 445, 448 (1981) ("Technology assessment is seen as a comprehensive form of policy research that examines short- and long-term social consequences (e.g. societal, economic, ethical, legal) of the application of technology.").
79. See infra notes 91-97 and accompanying text.
80. See supra note 77 and accompanying text. In contrast, when informal technology assessment is undertaken for practical, day-to-day health care decisionmaking, the choice of technologies is likely to be dictated largely by patient management considerations.
cluding both those with high per-unit costs and high aggregate costs due to the volume of use. Conceivably the most expensive technologies would be assessed first, followed by less expensive ones, until assessment resources had been exhausted.

Assessment priorities might be further established on the basis of the expected magnitude of net benefit, its probability of occurrence, and the size of the treatment population. This would lead to the following breakdown:

**TABLE 1**

<table>
<thead>
<tr>
<th>Technology</th>
<th>Net Benefit</th>
<th>Probability</th>
<th>Patient Population</th>
<th>Unit Cost</th>
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</table>

At one extreme, technologies A and B are most likely to be regarded as potentially wasteful, and therefore in need of assessment. Their small benefit, coupled with the low probability of its occurrence, will produce valid negative results with relatively small patient populations in clinical trials. At the other extreme, technologies J, K, and L, which offer the most favorable benefit-probability ratios, are also likely to be easily and cheaply evaluated in small studies. The remaining technologies, on the other hand, offer only marginal net benefit (benefit minus risk), either because the benefit is small, or because the probability of its achievement is low, or both. Moreover, these are likely to be the most expensive and most difficult technologies to assess, with large populations required to generate statistically significant results. They are less

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81. An assessment system not designed primarily to control costly technology would presumably make an initial selection of which technologies to assess on some other basis. Presently, technologies are chosen for assessment either because they are new drugs or medical devices, see infra note 82 and accompanying text, or because they are existing technologies that compete with new technologies. See OTA STRATEGIES, supra note 4, at 98; Arnstein, *Strategy for Health Technology*, 13 MED. INSTRUMENTATION 14, 15 (1979) (existing technologies assessed primarily by serving as controls in studies of new technologies).
likely than the other four technologies to be extremely wasteful or useful, however, and therefore their continuing spread and use or lack thereof is arguably of less immediate concern. Their assessment priority accordingly should be lower.\textsuperscript{82}

\textsuperscript{82} This system of priorities assumes that the net benefit, probability of its occurrence, size of the patient population and unit cost are known or can be accurately estimated. This is less likely to be true of new than of existing technologies with which there has been some experience, and is one of the reasons that technology assessment might focus on the latter rather than on the former. Another reason for focusing on existing technologies is that many may be obsolete. The Health Industry Manufacturers Association (HIMA), a trade association of manufacturers of medical devices, has advocated concentrating technology assessment on "relatively old" technologies since many are mere "historical carryovers" in need of assessment. \textit{Health Care Research and Research Training Amendments of 1981: Hearings on S. 800 Before the Senate Comm. on Labor and Human Resources, 97th Cong., 1st Sess. 51} (1981) [hereinafter cited as \textit{Hearings on S. 800}] (testimony of Dimitri V. d'Arbeloff on behalf of HIMA). Furthermore, singling out new technologies for assessment might hinder their development, and this might prevent or unduly postpone the availability of important medical advances. \textit{See Health Care Technology Assessment: Hearings on S. 2504 Before the Senate Comm. on Labor and Human Resources, 98th Cong., 2d Sess. 117} (1984) [hereinafter cited as \textit{Hearings on S. 2504}] (testimony of Frank E. Samuel, Jr., President of HIMA); \textit{Hearings on H.R. 4869, supra} note 16, at 381-82 (testimony of the American Medical Association). A negative impact on technological innovation is premised on the belief that unrecoverable assessment costs will be borne by the innovator and that the increased cost of capital necessary to compensate for the increased project risk will exceed the expected return on investment.

On the other hand, it might seem wise to concentrate on new technologies since, due to the lack of experience with them, less may be known about them than about existing technologies, and therefore it may be harder to identify those that are wasteful without some special effort. Furthermore, new technologies may be less entrenched than existing ones, and therefore wasteful new technologies may be easier to eliminate. \textit{See Schroeder, Medical Technology and Academic Medicine: The Doctor-Producers' Dilemma}, 56 J. MED. EDUC. 634, 635 (1981). The process by which wasteful technologies might be eliminated is discussed infra at notes 245-95 and accompanying text.

New technologies might be assessed routinely as they reached a particular stage of development, thus avoiding the need to predict their net benefit, probability of the benefit occurring, size of their future patient population, and unit cost. This is essentially the selection system imposed on the Food and Drug Administration by the Federal Food, Drug, and Cosmetic Act. \textit{See OTA STRATEGIES, supra} note 4, at 94. Even so, the FDA reviews technologies according to a priority system. New chemical entities believed to offer significant benefits over existing products are required to undergo a rigorous assessment process, but the agency gives them review priority over other products. On the other hand, products that are merely minor modifications of existing products, such as drugs that differ in dosage strength from those on the market, are put through a less rigorous approval process but at a slower pace.

In lieu of the priority system suggested in the text, another system that has been suggested is to select for assessment first those technologies that are believed to provide some benefit but that are suspected of being capable of providing more under different patterns of use, followed by technologies suspected of being dangerous or useless, followed in turn by technologies that are widespread or expensive. \textit{See Banta, Behney & Andrulis, Assessing Medical Technologies}, 54 BULL. N.Y. ACAD. MED. 113, 118 (1978). The authors do not explain why technologies with greater potential benefit deserve to be assessed ahead of those that pose risks.

Due in part to objections that assessment stifles new technologies, a major federal technology assessment agency, the National Center for Health Care Technology (NCHCT), formed
2. **Timing**

Related to the issue of which technologies to assess is the determination of when to conduct the assessment. Timing is likely to be a concern primarily with formal, programmatic technology assessment, such as investigations of the safety and efficacy of new technologies conducted for the FDA. Because informal, day-to-day technology assessment usually occurs at the time the technology is identified as a patient management option, timing is not an issue in that context.

Technology develops in stages: basic research and development, applied research, introduction in humans, diffusion, and eventually obsolescence. Technology can be assessed at a number of these stages. The later the assessment, the less its result can influence the developmental process. To facilitate identifying wasteful technologies before they become so widespread as to cause substantial harm or economic disutility, or become so entrenched that curbing their

during the Carter administration, was subsequently denied funding by the Reagan administration. See infra notes 154-55 and accompanying text. In an effort to keep the agency alive in the face of criticism, its director, Seymour Perry, acknowledged that “emerging” technologies (which he defined as “actively evolving”) should only be the subject of “full blown assessment . . . in unusual circumstances involving serious ethical or legal issues,” and not merely because such technologies promised to be costly. Perry, *The Brief Life of the National Center for Health Care Technology*, 307 New Eng. J. Med. 1095, 1099 (1982).

83. See Greer, *supra* note 39, at 130.

84. See infra note 85 and accompanying text. The Federal Food, Drug, and Cosmetic Act mandates the assessment of a technology under the agency’s jurisdiction before it is marketed. New products, such as new drugs and medical devices, must be assessed before they are allowed to be shipped in interstate commerce. See supra notes 42-44 and accompanying text. Agency approval is conditioned upon a finding that a drug product has been shown, by substantial evidence consisting of adequate and well-controlled investigations, to be safe for use under prescribed conditions, and to have the effect it is represented to have under those conditions. 21 U.S.C. § 355(d). Agency approval to ship a device must be based on a showing of reasonable assurance that the device is safe and effective under the conditions of use in its labelling. 21 U.S.C. § 360e(d).

FDA assessment and approval is required not only for commercial introduction, but for shipment for purposes of clinical assessment (the term “clinical” in connection with experiments refers to experiments in human subjects); a manufacturer is prohibited from shipping a technology to a research establishment for testing in humans without obtaining prior FDA approval. 21 U.S.C. § 355(i) (providing procedure for obtaining FDA approval for shipping investigational drug); 21 U.S.C. 360j(g) (providing procedure for obtaining FDA approval for shipping new device). In determining whether or not to permit a drug or device to be shipped for purposes of conducting human experiments, the agency examines chemistry, laboratory, and animal data submitted by the sponsor of the study. In the case of a product that already has been approved, the FDA requires a separate approval before the manufacturer lawfully may promote the product for a new use. The FDA has no jurisdiction to require approval of a new use that the manufacturer does not promote, such as an unapproved new use by a physician on his patients. Nor does the agency have jurisdiction over medical and surgical technologies, except to the extent of their use of drugs and devices.
use would encounter substantial public opposition, it is advisable to conduct technology assessment as early as possible.\footnote{85. The developmental stages of medical technology have been likened to an S-curve, with the extent of human use plotted on the X axis and time plotted on the Y axis. The curve is flat along the time axis until the technology is first introduced in humans; it then ascends fairly steeply before levelling off at the point of maximum acceptance or saturation. Eventually it may fall back as the technology becomes obsolete. See Banta, supra note 16, at 65; Greer, supra note 39, at 134.}

The basic research and development stage is generally conceded to be premature for assessment, since the resulting technology is as yet insufficiently defined for meaningful assessment.\footnote{86. See Banta & Behney, Medical Technology: Policies and Problems, 5 HEALTH CARE MANAGEMENT REV. 45, 50 (1980).} The first assessment opportunity, therefore, is at the applied research stage. However, early assessment risks stifling new technologies that might later prove nonwasteful.\footnote{87. See Schroeder, supra note 82, at 635; Hearings on H.R. 4869, supra note 16, at 381-82 (testimony of the American Medical Association).} This stems from the fact that technologies and the contexts in which they are applied change over time.\footnote{88. See Fineberg & Hiatt, supra note 30, at 1087; Banta, Behney & Andrusiak, supra note 82, at 118.} Indeed, technologies may change during the assessment period,\footnote{89. This period may be protracted. See infra note 90. See Derzon, Influences of Reimbursement Policies on Technology, in CRITICAL ISSUES IN MEDICAL TECHNOLOGY, supra note 72, at 149 (third-party payors "cannot wait the desired length of time needed to assess many technologies" before deciding whether or not to pay for them).} so that by the time the assessment data are available, the technology has evolved and the results no longer apply.\footnote{90. See Fineberg & Hiatt, supra note 30, at 1087-88. This problem, known as latency, arises when the rate of change in a technology exceeds the rate at which it can be assessed. See Eddy, Measuring the Effectiveness of Therapeutic Surgical Procedures: A Master Plan, in NAT'L CENTER FOR HEALTH SERVS. RESEARCH, MEDICAL TECHNOLOGY 40, 43 (1979) [hereinafter cited as MEDICAL TECHNOLOGY]. It is compounded by the length of time necessary to measure certain health outcomes; cancer survival, for example, is typically measured in five- or ten-year units. Id. at 43-44. Moreover, some types of technology assessment, such as the randomized, controlled clinical trial, cannot easily be changed midstream to take account of a change in the technology under investigation. See id. at 44.} Moreover, the risks, costs, and benefits of a technology at an early stage of development are hard to foresee, and the earlier the stage of development of the technology, the less confident the projection.

3. \textit{Shortage of Data}

Technology assessment is an analysis of information on a technology. Its quality and hence its usefulness are proportional to the quality and quantity of the data on which it is based. The lack of adequate assessment data creates a serious obstacle to identifying
wasteful technologies.91 The shortage extends not only to economic cost and benefit data required for cost-effectiveness and cost-benefit analyses,92 but also to the data needed to conduct basic assessments of safety and effectiveness. The Office of Technology Assessment has estimated that only between ten and twenty percent of all technologies used in medical practice have been shown to be efficacious in controlled clinical investigations.93 Safety and effectiveness data are particularly scant for technologies other than those drugs and devices that require FDA approval prior to being marketed.94 Furthermore, the more novel the technology, and therefore arguably the greater the need to predict its future risks, costs and benefits, the less data that are likely to be available.95 While techniques have been developed to facilitate technology assessment in the absence of hard data, generating such data must remain a

91. See Klarman, supra note 53, at 234 (noting especially the lack of longitudinal data); Weinstein, supra note 47, at 317-18 (noting the "softness" of data to establish probabilities for predicting future costs and benefits).

92. See infra notes 211-29 and accompanying text.

93. Controlled clinical trials are required to determine the safety and efficacy of technologies. See infra notes 193-94 and accompanying text.

94. See Banta & Behney, Policy Formulation and Technology Assessment, 59 MILBANK MEMORIAL FUND Q. 445, 454 (1980). For a description of the FDA approval process, see supra notes 41-45 and accompanying text.

95. See Warner, Effects of Hospital Cost Containment on the Development of Medical Technology, 56 MILBANK MEMORIAL FUND Q. 187, 190 (1978). This perhaps puts novel technologies at a relative disadvantage; the absence of available data and greater risk of safety, efficacy, or cost problems makes such technologies less likely to be adopted than technologies more similar to existing technologies. On the other hand, there might be a bias in favor of novel technologies, especially compared with existing technologies that have a known but somewhat disappointing track record.

96. One such technique is sensitivity analysis. See Weinstein, supra note 47, at 317; Hearings on H.R. 2562, supra note 73, at 462-63 (testimony of the National Center for Health Care Technology); Klarman, supra note 53, at 236; OTA STRATEGIES, supra note 4, at 67. Sensitivity analysis tests the sensitivity of the end result to variations in the uncertain variables. By testing across a complete range of possible values, sensitivity analysis determines whether or not that factor is significant. For example, in testing for net benefit, if even the worst-case value for one factor, say the discount rate, yielded a positive dollar figure, one would properly conclude that the assessment was not sensitive to the selection of the discount rate. On the other hand, if the outcome varied substantially depending on the discount rate, greater resources could be devoted to predicting the rate with accuracy, or the assessor could resign himself to a weak result produced by the uncertainty in the rate. See OTA STRATEGIES, supra note 4, at 67.

Sensitivity analysis can also be used to calculate best- and worst-case estimates for specific technologies. See K. WARNER & B. LUCE, supra note 1, at 101. One example is "mini-analysis," as urged by Kristein, in which, to determine if a technology is cost-beneficial, benefit is calculated using for uncertain variables the highest values within the range, while cost is calculated using the lowest. If the result does not reveal a net benefit for the technology under these "best-case" conditions, then the technology is not likely to be cost-beneficial in reality. See Kristein, supra note 47, at 215. The process of mini-analysis resembles the use of
high priority in attempting to control health care costs by identifying wasteful technologies.\textsuperscript{97}

4. Isolating Effects

Technologies are employed within a health care context that may include prior or subsequent use of other technologies, all of which may affect patient outcome,\textsuperscript{98} costs, and other trade-offs. Consequently, it is difficult to isolate the impact of the particular technology being assessed.\textsuperscript{99} This problem is exacerbated in assessing diagnostic technologies that may have multiple applications (for example, a multichannel blood analyzer that can diagnose a large variety of abnormal conditions), or that may lead to different further interventions, such as further diagnostic tests or different treatments.\textsuperscript{100}

\textsuperscript{97} See Bunker, Fowles & Schaffarzec, supra note 19, at 688 (primary objective of proposed quasi-public Institute for Health Care Evaluation is establishing a uniform patient data base to facilitate technology assessment). For a listing of data bases currently available for technology assessment, see OTA STRATEGIES, supra note 4, at 113-26 app. A, B.

\textsuperscript{98} Decision analysts term this the problem of "downstream decision nodes." See Weinstein, supra note 47, at 316-17.

\textsuperscript{99} See Greer, supra note 39, at 130.

\textsuperscript{100} See id. at 131; infra notes 175-84 and accompanying text. An additional problem with technology assessment is its susceptibility to biases. Entities with a proprietary interest in the technology or with a financial stake in producing results beneficial to the sponsor (such as a contract laboratory assessing a technology on behalf of a manufacturer) may knowingly or unknowingly color the findings. See Ezekowitz, The Uncontrolled Proliferation of Technology, 81 CHEST 140 (1982). There may always be negatively biased assessments, for instance where the manufacturer of a competing technology sponsors an assessment of the rival technology with the intention of producing negative results. See id. Another source of bias is the preference of scientific journals for publishing positive results. See id.
5. Cost of Assessment

Formal technology assessment is extremely costly to conduct. Clinical testing to establish the safety and efficacy of drugs often costs millions of dollars per drug.101 Even an analysis of preexisting data to determine the costs and benefits of a technology can run into hundreds of thousands of dollars.102 One commentator recommends a national technology assessment effort with a budget of $200 to $300 million.103

This raises the question whether comprehensive technology assessment is itself cost-beneficial. Under certain conditions, for example, where costs of assessment exceed the cost of the technology, assessment is wasteful.104 However, it is not always possible to project such conditions.105 Nevertheless, an effort must be made to identify prior to assessment those technologies that are only marginally wasteful and yet would be costly to assess. The breakdown of technologies in Table 1 may provide a starting point for this analysis.

A related issue is who should bear the cost of technology assessment. For new drugs and medical devices, the burden of paying for technology assessment falls substantially on the manufacturer, who must sponsor the safety and efficacy trials necessary to obtain FDA approval.106 Insofar as technology assessment is aimed at identify-

101. For an attempt to estimate the costs and benefits of a series of large, controlled clinical trials, see Hawkins, supra note 16, at 19-20. To the out-of-pocket expense of conducting the tests must be added the costs of the delay in making the technology widely available while the testing is conducted.
102. See Banta & Behney, supra note 86, at 48.
104. See Fuchs, supra note 59, at 938.
105. While urging that cost-effectiveness and cost-benefit analyses not be performed when doing so would not be cost-effective, Fuchs does not specify how this can be determined before the assessment is conducted. Id.
106. However, safety and efficacy studies on some products, such as certain cancer drugs, are sponsored in large part by the federal government. Furthermore, the Orphan Drug Act provides manufacturers with a tax credit of 50% of the costs of research and development, and a minimum of seven years of exclusive marketing, for drugs with such small patient populations that manufacturers would not otherwise expect sufficient return on investment to justify the costs of obtaining FDA approval. 21 U.S.C. § 355 (1982).

An additional cost of technology assessment is the cost of the FDA's review. The agency's activities are funded by federal taxes. Recently, however, the agency proposed that manufacturers submitting data for review for purposes of obtaining permission to market new products be required to pay a "user fee." See 50 Fed. Reg. 31,726 (1985). The FDA did not propose to charge directly for the review of requests to ship products for clinical experiments. Instead, the agency proposed that one-half the cost of that review be added to the charge for reviewing a request for marketing approval. Id. at 31,728. In effect, then, only technologies
ing wasteful technologies, cost-effectiveness and cost-benefit studies are needed in addition to the safety and efficacy data currently required from the sponsor, and the cost of these additional studies might be imposed on manufacturers seeking government approval of their products. Manufacturers, in turn, fear that these extra costs will prevent the development of drugs for small markets and will drive small manufacturers out of business.

One alternative would be to spread assessment costs by charging manufacturers on some sort of pro rata basis, such as based on sales revenue. However, this ignores the fact that many technologies, including most medical and surgical procedures, are not proprietary; they are not patented, or sold or licensed to other physicians or surgeons. Thus, manufacturers would be forced to increase the price of their proprietary—i.e., non-medical and non-surgical—products in order to recover the assessment costs of their nonpro-

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107. See Anderson & Steinberg, supra note 13, at 184-85.


110. There does not appear to be any legal impediment to patenting new medical and surgical technologies that do not entail the invention of new drugs or devices. Presumably such technologies would be entitled to a process patent. See 35 U.S.C. 101 (1982) (allowing patents for "any new and useful process"). "Process" is defined as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b). The fact that the innovator is likely to publish the new technique in a scientific journal will not preclude obtaining a patent so long as the patent application is filed within one year of the publication. See 35 U.S.C. § 102(b). Nevertheless, patents for such technologies are virtually unknown. Telephone interview with Michael Lechter, Esquire, Foley & Lardner, Milwaukee, Wisconsin (Dec. 12, 1985). This apparently results from the fact that surgeons and medical innovators are primarily interested in maximizing the spread of their innovations; licensing arrangements with other practitioners might hamper efforts to expand development and use of technological innovations.

A further impediment to patenting such technologies might be the difficulty of detecting infringement, especially in cases of small changes in existing procedures or innovations with little public visibility. Conversely, the inventor of a new coronary artery bypass or human heart transplant procedure at one hospital can easily determine that another hospital has suddenly begun promoting the same procedure to the public. Proprietary claims on surgical and medical technologies might increase if cost control pressures intensify competition between providers or significantly reduce the incomes of innovating health professionals.
proprietary products. \textsuperscript{111} In a cost-sensitive market, this practice would discourage the use of proprietary technologies in favor of non-proprietary ones. In the absence of evidence that proprietary technologies, on the whole, are more likely to be wasteful than non-proprietary technologies, this result does not seem justified.

Another alternative is to finance technology assessment with contributions, either mandatory or voluntary, by insurers. \textsuperscript{112} However, as noted earlier, \textsuperscript{113} and discussed more fully below, \textsuperscript{114} insurers have a different perspective on waste than physicians, patients, or society. Insurers are therefore likely to sponsor technology assessment that focuses only on those approaches that have the greatest potential for reducing their costs. While the resulting data would be useful as part of an overall assessment program, they are liable to divert technology development and use away from technologies that might be nonwasteful when viewed from another perspective.

It has also been suggested that technology assessment be funded by a combination of private contributions and government funding, \textsuperscript{115} or that the government be the primary sponsor. The question then arises whether the entity that pays, particularly if it is the government, should perform or control technology assessment, a question that is addressed in the following section.

\textsuperscript{111} This confounds the suggestion of one commentator that the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-92 (1982 & Supp. I 1983), be amended to authorize the FDA to approve medical and surgical technologies, and that physicians and hospitals pay for the technology assessment data that is required by the FDA for approval. \textit{See Note, The Open-Ended Investigation: A Method for Regulation of New Medical Services,} \textit{91 Yale L.J.} 550, 560 n.53 (1982). For a discussion of other problems in regulating medical and surgical technologies, see discussion \textit{infra} at notes 185-91 and accompanying text.

\textsuperscript{112} \textit{See Willems & Banta, Improving the Use of Medical Technology,} \textit{1 Health Aff.,} Fall 1982, at 86, 91 (noting that insurance companies “have much to gain in both cost savings and improving the efficiency of the services that they support”).

\textsuperscript{113} \textit{See supra} note 69 and accompanying text.

\textsuperscript{114} \textit{See infra} note 243 and accompanying text.

\textsuperscript{115} \textit{See Fineberg & Hiatt, supra} note 30, at 1090 (“Government, health-insurance companies, corporations and foundations should provide the requisite financial resources.”); Bunker, Fowles & Schaffarzeck, \textit{supra} note 19, at 689 (advocating that technology assessment be paid for by third-party payors, including the government as the operator of Medicare and Medicaid). Congress recently adopted a joint private-public funding approach by creating a new Council on Health Care Technology. \textit{See Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, § 309(a)(1), 98 Stat. 2820.} The Council is funded in part by grants from the Department of Health and Human Services (DHHS), but the law stipulates that DHHS grants can defray a maximum of two-thirds of the Council’s start-up costs and only one-third of its operating funds. The remainder must come from non-federal sources. \textit{See id.} § 309(a)(2)(A)-(B). The Council, established under the auspices of the National Academy of Sciences and the new National Center for Health Services Research and Health Care Technology Assessment created within the DHHS, replaces the National Center for Health Care Technology, discussed \textit{infra} at notes 150-55 and accompanying text.
6. **Who Performs Technology Assessment**

Historically, technology assessment has been performed by a variety of government and private entities, depending on the type of technology (e.g., proprietary drugs, surgical procedures) and on the purpose of the assessment (e.g., safety and efficacy trials sponsored by a manufacturer seeking FDA marketing approval, cost-effectiveness study by third-party payor). Private assessment entities include physicians, hospitals, third-party payors, and medical professional organizations such as

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116. Physicians perform at least an informal technology assessment whenever they decide which technology alternative to provide their patients. Government physicians, such as those employed by the Veterans Administration, are considered private technology assessors for this discussion, insofar as their technology selection resembles that of private physicians.

117. The role of patients in technology assessment has been significantly increased by the growth of the doctrine of informed consent. Under that doctrine, patients are entitled to a description of alternative treatments, along with their risks and benefits, as part of the process of deciding which treatment they will be provided. See discussion infra notes 333-37 and accompanying text.

118. Hospitals conduct a variety of types of technology assessments. For example, hospitals must decide which technologies to acquire. This may entail a comprehensive evaluation of risks, costs and benefits, or a more limited inquiry to determine the most reliable manufacturer of a certain type of equipment. Massachusetts General Hospital, for instance, has established a Resource Allocation Board to evaluate requests for the acquisition of new technologies. See Sanders, *Adoption of New Technologies in Hospitals*, in CRITICAL ISSUES IN MEDICAL TECHNOLOGY, supra note 72, at 34. Hospital managers are being urged to adopt technology evaluation and acquisition methods, or "TEAM," to evaluate new technologies in terms of need, safety, effectiveness, reliability, cost and impact on hospital structure and function. See AHA Offers "TEAM" Program for Evaluating Capital Requests, 55 Hosp. 75 (1981).

A private, nonprofit organization called ECRI (formerly the Emergency Care Research Institute) evaluates smaller medical devices and other hospital equipment and produces "Consumer Reports"-like information for subscribers, typically hospital administrators. See OTA STRATEGIES, supra note 4, at 78. In addition to assessing technology proposed for purchase, hospitals also engage in a form of assessment when they conduct experiments on human subjects. In this event, they are required by federal law to establish Institutional Review Boards (IRBs) to evaluate ethical implications of the proposed research in terms of the risks to subjects. This entails a review of the likely safety and efficacy of the experimental technology. See, e.g., 21 C.F.R. §§ 56.110-111 (FDA IRB regulations).

119. See Greenberg & Derzon, *Determining Health Insurance Coverage of Technology: Problems and Options*, 19 MED. CARE 967, 972-73 (1981). In 1977, the largest private third-party payor, the Blue Cross/Blue Shield Association, began a Medical Necessity Project in conjunction with the American College of Physicians, the American College of Surgeons and the American College of Radiology. See id.; Hellinger, supra note 58, at 38-39 (1982). Its purpose is to obtain information to facilitate curtailing payment for "outmoded, unproven or duplicative" technology. Greenberg & Derzon, supra, at 972. Since 1977, Blue Cross/Blue Shield has proposed to discontinue payment for 68 specific surgical and diagnostic procedures. See id. These tend to be noncontroversial. See Hellinger, supra note 58, at 38. In addition, a medical advisory committee, composed of the medical advisors of six affiliates, makes over 100 recommendations a year on reimbursement issues involving specific technologies. See Greenberg & Derzon, supra, at 972.

120. See supra note 106 and accompanying text.
the American Medical Association121 and the American College of Physicians.122 There are now at least forty-five groups in the private sector engaged in some form of technology assessment,123 leading the congressional Office of Technology Assessment to describe the present system as "pluralistic."124

Along with these private assessment efforts, the government has long been involved in various aspects of technology assessment. The Food and Drug Administration reviews safety and efficacy data submitted by manufacturers to determine whether or not to approve a drug or device for introduction into interstate commerce.125 In 1972, the Office of Technology Assessment (OTA) was established to advise Congress on the consequences of technological change.126 A specific program to address medical technology was initiated by the OTA in 1975.127 Like the FDA, the OTA does not generate substantial technology assessment of its own; instead, it reviews and synthesizes existing data and disseminates the results.128 The National Institute of Health generates a great deal of safety and efficacy data, either directly or by sponsoring extramural research. It does not, however, evaluate the social and economic impact of the technologies it assesses.129 The newly established Prospective Pay-
ment Commission (PROPAC)\textsuperscript{130} is authorized by statute to commission technology assessment. PROPAC has yet to exercise this mandate, and it is unclear how extensively it will do so in the future.\textsuperscript{131}

The agency responsible for implementing the Medicare program, the Health Care Finance Administration (HCFA), also reviews and commissions technology assessment.\textsuperscript{132} This assessment function is known as HCFA's "coverage" program. HCFA assesses technologies both on its own initiative, based on trends in technology development, as well as in response to specific coverage questions.\textsuperscript{133} The responsive aspect of HCFA's coverage program is complicated by the relationship between the agency and its program elements. Medicare is administered at the local level by a system of contractors hired by HCFA to handle individual claims.\textsuperscript{134} One of the responsibilities of these contractors is to process claims for reimbursement received from individual providers, such as hospitals or physicians, or directly from patients. In processing claims, the contractor will deny payment for technologies that it deems are not covered under the statutory scheme.\textsuperscript{135} A coverage question that the contractor is unable or unwilling to resolve itself\textsuperscript{136} is referred to one of HCFA's regional offices which, in turn, can refer it to HCFA national headquarters.\textsuperscript{137}

Technologies are first assessed in terms of whether they fall within the statutory provision prohibiting Medicare from reimburs-

\begin{itemize}
\item \textsuperscript{130} See supra note 18 and accompanying text.
\item \textsuperscript{131} See Blumenthal, supra note 129, at 598.
\item \textsuperscript{132} See supra note 19 and accompanying text.
\item \textsuperscript{133} In 1981, 25\% of the coverage issues handled by HCFA at the national level were presented by manufacturers of specific technologies seeking an HCFA ruling on whether or not Medicare would reimburse for their provision. See Ruby, Banta & Burns, Medicare Coverage, Medicare Costs, and Medical Technology, 10 J. Health Pol., Pol'y & L. 141, 146 (1985).
\item \textsuperscript{134} Under the portion of the Medicare program that covers hospitalization, known as "Part A" (after the part of the Social Security Act in which it is established) these contractors are called "fiscal intermediaries." Greenberg & Derzon, supra note 119, at 968, and are often local Blue Cross affiliates. In 1982, there were 77 fiscal intermediaries, each covering a different geographic area. Hellinger, supra note 58, at 37. Under Part B of the Medicare program, which covers physician charges, the contractors are called "carriers." Greenberg & Derzon, supra, at 968. There were 43 carriers in 1982, often Blue Shield affiliates. Hellinger, supra, at 37.
\item \textsuperscript{135} Note that the contractor must ascertain that such a technology has in fact been provided before it can rule on whether or not it is covered. The claims system under Medicare makes this task rather difficult. See infra note 275 and accompanying text.
\item \textsuperscript{136} Contractors vary in the aggressiveness with which they pursue coverage issues. See Greenberg & Derzon, supra note 119, at 968.
\item \textsuperscript{137} See id. at 969; Banta & Behney, supra note 78, at 458.
\end{itemize}
ing for "items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."\textsuperscript{138} This assessment differs in scope depending on whether it is being performed by HCFA’s national office or by one of the Medicare contractors. A contractor's assessment triggered by a claim for reimbursement will usually be limited to an evaluation of whether the technology was medically necessary in the particular case (a fairly straightforward determination of whether it is generally accepted medical practice to provide the technology to a patient under the circumstances of the case) and whether or not it was provided in an appropriate setting (for example, whether it could have been provided on an outrather than on an in-patient basis).\textsuperscript{139} However, contractors may extend their evaluation to matters such as whether the technology is generally accepted by the medical community (a broader inquiry than whether it is appropriate for a particular patient), and whether development of the technology has progressed to the point appropriate for Medicare reimbursement.\textsuperscript{140}

If the coverage question reaches HCFA’s national office, it is referred to the Office of Coverage Policy.\textsuperscript{141} When medical advice is deemed necessary to decide the coverage question, a panel of medical experts on contract with the agency reviews the technology. This panel may decide the question itself or refer it to the Public Health Service, either as an informal inquiry or with a request for full-scale assessment.\textsuperscript{142} Within the Public Health Service, the matter is referred to the National Center for Health Services Research and Health Care Technology Assessment (NCHSRHCTA),\textsuperscript{143} where it is reviewed by the Office of Health Technology Assessment (OHTA). OHTA conducts a review of the literature on the technology, and, in the case of a full-scale assessment, issues a notice of

\textsuperscript{139} See Ruby, Banta, & Burns, supra note 133, at 145, 146-47 (1985).
\textsuperscript{140} See Banta & Behney, supra note 78, at 458; Greenberg & Derzon, supra note 119, at 968.
\textsuperscript{141} See Ruby, Banta, & Burns, supra note 133, at 147.
\textsuperscript{142} See Brandt, Technology Assessment, a Private-Public Partnership, 99 PUB. HEALTH REP. 329 (1984); Ruby, Banta & Burns, supra note 133, at 147.
\textsuperscript{143} Ruby, Banta & Burns, supra note 133, at 147, n.31. The National Center for Health Services Research and Health Care Technology Assessment was recently created by Congress. See infra notes 160-62 and accompanying text. Formerly, the agency was called the National Center for Health Services Research, and contained a small Office of Health Technology Assessment to perform the agency's technology assessment function. While this office still exists, its importance has been upgraded, as reflected by the change in the agency's name.
its inquiry in the Federal Register, soliciting public input. A special consensus conference, sometimes sponsored jointly by the Office of Medical Applications of Research in the National Institutes of Health, may be held to permit experts to discuss and synthesize available assessment data. A draft assessment document is eventually prepared and circulated within the Public Health Service, and a final coverage recommendation is sent to HCFA. HCFA then issues a coverage ruling, and publishes the ruling in manuals distributed to Medicare contractors.

As this discussion reveals, federal technology assessment is fragmented among a number of agencies. After the failure of early efforts to form a coordinating umbrella organization, Congress established the National Center for Health Care Technology

144. See Brandt, supra note 142, at 329.
145. See infra notes 203-07 and accompanying text.
146. See supra note 129 and accompanying text.
147. See Ruby, Banta & Burns, supra note 133, at 147.
148. The rulings are also circulated to state Medicaid agencies, which tend to follow HCFA in making coverage decisions concerning Medicaid, to the American Hospital Association, where the HCFA rulings are reported in the association's Annual Technology Guide, and to insurance companies and other third-party payors. See Brandt, supra note 142, at 329.
149. In the early 1970's, Senator Edward Kennedy (D. Mass.) and Representative Andrew Maguire (D. N.J.) attempted to establish within the Public Health Service a National Institute for Health Care Research, on a par with the National Institutes of Health (NIH). See Greenberg, Health-Care Technology: A Small Office vs. A Big Problem, 302 New Eng. J. Med. 243 (1980). The new institute would have consisted of the existing National Center for Health Statistics and the National Center for Health Services Research, as well as a new National Center for the Evaluation of Medical Technologies. The concept was to create an agency at a sufficiently high level within the Department of Health and Human Services to provide department-wide coordination and leadership. Id.

Kennedy and Maguire did not regard any of the existing administrative units as appropriate to be given this role. The NIH excludes consideration of social and economic impact from its own research efforts. See supra notes 129 and accompanying text. Indeed, in the mid-to-late 1970's, the NIH did not employ a single professional economist. See Blumenthal, supra note 129, at 585. Kennedy and Maguire felt that the National Center for Health Services Research lacked sufficient prestige, appearing to be on the decline, having suffered a budget reduction from $80 million in 1968 to $30 million in 1978. See Greenberg, supra, at 243. Finally, the Health Care Finance Administration, which would make the most direct use of technology assessment in determining which technologies to reimburse for under Medicare, lacked the personnel and experience to conduct technology assessment on its own. See id. at 244. Kennedy and Maguire may also have been concerned that HCFA would be biased against technologies that did not reduce costs.

The effort by Kennedy and Maguire encountered heavy opposition from technology manufacturers, and was defeated. See Greenberg, supra, at 243. Joseph Califano, who was then secretary of the Department of Health and Human Services, responded by establishing a new Office of Health Technology in the office of the Assistant Secretary for Health. This was eventually absorbed by the National Center for Health Care Technology, discussed infra at notes 150-55 and accompanying text.
(NCHCT) in 1978. The NCHCT coordinated federal technology assessment by assembling a list of emerging technologies and identifying those particularly in need of assessment, sponsoring actual assessments, including the generation of assessment data, and disseminating the results both to HCFA and to the public. Nevertheless, the NCHCT met stiff opposition from a number of directions. Following the Reagan administration's refusal to seek

150. Pub. L. No. 95-623, § 309, 92 Stat. 3447. The NCHCT was placed under the control of the Assistant Secretary for Health in the Department of Health and Human Services, and was on the same level as the National Center for Health Services Research and the National Center for Health Statistics. The agency replaced and absorbed the Office of Health Technology in the Office of the Assistant Secretary for Health. See infra notes 156-157. Under an earlier proposal, the agency was to be amalgamated with the National Center for Health Services Research and the National Center for Health Statistics. See id. No doubt to avoid opposition from those bureaucracies, Congress instead retained them alongside the new agency.

For a description of NHCHT's activities, see Perry & Eliastam, The National Center for Health Care Technology, 245 J. A.M.A. 2510, 2511 (1981); Perry, supra note 82, at 1096-97. The NCHCT was directed by Seymour Perry, M.D., who had been the first director of the Office of Medical Applications of Research (OMAR) when it was established within the National Institutes of Health in 1977. See Banta & Behney, supra note 86, at 49-50. For a discussion of OMAR, see supra note 129 and accompanying text.

151. The NCHCT sponsored two sorts of technology assessments: reimbursement-oriented assessments, a limited effort usually conducted in-house to guide HCFA's administration of the Medicare program; and multifaceted assessments on major new technologies like coronary artery bypass surgery, usually performed by outside contractors. See Perry & Eliastam, supra note 150, at 2511.

152. The NCHCT responded to over 70 requests from HCFA for assistance in making coverage determinations under Medicare and Medicaid, and HCFA almost invariably followed the center's recommendations. See Blumenthal, supra note 129, at 604. Blumenthal notes that HCFA benefitted from the arrangement by being able to attribute politically sensitive coverage restrictions to the center's scientific assessments. Id. at 605. By identifying and assessing emerging technologies, the NCHCT also would enable HCFA to anticipate controversial coverage decisions in advance. See Hearings on H.R. 2562, supra note 73, at 538 (testimony of Dr. Helen Smits).

153. Private health insurers were especially interested in the center's assessments. See Perry, supra note 82, at 1098. The NCHCT sent its findings, for example, to the American Council of Life Insurance for distribution to other commercial companies. See id.

154. The NCHCT incited a turf battle within the Department of Health and Human Services with the National Institutes of Health (NIH), the National Center for Health Services Research (NCHSR) and the Office of Research and Demonstrations within the Health Care Finance Administration, entities that also had jurisdiction over technology assessment. See Blumenthal, supra note 129, at 595. As Blumenthal observes, "[t]he Center's research mission embroiled it in the politics of health care research, an arena in which the warfare is no less intense for the fact that the gladiators sometimes don white coats." Id. at 599. Of these opponents, the most powerful was the NIH, which viewed the NCHCT as a direct competitor for congressional appropriations. See id. at 596.

Another source of opposition to the NCHCT were those who objected to what they viewed as excessive government regulation of the health care system and the technology industry. See id. at 606. David Stockman, then Director of the Office of Management and Budget, referred to the center and its supporters as "latter-day Luddites." Id. The center was
funding for fiscal year 1982, the Center ceased to exist in October of 1981.155

For two years after the NCHCT's demise, its functions were taken over by the small, understaffed Office of Health Technology (OHT) in the National Center for Health Services Research.156 Despite responsibility for coordinating all technology assessment activity within the Department of Health and Human Services, including advising the HCFA on coverage policy, OHT employed only four professionals—two registered nurses and two health services researchers.157

The inadequacy of this effort prompted the powerful Institute of Medicine of the National Academy of Sciences to call for the estab-

attacked by such powerful lobbies as the American Medical Association (AMA) and the Health Industry Manufacturers Association (HIMA), a trade association comprising over 450 manufacturers of medical devices. Id. at 600-01. The AMA was particularly concerned about a provision in the NCHCT's enabling legislation that authorized it to establish norms and criteria for technology use. While none were ever proposed, the AMA argued that this provision authorized the center to interfere with the physician's patient treatment prerogatives. See id. HIMA particularly opposed the NCHCT's authority to establish a list of emerging technologies, fearing that the mere appearance of a technology on the list, possibly targeting it for technology assessment at an early stage of development, would discourage innovation. See id. at 601; OTA STRATEGIES, supra note 4, at 85; Hearings on S. 800, supra note 82, at 27 (testimony of HIMA).

In response to these criticisms, the center and its supporters argued that the center was not a regulatory agency, and that its critics, therefore, had nothing to fear in terms of its impact upon their activities. See Perry, supra note 82, at 1099. Nevertheless, its director admitted that the Center's activity was bound "to constrain industry's freedom in the marketplace," id., and amid objections that its regulatory disclaimer was disingenuous (see Hearing on H.R. 2562, supra note 73, at 578 (testimony of Dr. Joseph Boyle, AMA), the chairman of the Center's national advisory committee acknowledged that it was at least a "quasi-regulatory" body. Hearing on S. 800, supra note 82, at 35 (testimony of Dr. Charles A. Sanders). In a last-ditch survival effort, the NCHCT shifted its focus from new technologies to those already in existence, but to no avail. See Perry, supra note 82, at 1100.

The NCHCT was also hampered by a lack of support from an identifiable constituency, beyond the relatively small and powerless assessment contractors it directly funded. The NIH, on the other hand, could mobilize the numerous beneficiaries of its biomedical research program. See Blumenthal, supra note 129, at 594.

155. See Blumenthal, supra note 129, at 593. The Senate had voted in 1981 to dismantle the NCHCT, but the House of Representatives reauthorized it after Congressman Henry Waxman (D.Cal.) tacked the measure onto a Medicaid bill that had strong backing from state governors. The House prevailed in conference. Id. at 592-93. The NCHCT's enabling legislation authorized a three-year appropriation of $73 million, but in 1981 Congress reduced the budget authorization for the following three years to $12 million. Only $7.8 million had actually been appropriated by the time the center ceased to exist in 1981. Id. At the time of its demise, the center was funding approximately 20 technology assessment projects. It had an official staff of 20, but actually employed 39. Id. at 592-93.


157. See id.
lishment of a quasi-public consortium to assess technology. This development, in turn, led to the enactment of the Health Promotion and Disease Prevention Amendments of 1984 and to Congress's creation of the National Center for Health Services Research and Health Care Technology Assessment (NCHSRHCTA). This expansion of the former National Center for Health Services Research encompassed an additional responsibility of advising the Secretary of Health and Human Services on specific technologies and reimbursement by federally financed health programs, while taking into account the "safety, efficacy, and effectiveness, and, as appropriate, the cost-effectiveness and appropriate uses of the technology." In addition, the law established a non-profit, quasi-public Council on Health Care Technology in conjunction with the National Academy of Sciences to promote, coordinate and sponsor technology assessment.

158. See id. at 511.
160. See id. § 5.
161. See id. § 5(a)(3).
162. Id.
163. Id. § 8. Public Law 98-551 also established a National Advisory Council on Health Care Technology Assessment to advise the National Center for Health Services Research and Health Care Technology Assessment (NCHSRHCTA) on criteria and methods to be used in making coverage recommendations. Id. § 5(a). A number of factors may have been responsible for Congress's reinstatement of federal technology activities resembling those of the NCHCT so soon after its demise in 1981. First, it may have become clear that technology assessment was necessary to control health care costs, and that the Office of Health Technology in the National Center for Health Services Research (NCHSR), which had inherited the tasks of the NCHCT, did not have the resources to handle the responsibility. This view was reflected in the strong support for the bill to create the new agency by the American Association of Retired Persons, the Health Industry Association of America, the Blue Cross and Blue Shield Association, the American Association of Medical Colleges, and the American College of Physicians, but most of all, by the Reagan administration. See Hearings on H.R. 5496, supra note 108. Assistant Secretary for Health Brandt represented the administration during hearings on H.R. 5496, the bill introduced by Congressman Henry Waxman (D. Cal.) that eventually became Public Law 98-551, and endorsed the key features of the proposal—the creation of a public/private partnership to undertake technology assessment, with the public function to reside in the NCHSR. Id. at 469-71 (testimony of Assistant Secretary Brandt).

Second, the new entity's location within the NCHSR probably defused a considerable amount of opposition within existing units of the Department of Health and Human Services, since the bill avoided the creation of a new, high-level agency with sole responsibility for technology assessment. Furthermore, the concept of a quasi-public technology assessment council, including representatives from technology manufacturers, health professionals, hospitals, insurers, employers and consumers, and with only three members appointed by the Secretary of Health and Human Services, may have satisfied those who opposed federal dominance of the technology assessment field. Nevertheless, both the American Medical Association (AMA) and the Health Industry Manufacturers Association (HIMA) opposed the measure. The AMA reiterated its long-stated resistance to a government role in technology
Although it is too soon to evaluate the performance of either the NCHSRHCTA or the Council on Health Care Technology, their creation has revived the issue of government's proper role in technology assessment. Some favor leaving technology assessment largely to the private sector.\(^\text{164}\) Strong arguments can be advanced in support of this view: government often has its own agenda, including bureaucratic self-preservation, which may not be consistent with appropriate technology assessment; government may lack the necessary technical expertise and personnel, which may be attracted to the private sector by better salaries and opportunities for advancement; bureaucrats tend to be removed from the real world of medicine, and their judgments, therefore, may be erroneous and meddlesome; and finally, bureaucracy is costly and inefficient.

On the other hand, several factors militate against a purely private approach. As the country's single largest purchaser of health care—providing care directly to the military and to veterans, and indirectly to Medicare and Medicaid beneficiaries\(^\text{165}\)—government has a vested interest in ensuring efficient operation of the health care system. Moreover, technology assessment data resemble a public good, insofar as it is difficult and contrary to public policy to allow them to remain the private property of a private sponsor.\(^\text{166}\) Private sponsorship of technology assessment thus gives rise to a free-rider problem, since those who do not pay for the assessment can nonetheless appropriate it for their own use.\(^\text{167}\) This might lead

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\(^{164}\) The AMA has consistently opposed federal technology assessment, at least beyond that performed by the Food and Drug Administration. See supra note 154 and accompanying text. See also Blendon & Altman, supra note 20, at 15.

\(^{165}\) See OTA STRATEGIES, supra note 4, at 157 app. B. Medicare alone accounts for 40% of all community hospital inpatient revenue. DHHS, HCFA, Medicare Program: Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1987 Proposed Rates; Proposed Rule, 51 Fed. Reg. 19,970, 20,017 (1986).

\(^{166}\) See Bunker, supra note 19, at 689; OTA STRATEGIES, supra note 4, at 5-6. Safety and efficacy data submitted by drug and device manufacturers to the Food and Drug Administration, the details of which are kept secret due to the free-rider problem discussed infra at notes 167-68 and accompanying text, provide an exception to this view. Public policy would seem to favor widespread dissemination of technology assessments to achieve better patient management decisions as well as to curb waste. At the same time, it is difficult to keep the results secret because of the impetus to publish them in the scientific literature, if only to communicate positive results to prospective purchasers and users.

\(^{167}\) See Bunker, supra note 19, at 689.
to less than optimal amounts of technology assessment. The free-rider problem is normally alleviated by collective purchase of the goods. Technology assessment by public, governmental institutions would, therefore, address the free-rider problem. For these reasons, it seems appropriate for the government to play at least some role in the production of technology assessment.

The extent of governmental involvement in technology assessment, assuming it should have at least some role, is open to question. One possibility is direct sponsorship of assessment as well as selection of the technologies to be assessed, as was the case with the NCHCT and is somewhat the system adopted for the new NCHSRHCTA and Council on Technology Assessment. Alternatively, government could underwrite technology assessment performed by private entities. Another approach would require private sponsors to submit technology assessments to the government in order to market technologies, or in order to qualify for reimbursement under government-operated third-party health programs.

All of these alternatives have serious drawbacks. Government assessment, whether direct or subsidized raises the objections of bu-

168. Less than optimal amounts of technology assessment might result because the nonexclusivity of the assessment would diminish its value to any potential private purchaser. This nonexclusivity would lead to the purchase of less assessment than if the purchaser based his decision of how much assessment to purchase on the total value of the assessment measured across all who might benefit.

169. See supra notes 160-63 and accompanying text.

170. See Hearings on H.R. 2562, supra note 73, at 542 (testimony of Dr. Peter Bunker). Bunker advocates that the government rather than private sponsors pay for all clinical trials on new technologies. A related alternative is for the government to subsidize private assessments by providing interim Medicare reimbursement while assessments are undertaken. See Greenberg & Derzon, supra note 119, at 974-75.

171. This is the policy embodied in the Federal Food, Drug, and Cosmetic Act for new drugs and devices. See supra note 106 and accompanying text. As noted earlier, however, the Act does not authorize the Food and Drug Administration to compare the costs and benefits of a technology, nor does the FDA regulate surgical and medical technologies, except insofar as they employ new drugs and devices. See infra note 187 and accompanying text.

172. Former Secretary of Health and Human Services, Patricia Harris, announced in 1980 that new technologies such as the artificial heart should be evaluated on the basis of their "social consequences" as well as their safety and efficacy before the Health Care Finance Administration financed widespread use. See Evans, supra note 30, at 2050. Banta recommends technology assessment prior to reimbursement rather than a prohibition on disseminating a technology without such assessment. See Banta, supra note 16, at 82-84. See also OTA MEDICARE, supra note 2, at 25; Russell, supra note 15, at 41-42. France has adopted a policy that the government will not pay for new drugs under that country's national health system unless the drug has been shown to be either more efficacious or cheaper than existing alternatives. See H.D. BANTA, C. BEHNEY & J. WILLEMS, supra note 24, at 177.
reappraisal of the earlier described political agendas mentioned earlier. While restricting either dissemination or reimbursement pending assessment could deter unwarranted diffusion of untested technologies, focusing on reimbursement alone could cause disproportionate burdens to fall on those patients who cannot afford a new technology absent third-party payment.

B. Specific Problems in Assessing Specific Technologies

In addition to the general issues and problems connected with technology assessment, three specific types of technologies create particular obstacles for assessment.

1. Diagnostic Technologies

Diagnostic technologies are particularly difficult to assess because of the difficulty in associating a specific diagnostic technology with a specific patient outcome, and hence with a specific set of risks, costs and benefits. A range of medical interventions are likely to occur after the use of the diagnostic technology. A treatment decision may be the product of a number of diagnostic inputs and prior treatments, making it hard to isolate the role of a particular diagnostic technology in the treatment decision, let alone in the resulting outcome. Complicating matters further, a diagnostic technology may be used to detect a number of different conditions.

The costs of a diagnostic technology may also be difficult to gauge, thereby impairing cost-based technology assessments. The

173. See supra note 164 and accompanying text.
174. On the other hand, a system in which wealthy patients financed technology assessment in return for access to speculative technologies might be desirable. The additional price the wealthy would pay for the assessment on top of the other costs of the technology would be offset by giving them the first access to new, potentially beneficial technologies. The poor would not have this opportunity, but would also not bear the risk of exposure to potentially unsafe or ineffective technologies. In addition, a "market" in unproven technologies would be established that might help in valuing health benefits by assigning prices to them on the basis of expected or hoped-for results. Finally, a market for technology assessment would be created, which might help in determining its cost-effectiveness.
175. See OTA STRATEGIES, supra note 4, at 24; Hellinger, supra note 58, at 41; Rock, Technology Assessment in Laboratory Medicine: Rationalizing or Rationing, 1 CLINICS LABORATORY MED. 3, 13-14 (1981).
176. See OTA STRATEGIES, supra note 4, at 24.
177. See Hellinger, supra note 58, at 41.
178. For example, an automated multichannel chemical analyzer is used not only for diagnosing patients but for screening them and monitoring their progress. It provides data enabling the detection of a host of abnormal values indicative of a large number of diseases. It is therefore difficult to assess the device as a whole. See Rock, supra note 175, at 13-14.
hospital or laboratory charge for a diagnostic test is often an unreliable cost indicator because it may be inflated to cover the expenses of other services.\textsuperscript{179} Furthermore, providers tend to employ old and new diagnostic technologies in tandem until adequate experience has been gained with the new technology to permit confidence in its use. Thus the initial cost of a new diagnostic technology may be high, but may decline with time.\textsuperscript{180} Initial cost-benefit ratios therefore may be unduly pessimistic predictors of future cost-benefit relationships.\textsuperscript{181}

The benefits of diagnostic technologies also present assessment problems. Based on the results of initial assessments, diagnostic technologies may appear to present greater benefit than they will actually produce in later, full-scale use.\textsuperscript{182} Many diagnostic technologies are first evaluated at large hospitals where the target disease is more prevalent.\textsuperscript{183} As a result, a diagnostic technology may appear to be more efficacious (i.e., better able correctly to diagnose the disease) than when employed among populations with a lower prevalence of the disease in question.\textsuperscript{184}

2. \textit{Surgical and Medical Technologies}

Although surgical procedures account for approximately thirty percent of the total U.S. expenditures for health care,\textsuperscript{185} they are largely unregulated and unassessed. The practice of surgery is regulated primarily by state licensing laws which address practitioners' qualifications.\textsuperscript{186} The Food and Drug Administration regulates sur-

\textsuperscript{179} See id.
\textsuperscript{180} See Schroeder, supra note 81, at 635.
\textsuperscript{181} Initial costs, however, may be an overly optimistic indicator of future cost per case. Since the cost of a diagnostic procedure is a function of the prevalence of the target disease, the cost per newly detected case rises as the number of undetected cases declines. The more successful the technology is in detecting a disease, the more it will reduce the number of remaining undetected cases, further increasing its cost. See Steinwachs, \textit{Cost-Effectiveness Analysis: Role in Evaluation of Alternatives for Improving High Blood Pressure Control}, 33 MD. STATE MED. J. 225, 226 (1984).
\textsuperscript{182} See Rock, supra note 175, at 11.
\textsuperscript{183} See id. Testing sites for diagnostic and indeed for all technologies are selected in part to maximize the size and severity of illness of the target patient population to ensure enough subjects to produce statistically significant positive results. See id. For a discussion of statistical significance, see infra note 195 and accompanying text.
\textsuperscript{184} See id. The accuracy of a diagnostic technology assessment could be increased by employing the technology in a variety of settings, but this would significantly increase assessment costs. See id.
\textsuperscript{185} See Moore, supra note 19, at 134 (1985). In 1981, this amounted to about \$90 billion. \textit{Id.}
\textsuperscript{186} See OTA STRATEGIES, supra note 4, at 160 app. D.
gery indirectly through its regulation of surgical drugs and devices. As a result, some surgical technologies, such as transplants of artificial hearts, are subject to pervasive FDA controls while other surgical technologies intended to achieve similar patient outcomes, such as human heart transplants (or even transplants of xenografts, i.e., organs from nonhuman species), go largely unregulated due to the fortuity that there is no device central to the procedure. The same is largely true of medical technologies that do not employ drugs or devices. The lack of oversight of surgical and medical technologies is especially striking when contrasted with government regulation of drugs and devices. The Office of Technology Assessment regards the lack of assessment of surgical and medical technologies as the "overriding weakness" of this country's technology assessment program.

The lack of medical and surgical assessment is explained partly by the difficulty of detecting new surgical or medical procedures or changes in existing ones. Due to the complexity of some surgical procedures, it is difficult to detect a subtle change in the way they are conducted. Over time, however, numerous incremental changes in a complex procedure will yield a different procedure, with different risks, costs and benefits than the original technology. The difficulty of assessing medical and surgical technologies suggests that surgical and medical waste is more likely to go undetected than other types of wasteful health care practices.

187. See id.; Banta & Behney, supra note 78, at 454. For a discussion of medical procedures, see supra note 187 and accompanying text.

188. See Banta & Behney, supra note 78, at 454. However, the Food and Drug Administration does not regulate the prescribing behavior of physicians. Physicians therefore are free to prescribe a drug for uses the agency has not approved. Insofar as surgery and medical treatment that does not employ drugs or devices are applications of techniques by a health professional, they may be deemed comparable to physician prescribing, and their nonregulation by the FDA may therefore be unremarkable.

189. OTA STRATEGIES, supra note 4, at 99.

190. The long-standing opposition of powerful physician groups like the American Medical Association no doubt is also a significant factor.

191. See Greenberg & Derzon, supra note 119, at 970. Another factor complicating the assessment of surgical technologies is the ethical constraints on conducting controlled surgical research. See OTA STRATEGIES, supra note 4, at 130 app. C. This results from the risks associated with the typical invasive surgical procedure. It would be highly unethical, for example, to evaluate a new coronary repair procedure by opening up every subject's chest but only performing the repair on the group of subjects designated as experimental. Without this type of placebo control, however, it may be difficult to isolate the effects of the surgical technology from the effects of havings one's chest opened.
C. Problems Associated with Particular Types of Assessment

Beyond the issues raised in connection with technology assessment generally and in connection with assessment of diagnostic, surgical and medical technologies in particular, a number of concerns relate to specific assessment techniques.

1. Safety and Efficacy Assessments

The basic tool for safety and efficacy assessment is the controlled clinical investigation.\textsuperscript{192} To understand the value of the controlled clinical investigation, consider the alternative case report or anecdotal method which involves administering a technology to patients in an uncontrolled fashion and simply observing and reporting the results. With the exception of technologies that treat previously incurable conditions, so that any improvement is per se a demonstration of net benefit,\textsuperscript{194} uncontrolled trial and error is of little true assessment value. Without a group of control subjects, there is no way to tell if the patient outcomes are the result of the technology or of chance or some peculiar characteristic of the patients being tested. Assessment conclusions based on case report data are therefore unreliable. Nevertheless, because they are relatively simple and inexpensive, case report data probably provide the basis for an overwhelming majority of treatment decisions.

The controlled clinical investigation, in contrast to the case report, is a powerful assessment tool. In theory, it can identify technologies that are unsafe or inefficacious. By adding multiple control groups exposed to alternative technologies, technologies that are unsafe or inefficacious on a relative basis can also be identified. Un-

\textsuperscript{192} Formal safety and efficacy assessment dates back at least to John Lind's scurvy experiments 200 years ago. See Fineberg, supra note 4, at 663.

\textsuperscript{193} For a general description, see Moses & Brown, supra note 33, at 271. Controlled clinical investigations can either be experimental or observational. In the former case the investigator controls who gets what technology, while in the latter case the investigator observes the results in subjects whose exposure to the technology has been independent of the investigator. See, e.g., OTA STRATEGIES, supra note 4, at 34-39. The standard experimental study is a randomized, controlled trial. See id. at 34. A common observational study is an historically controlled investigation, in which the control population has been treated prior to the development of the technology being assessed, and can therefore serve as a group that has not been exposed to the technology for purposes of comparison with the group that has been exposed. See id. at 134 app. C. For a discussion of historically controlled studies, see Moses & Brown, supra note 33, at 274-76.

\textsuperscript{194} In this case, the experiment more nearly resembles an historically controlled study than an uncontrolled experiment, since patients treated unsuccessfully prior to the advent of the experimental technology in effect serve as controls.
 fortunately, its theoretical value is compromised by several shortcomings.

The use of controlled clinical trials is significantly limited by their cost and their ethical problems. Because of the large populations that must be studied to yield statistically significant results, controlled trials are very expensive to conduct. Ethical problems arise because of the need to compare the experimental technology to a placebo or alternate technology. Withholding a known effective technology from a patient is unethical, even if doing so facilitates the evaluation of a potentially superior technology. Randomized, controlled trials therefore can be employed ethically only in two cases: (1) if there is no technology known to be safe and effective for the condition in question; or (2) if the risks and benefits of the experimental technology are truly uncertain. In these cases, a positive control, in the form of another technology that may not prove to be as safe or effective when the experiment is completed, may be used clinically as the standard of comparison.

A more serious drawback is the limited ability of controlled clinical trials to identify wasteful technology due to the fact that

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195. Large study populations reduce the risk of erroneous negative conclusions (known as "false negatives" or beta type II error) that can result from small sample sizes. See Russell, The Role of Technology Assessment in Cost Control, in CRITICAL ISSUES IN MEDICAL TECHNOLOGY, supra note 72, 133-34. For example, many new technologies represent only modest improvements in patient outcomes. A large test group is needed to detect the positive effect of these technologies and to establish that the effect observed is not due to chance. See Moses and Brown, supra note 33, at 275. A survey of 71 investigations reporting negative results, for example, revealed that the negative results were due primarily to the small size of the study populations. See Freiman, Chalmers, Smith & Kuebler, The Importance of Beta, The Type II Error and Sample Size in the Design and Interpretation of the Randomized, Controlled Trial: Survey of 71 'Negative' Trials, 299 NEW ENG. J. MED. 690 (1978). In 67 of these studies, there was a greater than 10% chance of missing a true 25% therapeutic improvement, and 50 of the studies had a greater than 10% chance of missing a true 50% improvement. See id. Avoiding such error, however, requires large populations, which drives up the cost of the study, since cost is primarily a function of the number of subjects. See Hawkins, supra note 16, at 13-14. Moreover, the high cost of avoiding beta type II error, and thus the costs of controlled trials, increases as the marginal expected health benefit from the experimental technology decreases. See H.D. BANTA, C. BEHNEY & J. WILLEMS, supra note 24, at 117.

196. See Butt & Neuhauser, supra note 51, at 142; OTA STRATEGIES, supra note 4, at 93; Eddy, supra note 90, at 44; Moses, Statistical Concepts Fundamental to Investigations, 312 NEW ENG. J. MED. 890, 896 (1985) ("there may be ethical obstacles; if a patient can definitely be expected to benefit more from Treatment I than from Treatment II, that should preclude his being assigned to Treatment II").

197. See Eddy, supra note 90, at 44; Moses, supra note 196, at 896.

198. See Moses, supra note 196, at 896; OTA STRATEGIES, supra note 4, at 93 ("However, when a technology is in widespread use, risks and benefits are either already known or are widely believed to exist, and randomization may be neither possible nor appropriate"); Eddy, supra note 90, at 44.
they tend to assess efficacy but not effectiveness. Deliberately conducted in a carefully contrived and controlled setting, such as a prestigious medical research center, with highly trained investigators following a detailed protocol or set of instructions, the results of these studies are unlikely to reflect the risks, costs and benefits of the technology in actual clinical use. This does not present a problem if the results of the study are negative; a technology that is unsafe or inefficacious in a carefully controlled experiment is not likely to be safer or more effective in actual use. Risk, benefit and cost projections based on positive results from a controlled trial, however, may be highly overoptimistic.

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199. This distinction is discussed supra at note 28.
200. See Fineberg & Hiatt, supra note 30, at 1087 ("The results of technology assessment in one setting may not apply to others . . . The performance of a medical technology depends on the particular circumstances in use"); Hellinger, supra note 58, at 35. Hellinger cites the example of human heart transplants, which achieved a much higher rate of success when initially performed at Stanford University than after the technology spread to other medical centers. Factors that tend to limit the applicability of the results of controlled, clinical investigations to other settings include differences in skill between researchers and practitioners (see Note, supra note 111, at 552) and greater patient compliance with the treatment regimen under experimental conditions. Cf. Hawkins, supra note 16, at 16. Particularly in the case of drugs, patient compliance may reflect cost considerations. Since even insured patients often must pay for their own drugs, there is a tendency to reduce dosage and frequency of administration to save money, thereby reducing drug effectiveness. In clinical studies, however, the subjects typically do not pay for the experimental technology. Cf. id. at 19.
201. The same may not be true for an assessment of cost. Administrative costs are likely to be higher under controlled study conditions than under normal conditions of use, and economies of scale may be realized as the technology is diffused. On the other hand, in the case of proprietary technologies such as drugs and devices, the price of the technology at the experimental stage may be less than after it is introduced commercially because the manufacturer may not be able to charge a profitable price or perhaps any price for a technology under investigation. Food and Drug Administration regulations, for example, prohibit a sponsor of an experimental device from charging more than the reasonable costs of manufacture, research and development. 21 C.F.R. § 812.7 ("A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not . . . commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling."). While there is no comparable prohibition on commercializing experimental drugs, investigators and subjects typically are not charged for these technologies in controlled clinical experiments.
202. Randomized, controlled trials on chemonucleolysis, a new technology to treat slipped discs involving the injection of an enzyme called chymopapain into the disc, showed that the technology was extremely safe as well as effective, and much less costly that the traditional surgical treatment (laminectomy). In actual use, however, adverse reactions began to occur at much higher rates, perhaps because the injections were performed by less well-trained personnel than in the clinical experiments. Drug for Slipped Disks is Linked to 5 Deaths, 28 Serious Disorders, Wall St. J., June 7, 1984, at 7, col. 1.

A number of technical difficulties also arise in attempting to assess technologies for safety and efficacy, but in contrast to the problems of cost, ethical constraints and projection to actual use, they are somewhat amenable to technical solutions. Defining the end-point of a clinical trial is often difficult. In the case of coronary artery bypass graft surgery, for exam-
2. Consensus Conferences

Another assessment method that presents special problems is the consensus conference. This widely-used technique consists of a group of experts reviewing the available data on a technology and reaching an accord on its risks, costs, or benefits. The major drawback of this technique is that it does not generate data but only reviews, synthesizes and disseminates existing data. Consensus conferences therefore may be prone to conclusions based on inadequate data or bias on the part of the conferees. Nevertheless, the consensus method is a relatively inexpensive means of obtaining at least some expert assessment of a technology. To the extent that

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203. The use of consensus conferences as a methodology for assessing health care technologies began within the National Institute of Health (NIH). The first consensus conference was held in 1977 to assess screening methods for detecting breast cancer. See Ferry, supra note 100, at 97-98; see also Iglehart, supra note 15, at 50-55. The NIH brings together a panel of experts to listen to presentations over a two day period. On the eve of the second day, the panelists draft a “consensus statement,” which they read to the audience for their reaction. This is followed by a press conference to announce the tentative results of the conference. The panel then disperses, and the statement is circulated to them for finalization. See OTA STRATEGIES, supra note 4, at 63.

204. See L. Russell, supra note 15, at 134 (consensus approach “assumes, of course, that whatever steps the profession has taken to learn about the benefits of various technologies are sufficient to support the judgments that are made”).

205. See OTA STRATEGIES, supra note 4, at 94 (“Many syntheses are informal, overly subjective, group-generated norms and are not based on a rigorous assessment of the scientific evidence”); Hearings on S. 2504, supra note 82, at 120 (“The consensus method is vulnerable to oversimplification, errors in reasoning, and obvious biases, such as financial and professional biases.”)

The risk of bias influencing an assessment may be reduced by selecting neutral panelists. However, it is unlikely that any expert panelist would lack a personal or professional viewpoint on the technology being assessed. An approach that can reduce the potential for bias is the Delphi technique, which feeds panelists’ views back to one another anonymously. See K. Warner & B. Luce, supra note 1, at 99; OTA STRATEGIES, supra note 4, at 62. However, Delphi sacrifices face-to-face group interaction.

206. See Hearings on S. 800, supra note 82, at 25 (Testimony of the Health Industry
they reflect the shared views of leading experts in the field, moreover, consensus conclusions tend to be less controversial than those reached by more independent or objective methods. At the price of rigor, therefore, consensus assessment may be more politically acceptable than other approaches.207

3. Cost-Sensitive Analyses

Special problems arise with cost-effectiveness and cost-benefit analysis. Cost-effectiveness analysis aims at identifying technologies that are not the most cost-effective methods of achieving a desired health outcome.208 The analysis entails a number of steps. First, the health problem and the desired objective must be identified (for example, for patients with coronary heart disease, the objective might be to ameliorate the symptoms of angina pectoris); next, various technologies for achieving the objective must be considered (for example, the desired goal could be reached by use of drug therapy, a combination of therapy and lifestyle changes, or through coronary artery bypass graft surgery); finally, the costs and benefits of each technology must be calculated and compared to determine which provides the greatest net benefit at the least cost.209 Many of these steps are technically troublesome. Cost-effectiveness analysts often fail to consider all of the available alternate technologies,210 and

Manufacturers Association). There are no data available on the percentage of consensus conclusions later proven erroneous by more rigorous assessment.

207. Arguably, consensus findings are more likely to be accurate for technologies that, by virtue of being toward the extreme ends of the risk, cost and benefit continua, present the clearest cases of waste, than for those that are merely marginally wasteful or nonwasteful. See supra notes 81-82 and accompanying text. Consequently, the primary risk is that a marginal technology might be erroneously praised or condemned. This risk may well be outweighed by the advantages of a relatively simple, inexpensive assessment method like consensus.

208. See supra notes 47-55 and accompanying text. Selma Mushkin introduced cost-effectiveness analysis into the health care field in 1958. See Mushkin, Toward a Definition of Health Economics, 73 PUB. HEALTH REPTS. 785-93 (1980); See also Klarman, The Road to Cost-Effectiveness Analysis, 60 MILBANK MEMORIAL FUND Q. 585 (1982).


210. See Weinstein, supra note 47, at 313. This results in part from the analyst's bias. For example, a surgeon tends to compare alternate surgical procedures but to ignore nonsurgical alternatives such as drug therapy; from the surgeon's standpoint, what is relevant is which of his tools is the most cost-effective. In addition, comparisons among technologies are often difficult to make because of varying quality and quantity of data. Unless the analyst goes to the trouble and expense of conducting his own clinical trials, the data relied upon to establish the values for one technology may not be comparable to those for another; for instance, there may be a great deal of data of questionable quality for an old technology, and only a small amount of high quality data for a newer one. Furthermore, as noted supra at notes 88-90 and accompanying text, technologies change over time, which may render data
often encounter serious difficulties in identifying, measuring and valuing costs\textsuperscript{211} and benefits.\textsuperscript{212} on one version of a technology inapplicable to current or future experience. See Neuhauser, \textit{supra} note 54 at 33.

211. Measurement determines the quantity of inputs required to achieve the health objective, such as the number of physician hours, scalpels and drug tablets, while valuation assigns the inputs a dollar value. See K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 79-80. For purposes of cost-effectiveness analysis, the cost of a technology is assessed by the technology’s marginal opportunity cost (measured by the value of the resource in its next best use) rather than the technology’s average cost or market price. See \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 39-40; K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 108-09. To illustrate the distinction between marginal and average costs, Neuhauser calculates the cost per additional case of colon cancer detected by repeated stool guaiac tests to increase from approximately $1200 for the first test to $47 million for the sixth. See Neuhauser & Lewicki, \textit{What Do We Gain from the Sixth Stool Guaiac?}, 293 \textsc{New Eng. J. Med.} 226, 228 (1975). Using average rather than marginal cost would submerge the tremendous increase in cost per detected case.

Marginal cost, however, is not easy to calculate. See Weinstein, \textit{supra} note 47, at 320. Both measurement and valuation problems arise. See Klarman, \textit{supra} note 53, at 226. How should costs be measured when a technology is used for many purposes, or is employed in a treatment program along with a number of other technologies? See \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 40; Klarman, \textit{supra} note 53, at 230; K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 74. How should overhead be treated? Should only the marginal increase in overhead resulting from the technology be measured, or a proportion of fixed costs? See \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 40. Should research-and-development expenses be included? See K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 78.

Once the inputs are identified and measured, they must be valued. Inputs or goods traded in the marketplace may have a market price, but that price may not accurately reflect true cost. See Klarman, \textit{supra} note 53, at 226. For example, some hospitals charge more for some goods and services, such as laboratory tests, pharmaceuticals and radiological services, than their true marginal costs, a practice known as “cost-shifting.” \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 40; Conn, Aller & Lundberg, \textit{Identifying Costs of Medical Care, an Essential Step in Allocating Resources}, 253 \textsc{J. A.M.A.} 1586, 1587 (1985); K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 142-43. Other valuation problems arise because of the difficulty of predicting future uses of a technology, hence future economies of scale, See Hellinger, \textit{supra} note 58, at 35, 41; Greer, \textit{supra} note 39, at 132 (1981). Choosing the rate at which to discount future costs to present value can also be problematic. See \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 41; K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 93-95; Pliskin & Taylor, \textit{General Principles: Cost-Benefit and Decision Analysis}, in \textsc{Costs, Risks, and Benefits of Surgery}, \textit{supra} note 35, at 8-9; Klarman, \textit{supra} note 53, at 227-28. A high discount rate favors technologies with present benefits and with costs accruing in the distant future, while a lower rate favors technologies, such as preventive vaccination programs, that have present costs but future benefits. See K. \textsc{Warner} & B. \textsc{Luce}, \textit{supra} note 1, at 154; Klarman, \textit{supra} note 53, at 227-28; \textsc{Ota} \textsc{Strategies}, \textit{supra} note 4, at 41; Kristein, \textit{supra} note 47, at 215. To some extent, these valuation problems are amenable to conventions, such as assuming a particular interest rate for purposes of discounting; as long as they are applied consistently, such practices permit comparisons between multiple technologies. This assumes, however, that the data for each technology will be comparable in quality and quantity; if this is not true, both the reliability and the validity of the assessment results may be compromised.

212. The benefits of a technology include direct benefits, which are tangible costs that the technology averts (for example, the costs of future hospitalization that will not be necessary); indirect benefits (for example, future earnings made possible by restored health); and intangible benefits or nontransferable satisfactions (for example, additional years of life or days without pain). See Klarman, \textit{supra} note 53, at 229-33. Both measurement and valuations
Cost-benefit analysis\textsuperscript{213} includes all of the steps involved in cost-effectiveness analysis, and thus is faced with many similar problems.\textsuperscript{214} However, cost-benefit analysis also requires that the value of all benefits—direct, indirect and intangible—be converted to common units, often expressed in monetary terms.\textsuperscript{215} This creates particularly difficult problems in the valuation of intangible benefits.\textsuperscript{216}

Intangible benefits must be included in the cost-benefit calculation, for in their absence, the assessment is more likely to conclude, incorrectly, that a technology is wasteful. However, it is difficult, if not impossible,\textsuperscript{217} to value intangible benefits in a manner that allows various health care benefits and alternate expenditures to be compared.\textsuperscript{218}

problems arise when comparing the benefits from different types of technologies (diagnostic, preventive, palliative, curative). See Hellinger, \textit{supra} note 58, at 35. The most intractable of these problems, however, is the valuation of intangible benefits. See infra notes 216-229 and accompanying text.

213. Cost-benefit analysis, in the simplest sense in which some effort is made to associate costs with benefits, has been conducted for many years. It was employed by Richard Petty, a well-known English physician, in the 17th century, \textit{see} K. WARNER & B. LUCE, \textit{supra} note 1, at 50, and in France in the 19th century, when Dupuit analyzed the costs and benefits of alternate public works projects. \textit{See} Dupuit, \textit{On the Measurement of the Utility of Public Works}, in 12 \textit{READINGS IN WELFARE ECONOMICS} 255 (K. Arrow & T Scitovsky, eds. 1969). In the United States, Shattuck argued that the monetary benefits of sanitary reforms in 19th century Boston outweighed their costs; and a provision requiring the Army Corps of Engineers to employ cost-benefit analysis for proposed river projects was incorporated in the Rivers and Harbors Act of 1902. \textit{See} K. WARNER & B. LUCE, \textit{supra} note 1, at 50-51.


215. \textit{See} supra notes 56-59 and accompanying text; Pliskin & Taylor, \textit{supra} note 211, at 5.

216. Intangible benefits include relief from pain, restored mobility and freedom from anxiety of disease. \textit{See} Weinstein, \textit{supra} note 47, at 321; Hess, \textit{Cost/Benefit Analysis—Another Dimension}, 16 MED. INSTRUMENTATION 76, 76 (1982). Hess would include anxiety from loss of income as well as legal, ethical, social and moral considerations among intangible benefits. In this discussion, the term “intangible benefits” is used to refer to the types of benefits enumerated above because that is the standard term in the health economics literature. From a legal standpoint, a more accurate term to describe these benefits is “nontransferable satisfactions,” since the legal term “intangibles” refers to transferable items such as the goodwill of a business, while in cost-benefit analysis, the term is reserved for benefits such as years of life that cannot be bought or sold. My thanks to Ronald Coffey for pointing out this distinction.

217. \textit{See} Neuhauser, \textit{supra} note 54, at 34 (life is not so much “priceless” as “unpriceable”).

218. Contrary to Klarman (“[t]he dilemmas of valuation can be escaped by retracting from C-B [cost-benefit] analysis to C-E [cost-effectiveness] analysis”), \textit{supra} note 53, at 227; Warner and Luce (“[t]he reason for a nonmonetary measure of program effectiveness is either the impossibility or undesirability of valuing important outcomes in dollars and cents”), \textit{supra} note 1, at 48; and Evans (in contrast to cost-effectiveness, which “preserves a sense” of intangible benefits, cost-benefit analysis “typically notes these but fails to assess them”), \textit{supra} note 50, at 2209, the problem is not solved by only performing the type of cost-benefit analy-
Proponents of cost-benefit analysis suggest several methods for valuing intangibles. The "human capital" approach measures intangible benefit as the present value of the future income stream made possible by providing the technology. If a technology increased by ten years the lifespan of a patient who earns $50,000 a year, the value of the intangible benefit of the additional years of life would be $500,000 discounted to present value. The flaw in this approach is its basic assumption that the value of the intangible benefit is a function of wealth or increased earning capacity; that a young, white male, by virtue of having the greatest expected future earnings, would benefit more from an additional year of life than anyone else.\footnote{220}

sis that converts different health benefits into common units other than dollars, such as QALY’s. See supra notes 56-58 and accompanying text. Even under a QALY approach, the difficult problem of comparing the utility of different health outcomes, or of the same outcome in different populations must still be addressed. Is a year of life worth the same as five years without pain? Is an extra year of life for an 85-year-old worth the same as an extra year of life for a 25-year-old? Is the value of an average gain of an extra year of life worth the same if it is one year of life for an entire patient population, or five extra years of life for only 20% of the patients? See Klarman, supra note 53, at 235. Cf. Veatch, supra note 73, at 149-52 (objecting to the assumption that benefits can be summed over a number of individuals and then divided by their number).

Further questions arise when patients must compete for the same scarce technology. Assuming that the benefit from the technology is one additional year of life, and that the value of an additional year of life is the same for two patients—which may not be true because of differing interpersonal utilities, cf. Schelling, Self-Command in Practice, in Policy, and in a Theory of Rational Choice: The Richard T. Ely Lecture, 74 AM. ECON. REV. 1, 7-8 (1984)—does the loss of the extra year of life to one patient cancel out the benefit of the extra year to the other, so that the net benefit of the technology is zero and it is therefore wasteful? See also Green, Should Technology Assessment Guide Public Policy?, 69 A.B.A. J. 930 (1983) (the benefit of a superhighway to the automobile owner may be the detriment of a spoiled view to the nature seeker). Cf. Head v. Colloton, 331 N.W.2d 870 (Iowa 1983) (plaintiff in need of potentially lifesaving bone marrow transplant not entitled to breach confidential hospital-patient relationship to have identity of unrelated potential donor revealed to court or counsel so that donor can be contacted with specifics of plaintiff’s need when donor has indicated willingness to donate only to relatives).

The problem of different interpersonal utilities would also affect allocation of scarce technologies based on safety and effectiveness. For example, if a technology were provided to patient A rather than to patient B, on the ground that patient A would gain five years of extra life while patient B would only gain one, an assumption is being made that five years of life to patient A is worth more than one year of life to patient B. In view of the problem of verifying this assumption, a better result would be to provide technologies to all patients who would derive net benefit from them, but this may not be palatable in an era of cost containment and may not be possible in cases of absolute scarcity, where the availability of the technology is constrained by factors other than cost, such as technical obstacles to mass production.

219. See Weinstein, supra note 47, at 321-22; Hellinger, supra note 58, at 208; K. WARNER & B. LUCE, supra note 1, at 88. This approach either treats intangible benefits the same as indirect benefits or counts indirect benefits twice, once to measure indirect benefits and a second time to measure intangible benefits. See supra note 212.

220. See K. WARNER & B. LUCE, supra note 1, at 88. The famous heart surgeon
Another method for valuing intangible benefits suggested by cost-benefit analysts, the "willingness-to-pay" approach, equates the value of the intangible benefit with the amount one would be willing to pay for it. For example, if a 30-year-old person were willing to pay $10,000 to avoid a heart attack at age 40, then the discounted present value of the intangible benefits to be expected at age 40 and beyond (additional years of life, mobility, avoidance of pain, etc.) would be $10,000. One method for determining this discounted present value is by survey; people simply are asked how much they would be willing to pay. This has certain advantages over attempts to value intangible benefits to unidentified individuals by other means, such as by taking an average of jury awards in wrongful death actions. By asking people directly how much they would pay for certain benefits, the problem of having to guess what they would pay—and the resulting risk that A's estimate of the value to B will be different than B's because of differences in interpersonal utility or differences in perspective—can be

Debakey fell into this trap (or embraced the notion of equating wealth with entitlement to health care) in the following argument on behalf of expensive technologies: "If the cost of an operation is $15,000, and the patient resumes employment at $30,000 per year, in about six months he will have contributed the cost of his operation in social productivity, and thereafter he will continue to contribute other resources instead of withdrawing from them." Debakey, supra note 73, at 10 (1983).

221. The originator of the survey approach, Acton, asked respondents hypothetically how much they would be willing to pay to avoid a specified risk of a future heart attack. See Rhoads, How Much Should We Spend To Save a Life, in Valuing Life: Public Policy Dilemmas 292 (S. Rhoads ed. 1980).

222. The jury valuation method fails to consider interpersonal differences in utility. Furthermore, awards may well reflect the jury's estimate of the value of the decedent's life to survivors rather than its value to the decedent himself. Moreover, the jury's award may not accurately reflect what the decedent or anyone else would in fact have paid in order to prevent the death, which is arguably an element, if not the key element, of the intangible value of the decedent's life under a willingness-to-pay approach.

223. See Schelling, supra note 218, at 7-8.

224. The difference in interpersonal utility is only one type of difference in perspective. Perspective can refer not only to differences between individuals but to differences between groups of individuals and between individuals and organizations. See supra notes 69-70 and accompanying text. Moreover, while the difference in interpersonal utilities might be narrowly interpreted to refer to the difference in the value to A of a benefit to A and the value to B of the same benefit to B, the difference in perspective also includes the difference between the value to A of the benefit to A and the value to B of the benefit to A. By obtaining values of benefits to individuals from those individuals, willingness-to-pay alleviates this perspective problem. The problem could also be alleviated by asking A how much B should pay to provide A with the additional years of life. If reciprocity is assumed (A must be willing to pay the same amount for additional years of life for B), this suggestion accords with the principal of universalization in moral philosophy.
avoided.\textsuperscript{225}

The survey approach is nevertheless prone to serious inaccuracies. Respondents tend not to take hypothetical questions seriously; are unable to discriminate between small differences in probabilities that often must be used in willingness-to-pay questions to make them realistic; and give answers that do not reveal their own minds so much as what they think will please the interviewer.\textsuperscript{226} Furthermore, since the wealthy can pay more for a benefit than the poor, the same problem arises as with the human capital approach:\textsuperscript{227} the wealthy would be likely to say they would be willing to pay more than the poor, and therefore would seem to place a greater value on intangible benefits than the poor. The result thus favors technologies for treating illnesses that disproportionately affect the wealthy.\textsuperscript{228}

One solution might be to set the value of a technology as the highest amount that anyone would be willing to pay for it and to compare that figure with costs in a cost-benefit analysis. But this is likely to generate a net benefit for almost any technology that is expected to yield any patient benefit. Another solution to at least some of the problems of asking hypothetical questions would be to calculate the value of intangible benefits from what people actually pay for technologies, but this too encounters problems of interpersonal differences in utility (How can the amount that one person pays be extrapolated to other individuals?) and in wealth (If a wealthy person pays twice as much as a poor person for the same benefit, does this mean the benefit is worth twice as much to the one than to the other?). Moreover, since health care for many individuals—including Medicare beneficiaries—is paid for in substantial part by third-party payors, how is the value of intangible benefits to these individuals to be calculated on the basis of what others (e.g., bureaucrats within the Health Care Finance Administration) are willing to pay?

A further problem with the willingness-to-pay method of valuing intangible benefits is that the value of these benefits for any individual is likely to vary over time.\textsuperscript{229} The value of an extra year of

\textsuperscript{225} Inaccuracies resulting from differences in interpersonal utilities or perspective may recur, however, if the values derived from individual responses are averaged.


\textsuperscript{227} See \textit{supra} notes 219-20 and accompanying text.

\textsuperscript{228} See K. \textit{Warner} \& B. \textit{Luce}, \textit{supra} note 1, at 89-90.

\textsuperscript{229} See Schelling, \textit{supra} note 218.
life to one at age twenty five is likely to be different than to one at age eighty five. The value of a year without pain is likely to be different during the time one feels the pain than before or after. To be accurate, a willingness-to-pay system must somehow reflect these changing values, which entails both multiple (ideally constant) measurement and a method of transforming the resulting value stream into a single value for the individual.

III. A PROPOSAL FOR DEFINING AND IDENTIFYING WASTE

The foregoing problems with technology assessment are so formidable that its use seems fruitless—indeed wasteful—as a means to reduce technology waste and thereby control health care costs. Nevertheless, some form of technology assessment is inevitable in health care decisionmaking. A physician's choice of a technology for a specific patient is based on at least an implicit assessment of its relative safety and effectiveness compared to alternatives.

230. Green has stated that "[t]echnology assessment is a useful tool for public policy only if it is not taken too seriously." Green, supra note 219, at 933. Green argues that policy decisions should continue to be made by "ordinary political processes" which can better reflect what the public wants, rationally or irrationally. Id. Ruby, Banta and Burns concur that cost-effectiveness analysis in particular cannot in most cases be the dominant factor in decisionmaking because it ignores such nonquantifiable factors as equity and ethics. See Ruby, Banta & Burns, supra note 133, at 150. Even the OTA admits that the value of cost-effectiveness analysis lies more in going through the exercise than in its numerical outcome. See OTA STRATEGIES, supra note 4, at 60. The OTA's conception of the role of technology assessment resembles the function of an environmental impact statement under the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370a (1982 & Supp. 1983). When required by that Act, a federal agency must prepare a public document identifying and evaluating the environmental impacts of proposed action, and it must consider these impacts in determining whether or not to take the action. But it need not base its decision to go forward on the results of its analysis. See Strycker's Bay Neighborhood Council v. Karlen, 444 U.S. 223 (1980).

Necheles makes the important further observation that the utility of cost-benefit analysis is limited by its insensitivity: "[A]ny medical program that is ambiguous enough to require cost-benefit analysis is probably too ambiguous to be resolved by cost-benefit analysis." Necheles, Standards of Medical Care: How Does an Innovative Medical Procedure Become Accepted?, 10 LAW, MED. & HEALTH CARE 15, 17 (1982).

231. The basis for the physician's assessment may be more the views of influential opinion leaders than a personal familiarity with the existing assessment data. See Greer, supra note 39, at 134; Fineberg & Hiatt, supra note 30, at 1089. These opinion leaders may be resistant to new technologies, bringing them into conflict with ambitious innovators who see the new technologies as a means not only of improving patient outcomes but of furthering their own careers. See Greer, supra note 39, at 134. Fineberg and Hiatt list a number of factors that they regard as affecting the adoption of a new technology by practitioners, including the severity and urgency of the medical problem being addressed, whether any alternatives are available, financial advantages of employing the new technology, how compatible the new technology is with old technology, the prestige and visibility of its advocates, the manner in which information about the new technology is diffused, promotional efforts by manufactur-
larly, patients presented with a set of alternative technologies as part of the informed consent process are required to assess the technologies in some sense as well. A hospital's decision to purchase or to provide a new technology, a third-party payor's decision whether or not to reimburse for it, as well as a manufacturer's decision to develop it, are all based on some form of technology assessment, however informal. In the words of one commentator, "[t]here is no question that we are doing and will continue to do technology assessments. The only question is how well."

Nevertheless, not all types of technology assessment are equally worthwhile. Assessment is confounded by a number of difficult technical problems, such as how to select technologies for assessment or how accurately to measure costs and benefits. Some of these problems are amenable to conventions or to technical solutions. For example, if the precise value of a cost variable is uncertain, sensitivity analysis can reveal whether the range of results obtained from the range of likely values for the variable is too large to permit useful decisionmaking, in which case an increased effort can be made to derive a more precise value for the variable. Sim-

ers, legal forces, patient preferences, and the physician's attitude toward change. See Fineberg & Hiatt, supra note 30, at 1089. One point that is especially worth noting is that the scientific literature, where technology assessment results are published, is apparently not a very influential factor in physicians' decisions about new technologies. See Banta, supra note 16, at 76-77; Greer, supra note 39, at 139. This results at least in part from the delay between the first dissemination of assessment results—usually through the press, trade journals or talks delivered at conferences—and formal publication. See Banta, supra, at 76-77.

232. In the celebrated case of Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), the court explained that a physician is bound to disclose to the patient "all risks potentially affecting the [patient's] decision . . . 'whether or not to forego the proposed therapy.'" Id. at 787. Informed consent entails a presentation of the results of an assessment of the relative safety and effectiveness of the technology. Effectiveness enters into the court's discussion of "risks" because, in explaining the relative risks of alternatives to the patient, the physician must explain the risks of not undergoing the treatment, which include the potential lost benefits from the technology. See id. at 788.

233. Hearings on S. 2504, supra note 82, at 120 (testimony of David Eddy, M.D.). See also Eddy, supra note 90, at 40. Fuchs especially disagrees with Green's position that technology assessment should defer to "soft" political decisionmaking:

[Every choice necessarily reflects a set of values. We do not, as the critics [of technology assessment] imply, have an option between evaluating and not evaluating. The only option is whether to evaluate explicitly, systematically, and openly, as CBA/CEA [cost-benefit/cost-effectiveness analysis] forces us to do, or whether to evaluate implicitly, haphazardly, and secretly, as has been done so in the past.

Fuchs, supra note 60, at 937. Accord K. WARNER & B. LUCE, supra note 1, at 61 (the alternative to attempting to quantify intangible costs and benefits is to have them valued "subjectively and implicitly"); Kristein, supra note 47, at 203-04 (advocating cost-benefit analysis as necessary where either no market exists or it produces undesirable results).

234. See supra notes 80-82, 208-29, and accompanying text.

235. See supra note 96 and accompanying text.
ilarly, the choice of an appropriate discount rate might be settled by agreement.\footnote{236} Beyond these kinds of problems, however, technology assessment confronts two especially intractible perplexities: the problem of multiple perspectives in defining waste and the identification problem of valuing intangible benefits.\footnote{237} The problem of perspective cannot be solved by a technical improvement, at least not one that is presently foreseeable; instead, it remains a choice to be made between potentially inconsistent alternatives, such as the determination that a technology is wasteful despite its net patient benefit because it offers insufficient net benefit to a third-party payor, provider or society.\footnote{238} Adopting a convention that technologies be assessed from a particular perspective would permit assessment outcomes to be consistent with one another, but from other perspectives perhaps consistently wrong. Similarly, the problem of valuing intangibles\footnote{239} may be resolved by some future technical breakthrough, but it seems likely to remain a first order problem for some time.

If there were types of technology assessment that offered the potential of reducing waste without raising these twin problems, it would seem advisable to predicate cost control efforts on these methods, presumably at the same time that the search continued for better solutions to the remaining assessment obstacles. Only if the savings resulting from the reduction in waste by these methods were insufficient would it be necessary to confront whether or not to take action against technologies that could be deemed wasteful on the basis of the less defensible types of assessments.

Do any types of technology assessment minimize the problems of perspective and valuing intangibles, yet facilitate waste reduc-

\footnote{236} See supra note 211. Since discount rates are presumed to fluctuate over time, the agreement would more properly be on a suitable reference point, such as the prime interest rate, rather than on an actual number. The choice of this reference point is not likely to be either obvious or without controversy, however.

\footnote{237} See supra notes 66-76, 216-29, and accompanying text.

\footnote{238} Here, too, a type of sensitivity analysis might be employed whereby the technology is assessed from different perspectives and the results compared to determine the marginal difference in net benefit. If the assessments show that the technology is likely to yield a large net benefit from the patient's perspective (such as five additional years of life), but from the perspective of a third-party payor such as Medicare, the cost is high compared to other technologies that produce the same health outcome, although perhaps in different patients, it might be possible to decide whether the marginal increase in value of the technology from the patient's perspective is or is not a wasteful result.

\footnote{239} See supra notes 216-29 and accompanying text.
tion? Suppose waste were defined as follows: a technology or the use of a technology

(1) that does not provide net health benefit to the patient;
(2) that provides less net health benefit another technology;
(3) that produces no more net health benefit to the patient than another technology that costs less; or
(4) that produces less net health benefit to the patient than another technology at the same cost.

Defined in this manner, wasteful technology could be identified by two types of technology assessment: safety and effectiveness and cost-effectiveness assessment. Safety and effectiveness assessments would identify technologies that were wasteful under the first two criteria, while cost-effectiveness assessment would identify waste under the third and fourth. While economic cost would be a key factor in determining whether or not a technology is wasteful, the consideration of cost would be limited to whether the technology affords the greatest amount of a given health benefit for the money.

One advantage of this proposal is that a technology wasteful from a patient perspective would also be wasteful from any other standpoint. A technology unsafe from a patient standpoint, for example, is not safe from any other. Note that the reverse is not true for cost-effectiveness considerations. A technology that is not wasteful from a patient perspective nevertheless might be deemed wasteful from another perspective, such as that of a third-party payor; even though it was the most cost-effective method of achieving a desired health outcome for patients, it might not be the most cost-effective method of maximizing net revenue for the payor. Under the patient-oriented approach that is proposed, however, such a technology would not be regarded as wasteful.

Another advantage of this approach is that there is no need to attempt objectively and quantitatively to value intangibles such as additional years of life or days without pain by converting them into common units; in each particular case, the health outcome from the patient perspective can be taken as the benefit endpoint. This is not to say that knotty valuation problems would be avoided under this limited concept of waste. For example, if there were two technolo-

240. See supra notes 192-212 and accompanying text.
241. See supra notes 66-76 and accompanying text.
242. A technology that is unsafe for one patient might be safe for another. However, as between patients generally, as well as between other perspective levels within the health care system, an assessment of waste based on the suggested parameters would be consistent across all levels, and it is the conflict between levels that is at the heart of the perspective problem.
gies available to treat a disease, each providing different benefits and risks at different costs, it would be necessary to compare, hence value, different amounts of different "goods" and "bads." This is likely to be extremely complicated. However, it is not as complicated as assessing technologies from different perspectives and attempting to assign a value for intangible benefits.  

IV. IMPLEMENTATION PROBLEMS

Once waste is defined and wasteful technologies are identified, some method must be employed to eliminate them. A large part of this problem is outside the scope of this discussion. The implementation of anti-waste policy is achieved by the health care delivery system, which is the one aspect of health care that is not encompassed within the term technology as it is being used herein.  

But to understand the impact of the current prospective payment system on technology, and the potential of this system for implementing the approach to waste suggested in Section III, it may be helpful to describe the main features of alternative methods of controlling costs.

A. Purely Private Decisionmaking

At one extreme, just as there are those who favor leaving the task of performing technology assessment to the private sector, there might be those who favor no government role in effecting an anti-waste cost control policy. Instead, private decisionmakers, acting rationally in the medical marketplace, would avoid wasteful

243. The doctrine of informed consent suggests that the valuation of alternative technologies is to be made by the patient, whenever possible, and this valuation tends to take place in temporal proximity to when the technology is provided or withheld, thereby establishing the time as of which the patient's intrapersonal utility will be determined. See supra note 229 and accompanying text. This enables the patient in theory to select the technology that maximizes his or her own health outcome preferences by offering the best mix of goods and bads. For example, a patient can be offered a choice between a surgical treatment that promises to yield a certain number of additional years of life and days without pain, or a non-surgical treatment, such as diet and drug therapy, that offers fewer additional years of life or days without pain but with a lower risk of adverse effects.

This theory is vulnerable to a number of objections, not the least of which is that patients cannot effectively exercise their freedom of choice because of a lack of knowledge and expertise, and that they instead rely on physician's recommendations. But physicians' recommendations and the decisions patients would make if they possessed adequate information and expertise are most likely to coincide if the perspective and valuation problems are approached as herein suggested. Note that these same issues of substitute decisionmaking arise in the case of incompetent patients.

244. See supra notes 4-5 and accompanying text.

245. See supra note 164 and accompanying text.
technology as part of their effort to maximize their own utility. A number of factors make this approach untenable, however. As noted above, government dominates the market for medical goods and services. Medicare accounts for forty percent of all hospital revenues, while the largest single, private, third-party payor accounts only for between three and four percent. Unless government divested itself of its role as health care payor, which is unlikely in view of its distributive function of insuring adequate health care for the poor and the elderly, it will continue to be a major factor in the market. It therefore bears repeating that the government does not behave according to traditional, free-market principles.

Even within the private segment of the health care market, classic market forces are likely to be inoperative. The effect of government is powerful and pervasive even in areas it does not directly control; private third-party payors, for example, typically follow the government's lead in reimbursing for technology. Delivery of services is separated from payment, and the payor is often not the recipient of the services. Prices often do not reflect true costs due to cross-subsidization. Regulatory requirements create formidable barriers to entry and there are widespread externalities; for the whole range of preventive technologies, for example, social utility is arguably greater than utility to the individual patient. Services are not fungible due to specialization among practitioners. Perhaps most important, patients as consumers are ill-equipped to make rational choices because of their lack of skill and experi-

246. See supra note 165 and accompanying text.
248. See id. Antitrust law prohibits private payors from combining their market power. In any event, it would take the combined market shares of all 325 members of the Health Insurers Association of America to match the market share of the federal government. See id.
249. See id.
250. See OTA MEDICARE, supra note 2, at 9.
251. See Weinstein, Economic Evaluation of Medical Procedures and Technologies: Progress, Problems and Prospects, in MEDICAL TECHNOLOGY, supra note 90, at 52.
252. See OTA COMPETITION, supra note 67, at 26. Not only is there a widespread system of government and private health insurance so that patients do not pay the full cost of the services they receive, but physicians rather than the insurers still control 80% of the health dollars that are spent. See Sanders, supra note 118, at 27.
254. See id.
255. See id. at 26-27.
256. See Id.
In short, in a number of fundamental respects, there is no private medical market that alone can assume the task of controlling wasteful technology.\textsuperscript{258}

B. Fostering Private Controls on Waste Through Government Programs

Assuming some continued government role in health care, an effort might be made to create incentives within government programs for the operation of market forces to reduce wasteful technology. This is arguably\textsuperscript{259} the principal path that is now being taken, spearheaded by the new Medicare prospective payment system.\textsuperscript{260} Under this system, providers are paid a fixed amount per hospital admission, depending on the patient's diagnosis. The diagnoses are classified according to a grouping system of 468 categories, known as diagnosis-related groups or "DRGs."\textsuperscript{261} The amount of reimbursement the hospital receives for a specific patient admission can be increased if the patient qualifies as either a day or cost "outlier." For day outliers the hospital will receive an amount greater than the basic reimbursement under the particular DRG if the patient stays in the hospital a prescribed number of days beyond the mean.

\textsuperscript{257} See Weinstein, \textit{supra} note 251, at 52; OTA \textit{COMPETITION}, \textit{supra} note 67, at 26-27.

\textsuperscript{258} See Bunker, \textit{supra} note 19, at 691; Goddeeris, \textit{supra} note 68, at 57. Klarman argues that government involvement in health care is necessary not so much because there is no functioning market but because it functions in "undesirable ways," such as by producing unjust results. Klarman, \textit{supra} note 54, at 225.

\textsuperscript{259} The qualification is interposed because the current system creates incentives to regard as wasteful technologies that fall outside the limits of waste as proposed in this Article. \textit{See infra} notes 293-309 and accompanying text.

\textsuperscript{260} A number of other efforts have been made in this same direction, such as encouraging Medicaid programs to enroll patients in capitated health plans such as health maintenance organizations (HMOs) under 42 U.S.C. § 1396b (1982), 48 Fed. Reg. 54,013 (1983), and relaxing federal requirements for qualifying HMOs under the Health Maintenance Organization Act, 42 U.S.C. § 300e (1982), which requires certain employers to offer HMOs to employees as an option in employer-provided health care plans.

\textsuperscript{261} These in turn are based on the International Classification of Diseases, 9th Edition, Clinical Modification, known as "ICD-9-CM." For a general description of the DRG system, see Dolenc & Doherty, \textit{DRGs: The Counterrevolution and Financing Health Care}, \textit{Hastings Center Rep.}, June 1985, at 19; \textit{PROPAC} 1985, \textit{supra} note 1, at 15-17. Medicare's prospective payment system operates in all but four states: New Jersey, Maryland, New York and Massachusetts. \textit{See} 50 Fed. Reg. 24,366, 24,397 (1985). These states have been granted waivers under 42 U.S.C. § 1886(c) to operate their own cost control systems for Medicare reimbursement. New Jersey has employed its own version of a DRG system since 1978. Maryland has employed a revenue control system in which hospitals are reimbursed on the basis of DRGs, but with the reimbursement level adjusted to reflect the hospital's annual deviation from a base year amount. \textit{See id.} at 73; K. \textit{WARNER} & B. \textit{Luce} \textit{supra} note 1, at 33-34. For a description of the Massachusetts system, see \textit{Kinzer, Massachusetts and California—Two Kinds of Hospital Cost Control}, 308 \textit{NEW ENG. J. MED.} 838 (1983).
length-of-stay for patients with the same diagnosis. For cost outliers the hospital will be paid more than the basic DRG rate if the cost of caring for the patient exceeds a fixed dollar amount or a fixed multiple of the normal DRG rate for that patient. These provisions, however, offer only limited relief from the cost containment pressures of the prospective payment system. Not only is reimbursement lower than the extra costs hospitals incur for day or cost outliers, but the Medicare law itself sets a relatively low limit on the percentage of discharges that can qualify for outlier status within the entire system.

The essential feature of the prospective payment system is that net revenue to providers is inversely proportional to the amount of

262. For fiscal year 1986, in order to qualify as a day outlier, the patient must remain in the hospital the lesser of 17 days or 1.94 standard deviations beyond the mean length-of-stay for the applicable DRG. 50 Fed. Reg. 35,646, 35,709 (1985). A hospital is paid 60% of the average per diem payment under the applicable DRG for each day the patient stays in the hospital beyond a threshold number of days, which varies from one DRG to another. 42 C.F.R. § 412.82 (1985). For example, a patient who is assigned to DRG 33 (concussion, age 0-17), qualifies for day outlier status once he remains in the hospital 17 days beyond the mean length-of-stay for DRG 33, which is 1.6 days, if that is less than 1.94 standard deviations. See 50 Fed. Reg. 35,646, 35,722 (1985). The hospital is then reimbursed an additional amount beyond the standard amount of reimbursement for DRG 33 to reflect the long stay. This additional amount is 60% of the average per diem payment under DRG 33, and it is paid for each day the patient is hospitalized beyond the specific threshold for DRG 33, which is 5 days. Id. Thus, in the case of a patient whose condition is diagnosed as DRG 33 and who stays in the hospital 20 days, the hospital is paid only the basic amount of reimbursement under DRG 33, but 60% of the average per diem amount of that reimbursement for days 6 through 20. Clearly the system is designed to discourage hospitals from retaining patients rather than discharging them; not only does the hospital typically have to absorb 100% of the costs of care for the extra days of stay between the mean length-of-stay under the DRG and the DRG threshold (days 1.7 through 5 in the case of DRG 33), but it is only reimbursed 60% of the average per diem DRG rate for the additional qualifying days of stay.

263. See 42 C.F.R. § 412.80(a)(ii) (1985). For fiscal year 1986, the extra cost must exceed either $13,500 or 2.0 times the DRG rate to qualify as a day outlier. See 50 Fed. Reg. 35,646, 35,709 (1985). If either of these thresholds is exceeded, the provider will be reimbursed an extra amount, but only 60% of the adjusted cost (72% of the billed charges) of the covered services it has provided beyond the base DRG amount. See 42 C.F.R. § 412.84 (1985). Thus, as in the case of day outliers, supra note 263, the outlier system is designed to discourage provision of services the costs of which exceed the base rates. Note that a patient may qualify as a cost outlier if he does not qualify as a day outlier. Note further that additional payment for day outliers is mandated by the Medicare law, while extra reimbursement for cost outliers is up to the discretion of the Secretary of Health and Human Services. Compare 42 U.S.C. § 1395ww(d)(3)(A)(iv) (1983 & Supp. I 1984) with 42 U.S.C. § 1395ww(d)(5)(A)(ii), (iii).

264. By statute, outliers may not account for less than 5% nor more than 6% of the total projected annual payments to providers. See 42 U.S.C. § 1395ww(d)(5)(A)(iv) (1983 & Supp. I 1984). For fiscal year 1986, the limit is set at 5%. See 50 Fed. Reg. 35,646, 35,709. In contrast, the New Jersey prospective payment system permits up to 30% of patients to qualify for outlier status. See Dolenc & Dougherty, supra note 261, at 20.
resources expended per patient. In other words, except for the relatively rare cases that qualify for outlier payments, providers are reimbursed a set amount regardless of the cost of the care they provide. If they expend more per patient than they are reimbursed, they must absorb the difference as a loss. Conversely, if they expend less per patient than they are reimbursed, they retain the difference as net revenue or profit. The prospective payment system is thus the antithesis of the previous fee-for-service system under which providers were reimbursed in direct proportion to their charges per patient.

The incentives created by the prospective payment system will affect not only provider behavior, but the behavior of manufacturers and others who develop new technologies. Providers will channel their technology acquisitions toward technologies that minimize costs; this in turn will encourage developers to concentrate their research and development on those types of technologies.

On the other hand, the process of technology development to some extent is insulated from market pressures. Technological innovation is a complex process, characterized by a number of stages: basic research, applied research, prototype development, product development, introduction, and diffusion. Basic research is largely independent of any specific technology objective, and therefore not heavily influenced by the economic and regulatory pressures that may eventually affect the resulting technology. Furthermore, innovators include entities that are relatively insensitive to market forces, in particular academicians and health care professionals such as physicians and surgeons. Even commercial manufacturers may develop technologies for prestige or to gain entry to a market rather than strictly in response to cost-control pressures transmitted through their customers. Accordingly, the problem of wasteful technology is unlikely to be solved solely by the response of technology development to direct financial pressures on providers.

265. See supra notes 263-265 and accompanying text.
266. See supra notes 11-12 and accompanying text.
267. See Eden, The Engineering-Industrial Accord: Inventing the Technology of Health Care, in MACHINE AT THE BEDSIDE, supra note 10, at 58; see also supra note 84 and accompanying text.
268. Cf supra note 84 and accompanying text.
269. See OTA STRATEGIES, supra note 4, at 152 app. D; Eden, supra note 267, at 57.
C. Coverage System

The Medicare prospective payment system creates a certain set of financial incentives on providers. These incentives are intended to encourage providers to take a more cost-conscious attitude toward technology. An alternative to such an incentive system is a "coverage" system, in which the government or other third-party payor specifies which technologies it will reimburse providers for.270 Under a pure prospective payment system, the provider is reimbursed up to a set amount regardless of the technologies it provides to a patient.271 The choice of which technologies to provide is not dictated by the third-party payor. Under a coverage system, the payor only pays for selected technologies. The provider is free to provide a noncovered technology to a beneficiary, but must either obtain payment from the patient or some other source, or must absorb the cost itself.272

A prospective payment system might be combined with a coverage system. Providers and beneficiaries would be reimbursed a set amount under the DRG system, but only for certain technologies. This is nominally the case with Medicare; as mentioned earlier,273 the government does impose a type of coverage system on providers under Part A of Medicare.

Theoretically, however, the prospective payment system obviates the need for a coverage system, at least beyond one that merely provided assessment information to providers to aid them in identi-

270. Similarly, the government, and other third-party payors following suit, might reimburse providers in proportion to the net benefit provided by the technology furnished. See Banta & Behney, supra note 86, at 50; Hearings on H.R. 5496, supra note 108, at 504-05 (testimony of the American Association of Retired Persons); Neuhauser, supra note 55, at 37. In other words, a provider would be paid more for employing a more cost-effective technology than for a less cost-effective one. Implementing such a system would involve a complex set of rates, based on a sophisticated body of technology assessment data.

271. The same is true under a capitated system such as a health maintenance organization (HMO), but an HMO has incentives to provide different technologies to patients than, for example, a non-HMO hospital. See infra note 299 and accompanying text.

272. If the provider furnishes a Medicare beneficiary with a technology that the provider knows or has reason to know is not covered, the provider must absorb the cost, unless the beneficiary also knew or should have known that the technology was not covered—such as if the provider informed the beneficiary that the technology was not a covered item according to Medicare coverage policy, or that the contractor has previously refused to pay for the same technology in similar circumstances—in which case the provider may charge the beneficiary for the noncovered care. See 42 U.S.C. §§ 1395pp(b)-(c). If neither the provider nor the beneficiary knew or had reason to know that the technology was not covered, Medicare will pay for the technology even though it is not covered. See 42 U.S.C. § 1395pp(a). Although it remains the law, such a technology-based payment system no longer seems highly relevant to the Medicare prospective payment system. See infra notes 274-75 and accompanying text.

273. See supra notes 132-48 and accompanying text.
fying waste. Since under prospective payment, providers have an economic incentive to withhold wasteful technologies from patients, it is unnecessary for the government to impose additional restrictions on which technologies will be reimbursed. To the extent that the government believes that providers are overspending on patients in a particular DRG, the government can simply lower the amount it pays for care within that DRG, leaving it up to providers to determine which technologies to eliminate. Thus, with the advent of the prospective payment system, the coverage system’s role under Medicare Part A will likely diminish.

274. I am grateful to James Blumstein, Timothy Jost and Theodore Marmor for this observation.

275. Through its Peer Review Organization procedures, see infra notes 375-84 and accompanying text, Medicare can refuse to pay for a specific portion of a DRG charge that is attributable to a technology not covered by Medicare. See Health Care Finance Administration, Peer Review Organization Manual 59 (1985). Aside from the arguable redundancy of this approach, given the cost-cutting incentives of the prospective payment system, surveillance of the specific technologies furnished patients by providers is hampered by the Medicare reporting system. Medicare claim forms require only limited information about the specific treatment provided to patients; the thrust of the form is to provide diagnostic information for verification of the patient’s DRG assignment.

The principal and up to four secondary diagnoses are required to be disclosed on the claims form, along with the principal and two other “procedures.” But the term “procedures” is limited to surgical interventions, broadly defined to include “incision, excision, amputation, introduction, repair, destructions, endoscopy, suture, and manipulation.” Health Care Finance Administration, Medicare Intermediary Manual § 3670 (1985) Accordingly, information about nonsurgical and secondary surgical technologies would only appear on the patient’s actual medical record, which is not routinely submitted to contractors as part of the claims procedure. Interview with Barbara DeCaeser, R.N., Professional Relations, University Hospitals, Cleveland, Ohio; Ruby, Banta & Burns, supra note 133, at 145-48; Department of Health and Human Services, Health Care Finance Administration, Medicare Program: Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1986 Rates, 50 Fed. Reg. 24,369 (1985).

The medical record is reviewed by the PRO in certain cases, such as in a random sample of a percentage of all claims, and in 50% of all claims for outlier payments. Requiring PRO's or contractors to review all medical records, or requiring a much greater amount of detail on claims forms, might facilitate a stronger coverage policy, but would substantially increase administrative burdens and costs. Indeed, HCFA seems to be moving in the opposite direction. It recently authorized PRO's to reduce the percentage of outlier cases reviewed from 100% to 50%. See 50 Fed. Reg. 35,673 (1985). One method that Medicare uses to detect specific technologies under its combined coverage-prospective payment system is to assign specific DRGs for specific technologies; for example, DRG 355 is a non-radical hysterectomy (age less than 70). See 50 Fed. Reg. 24,414 (1985). Only some technologies are treated this way, since making reimbursement contingent on the technology provided to the beneficiary deviates from the general diagnosis-based approach of the DRG system. A payment system entirely based on technologies would resemble a rate-setting system rather than a prospective payment system.

Coverage systems continue to be important for private third-party payors such as Blue Cross/Blue Shield, see Hellinger, supra note 58, at 38, and commercial insurers, see, e.g., Dallis v. Aetna Life Ins. Co., 574 F. Supp. 547 (N.D. Ga. 1983) that have not yet adopted a
D. Restrictions on Acquisition of Technology

Reimbursement and coverage programs attempt to restrict waste by discouraging the use of certain technologies, either those that the provider chooses not to furnish patients under a reimbursement system, or those that a third-party payor decides should not be reimbursed for as a matter of coverage policy. An alternative to restricting the use of technologies is restricting their acquisition by providers. One approach is to require government approval before a technology can be purchased by a provider. This is generally the approach taken by certificate-of-need (CON) laws. While the CON program appears to have reduced the growth in the number of hospital beds, however, it does not appear substantially to have reduced the acquisition of new technology by providers. The ineffectiveness of the CON program may be attributable to the technological imperative and to the fact that the program is run by those local interests most likely to benefit from the acquisition of new technology.

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prospective payment or capitated reimbursement system. In the case of private third-party payors, the scope of coverage is defined by the contract of insurance between the payor and the beneficiary. Under Medicare, coverage is dictated by statute and administrative interpretation. See supra notes 138-48 and accompanying text. In the past, competitive pressures have made commercial insurers reluctant to deny coverage unless the technology was explicitly excluded by the terms of the contract. See Hellinger, supra note 58, at 37. Current cost control objectives may reverse this tendency. Medicare coverage policy also remains a critical cost containment tool under Part B of Medicare, since Medicare physician payments continue to be made under the old fee-for-service system.

276. Pursuant to the National Health Planning and Resources Development Act of 1974, 42 U.S.C. 300(k)-(m), the Certificate-of-Need (CON) program is run by the states as a prerequisite to receipt of federal health resource development funds. Although certain details vary from state to state, most purchases of major medical equipment or changes in the number of hospital beds must be approved by a state Health Planning and Development Agency, acting upon the recommendations of the local or area wide Health Systems Agency.

277. Despite the decrease in the growth rate of hospital beds, there has been an increase in the ratio of capital equipment to beds. See Salkever & Bice, Hospital Certificate-of-Need Controls: Impact on Investment, Costs and Use (1979), cited in K. WARNER & B. LUCE, supra note 1, at 41 n.10. One example of the inability of the CON laws to curb technology is the acquisition of CT scanners in Dade County, Florida. See Iglehart, supra note 15, at 32-33. In 1974, the Health Systems Agency recommended a total of three CT scanners for the area. By 1977, however, there were seven, including one in an ambulatory care center and one in a physician's office—both outside the jurisdiction of the CON laws. Id. For a general critique of the CON program, see OTA STRATEGIES, supra note 4, at 161; Maloney & Rogers, supra note 2, at 1415.

278. See supra note 15 and accompanying text.

279. See Cohen, Information Needs in the Public Sector, in MEDICAL TECHNOLOGY, supra note 90, at 19 (CON program fails because "[L]ocal people who get the benefit from any capital project, including new technology, decide whether they should have access to it. Their decision that they 'need' it triggers an unlimited flow of dollars into that area to pay for the costs. . . . We have a nonoperative constraint due to circularity.").
Another approach to restricting the acquisition, rather than the use, of technology is to limit the amount of capital expenditures by providers. In contrast to the CON program, a capital expenditure restraint limits how much providers may spend, but not what they may purchase. Capital expenditures can be limited either directly by the enactment of a legal ceiling, or indirectly through a reimbursement system. For example, Congress has mandated that beginning in 1986, Medicare—which currently fully reimburses providers for capital expenditures on behalf of Medicare patients—must instead restrict capital reimbursement to a percentage of actual provider expenditures. If the reimbursement rate for capital expenditures is low enough and the proportion of Medicare beneficiaries out of a provider's total patient population remains high enough, this could be a significant deterrent to technology acquisition.

However, it is not clear that the Medicare capital expenditure limitation will operate to reduce costs at least not beyond the short run; such limits tend to discourage providers from acquiring technologies with high initial capital costs even though the technology would be likely to reduce future capital or operating costs. Moreover, providers might purchase wasteful technologies with low initial acquisition costs even if the technology were not likely to be the most cost-effective technology later on.

E. Diffusion Controls

A more direct method of implementing controls on waste is to prevent wasteful technology from being disseminated in the first place. In the case of drugs and medical devices, this is the system imposed under the Federal Food, Drug, and Cosmetic Act. Before a new drug or device may be introduced into interstate commerce, the manufacturer must persuade the Food and Drug Admin-

\[280.\] Providers are reimbursed for capital expenditures on what is called a straight pass-through basis; reimbursement is determined by the proportion of the provider's capital expenditures that corresponds to the proportion of their patients who are Medicare beneficiaries. The same system operates under Medicaid. See DEPARTMENT OF HEALTH AND HUMAN SERVICES, PROVIDER REIMBURSEMENT MANUAL, Part I, § 2200.1 (1985); OTA MEDICARE, supra note 2, at 102-04 (1984).

\[281.\] Capital expenditure restrictions have been advocated as a means of controlling health care costs. See Hearings on H.R. 5496, supra note 108, at 504 (testimony of American Association of Retired Persons); Whitted, Medical Technology Diffusion and its Effect on the Modern Hospital, 6 HEALTH CARE MANAGEMENT REV. 45, 52 (1981).

\[282.\] See Whitted, supra note 281, at 52.

istration (FDA) that it is safe and effective. But the system of controls on drugs and devices is incomplete. For example, the FDA cannot control the use of drugs and devices once they are approved. Furthermore, the FDA has generally interpreted its statutory mandate to preclude a comparison of the safety or effectiveness of one product with another, or any consideration of cost. Any attempt to expand the scope of the agency's authority in these directions would probably encounter fatal opposition from drug and device manufacturers.

Furthermore, the FDA has no direct jurisdiction over surgical and medical technologies. As mentioned above, there are difficulties in identifying wasteful surgical and medical technologies, and even if they could be identified, it would be even more difficult to control their use. This would entail a monitoring system that would detect and penalize unapproved changes in non-marketed technologies that are provided in the relative privacy of the doctor's office or the operating room. The administrative costs of an effective surveillance system, even if one could be designed, are likely to outweigh any reductions in waste that would be achieved.

As an alternative to controlling the dissemination of new tech-

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284. Far more new technologies would be diffused if the government were required to show that a new technology was not safe and effective in order to prevent its being marketed. Waste control, in the sense of protecting the public from unsafe and ineffective technologies, would thus be sacrificed in favor of promoting innovation. This is essentially the system that is imposed on food additives under the Act. Cf. 21 U.S.C. §§ 321(S) (definition of food additive).

285. See Hellinger, supra note 58, at 36. The FDA can only control the use of drugs and devices after they are approved for marketing through their labelling, which the agency reviews and approves. 21 U.S.C. § 355(d)(6). If a manufacturer wishes to promote an approved drug for a purpose not set forth in the approved labelling, it must obtain the FDA's approval for a change in the labelling. 21 C.F.R. § 314.70(b)(3). While a physician is not liable under the Act for using or prescribing a drug or device in a manner not provided for in the labelling, doing so risks malpractice liability. See, e.g., Mulder v. Parke Davis & Co., 288 Minn. 332, 181 N.W.2d 882 (1970).

286. See supra note 45 and accompanying text.


288. See supra note 154 and accompanying text (discussing the demise of the National Center for Health Care Technology). For a model and critique of such an expanded role for the FDA, see OTA IMPLICATIONS, supra note 73, at 92-98. See also K. Warner & B. Luce, supra note 1, at 200 (objecting to discouraging innovation by requiring manufacturers to submit expensive cost-effectiveness data to the FDA).

289. See supra notes 185-91 and accompanying text.

290. See supra notes 190-91 and accompanying text.

291. For a proposal to do so, see Note, supra note 111, at 560 n.53. Requiring prior approval of surgical and medical technologies involves such problems as distinguishing between old and new technologies to determine which require approval. See id. at 568, n.80.
nologies to reduce waste, the government might instead attempt to control their development. A system that precluded the development of wasteful technologies would alleviate later battles over their dissemination, reimbursement, or provision to patients. It would also save sponsors some research and development expenses and, by reducing uncertainty as to which technologies the government would later approve, perhaps reduce the cost of research-and-development capital.

Controls on development to an extent are embodied in the present system: the FDA must give prior approval before a new drug or device may be shipped in interstate commerce for purposes of being tested in humans.\textsuperscript{292} If the agency does not believe that the proposed tests could show that the technology is safe and effective, it can delay or prohibit the testing, thus arresting the technology prior to the sponsor's request for FDA permission to disseminate it for commercial use.\textsuperscript{293} Conceivably the government might broaden the current system to embrace medical and surgical technologies as well as drugs and devices, and it might even institute a monitoring system that required it to be notified of and approve in advance any animal or even laboratory testing of technologies for human use, thus pushing the government's go/no-go decision even farther back.\textsuperscript{294} Aside from the overwhelming practical difficulties and cost of instituting and enforcing such a system, however, the intrusion of the government at such an early stage of development, where the future risks, costs and benefits of the technology are so unpredictable, is likely to result in highly arbitrary restrictions on technology development that preclude nonwasteful technologies before their benefits can be established.

\section*{F. Direct Control of Health Care}

The most extreme form of government control of waste would be for some agency to mandate detailed rules of medical practice as a prerequisite for reimbursement under any government health care program. These rules would specify the technologies to be used and the circumstances and manner in which they would be employed.

\textsuperscript{292} See 21 U.S.C. § 355(i).
\textsuperscript{293} See 21 C.F.R. § 312.1(d)(6) (FDA denial of permission for investigation that is not reasonable to establish safety and effectiveness).
\textsuperscript{294} Due to fear of the unknown, such an early warning system was in fact imposed, largely on a voluntary basis, on research on recombinant DNA technology. See Department of Health & Human Services, Guidelines for Research Involving Recombinant DNA Molecules, 49 Fed. Reg. 46,266 (1984).
This "protocol" approach has been severely criticised by organized medicine and others. As with the approach of requiring prior approval of technologies, it raises insuperable political policing problems.

**G. Shortcomings of the Current Approach**

The present prospective payment system rewards providers who reduce their technology costs per patient admission. This can be done in a number of ways. Providers can eliminate unsafe or ineffective technologies and can substitute cheaper, more cost-effective technologies for more expensive, less cost-effective ones. Thus far, providers would remain within the boundaries of the controls on waste proposed in Section III. But the system also penalizes providers who furnish technologies that increase their costs per admission, even if the technologies are safer or more effective than a cheaper alternative. In short, prospective payment is not neutral with regard to technology. It creates a distinct incentive in favor

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295. See, e.g., Moloney & Rogers, supra note 2, at 1415 (protocol approach inappropriate because clinical circumstances cannot be adequately foreseen). This resistance partially explains why a system of national health insurance, with an attendant risk that the government would attempt to dictate medical practices to providers, has not been adopted in the United States. Cf. Altman & Blendon, supra note 20, at 15 (national health insurance not a viable U.S. option for controlling costs in the foreseeable future).

296. The exception might be providers such as health maintenance organizations (HMOs) that furnish hospitalization and primary care, as well as being insurers of their subscribers. They might be willing to incur a higher cost for one admission to avoid the need for or to reduce the cost of future care, assuming that the discounted value of the savings were greater than the present value of the additional current expenditure. Providers that are not also insurers would have no comparable incentive under prospective payment to provide more expensive present care to avoid future expenditures, since they would not have the same expectation as an HMO that the patient would return to the same provider or that the savings in care would be in the form of reduced expenditures for a future admission rather than, say, in the form of better general health status or reduced physician office visits. In short, the utility of the more expensive care would be an externality for the non-HMO provider under the present system.

The only situation in which the non-HMO provider has an incentive to furnish more expensive care to reduce future costs for the same patient is when, in the absence of the more expensive care, the patient will end up being readmitted to the same hospital within a prescribed time for the same diagnosis. See OTA COMPETITION, supra note 67, at 47. This is deemed a premature discharge and readmission, and Medicare regulations prevent the provider from being paid an additional fee for the readmission. See 42 C.F.R. § 412.48.

297. A number of commentators recognize that prospective payment only encourages a free market approach toward wasteful technologies to the extent the payment system is neutral, providing neither positive nor negative incentive. See Moloney & Rogers, supra note 2, at 1416-17; Schroeder, supra note 82, at 638; PROPAC 1985, supra note 1, at 24,465. Propac states, for example, that "[t]he Medicare prospective payment system should have an unbiased effect on technological advancement. Prospective payment levels should not inhibit the
of cost-reducing technologies and against cost-increasing ones.298

Yet as suggested earlier,299 a technology is not wasteful merely because it increases costs. Whether or not it is wasteful depends on the relationship between the increase in cost and the increase in benefit it produces, the relative costs and benefits of alternative technologies, and the perspective of the assessment. A technology is not necessary wasteful even from a societal perspective merely because it increases the cost per patient admission.300 For example, under prospective payment, a hospital has no incentive to provide a technology that increases short run costs (i.e., costs per admission), even though it may significantly decrease the cost to patients, other providers, and society in the long run.301 Thus, a hospital (other than one run by an HMO)302 has no incentive to provide a patient with a

development or diffusion of new technologies and practices, nor should payment levels result in their inappropriate adoption.” Id.

In a free market, a provider might increase the quality of its product, and its cost, and expect to recover the additional cost by charging a higher price. This is foreclosed by the set fee-per-admission aspect of prospective payment (unless the patient can be charged a premium above the third-party payment). The system can only respond to cost-increasing technologies by increasing the amount of payment for the relevant DRGs, by relaxing the rules for patients to qualify for outlier status, or by increasing DRG weights across-the-board to reflect technology cost increases—a so-called “update factor.”

To an extent, these adjustments are being made. For example, the Health Care Finance Administration (HCFA) adopted a 1.5% addition to the annual DRG update factor (known as the policy target adjustment factor) for 1986, stating: “Certain technological changes, especially those related to the adoption of new product (with accompanying labor and nonlabor inputs), increase the operating cost of treating illness but also improve health status commensurately. We believe the prospective payment rates should recognize new science and technology factors, which are cost-increasing, but also enhance health status. This should provide positive incentives for continued technological and scientific excellence.” HCFA, Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1986 Rates, 50 Fed. Reg. 35,646, 35,707 (1985). To place this 1.5% increase in perspective, the annual historical increase in health care costs attributable to the increased use of technology or to the use of new technologies has been between 4% and 5%. See Anderson & Steinberg, supra note 13, at 182-83.

298. See PROPAC 1985, supra note 1, at 24,465; HCFA, Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1986 Rates; Proposed Rule, 50 Fed. Reg. 24,366, 24,443 (1985); OTA COMPETITION, supra note 67, at 19. These incentives are also clear to providers. For example, one of the largest chains of for-profit hospitals in the country, Humana, reports that it is seeking technologies that “increase efficiency, decrease costs, and are safe and efficacious.” Hearing on H.R. 5496, supra note 108, at 536 (testimony of Frank E. Samuel).

299. See supra notes 66-76 and accompanying text.

300. See PROPAC 1985, supra note 1, at 24,465 (adjustment may be needed in prospective payment system to encourage adoption of technologies “more costly on a per admission basis but ‘cost-effective’ when considered from a broader health care system perspective over a longer period of time”).

301. See Anderson & Steinberg, supra note 13, at 184.

302. See supra note 296.
more expensive but better quality prosthesis, even if it is more cost-effective in the long run by having a longer useful life.\textsuperscript{303}

The inherent bias of the prospective payment system leads to a more fundamental problem: it creates a conflict of interest between provider and patient by encouraging providers to withhold cost-increasing technology from patients, thus placing the provider's own financial interests above the health interests of patients.\textsuperscript{304} Since prospective payment under Medicare currently applies only to hospital inpatient care and not to office care by physicians,\textsuperscript{305} physicians now have little direct financial incentive to side with the hospital, and therefore less of a conflict of interest with the pa-

\textsuperscript{303} See Anderson & Steinberg, supra note 13, at 184. A similar case is the implantable infusion pump that administers chemotherapeutic agents automatically into patients with liver cancer. Although the cost-per-patient is $3,000, it may be more cost-effective than conventional chemotherapy by avoiding the cost of repeated hospital admissions. See Hearing on H.R. 5496, supra note 108, at 537 (testimony of Frank E. Samuel). Another consequence of prospective payment is to encourage providers to avoid admitting, or to transfer, more seriously ill patients who are likely to require more care than others. One commentator describes as follows the analogous situation in Canada where physicians are paid a set fee per patient visit regardless of the care provided: "Being paid the same amount to do a vaccination as to treat a case of jaundice, the Canadian general practitioner vaccinates like crazy and refers jaundice to an internist, who refers the case to a gastroenterologist, who refers it to a liver specialist, who, having no one to refer it to, emigrates to the United States." Fisher, supra note 73, at 33 (1983).

\textsuperscript{304} See, e.g., Moloney & Rogers supra note 2, at 1418 (advocating rewarding providers for "technology restraint"). In an article in a hospital journal recommending that hospitals establish policies on technology in response to cost-containment pressures, for example, hospitals are advised to "cost-out" a technology and to "assess its incremental effect on the profitability of services." Goodhart, Technological Acquisition Poses Thorny Dilemma to Hospitals, 58 Hosp. 34, 38 (1984). The recommendations are silent on assessing the effect of technology on quality of care.

It should be noted that, as pointed out by Capron and Brock, in this Symposium, the previous fee-for-service system also created a conflict of interest between patients and providers. Under the old system, however, it was in the provider's economic interest to provide more care than what might have been in a patient's interest, since the more care provided, the more the provider was paid. Under a prospective payment or capitated system, it is in the provider's economic interest to provide less care than might be in the patient's interest, in order to pocket the difference between the cost of the care furnished the patient and the amount of the prospective or capitated payment.

\textsuperscript{305} Outpatient care by hospitals is also covered under Part B, and therefore is also excluded from prospective payment coverage. See 42 U.S.C. § 1395k(a)(2)(B) (scope of benefits under Medicare Part B includes "medical and other health services"); 42 U.S.C. § 1395x(s)(2)(B) ("medical and other health services" defined to include outpatient services). Physicians continue to be reimbursed under Medicare on a "reasonable charge" basis, which is the lowest of several alternatives, including the physician's customary charge, the prevailing charge in the locality, and the actual charge. See 42 U.S.C. § 1395u(b)(3); 42 C.F.R. §§ 405.501, 405.502. Physician reimbursement has been frozen at 1984 levels in order to control costs. See Emergency Extension Act of 1985, Pub. L. No. 99-107, 99th Cong., 2d Sess. (1985).
Nevertheless, hospitals are seeking ways to put pressure on physicians to be cost-conscious, such as monitoring physician practices to identify those prone to "overspend" on patients. Furthermore, hospitals are devising more formal financial arrangements with physicians to encourage them to act in the hospital's best interests. These include joint ventures, such as MeSH plans, the object of which is to have physicians share with hospitals the financial risks and benefits of providing hospital care to their patients.

Consideration is also being given to extending prospective payment, or systems that create similar incentives, to physicians.

306. See Dunlop, supra note 73, at 44 (individual physicians, dealing with individual patients, cannot be expected to consider costs of care). In addition to pressures directly stemming from prospective payment systems, physicians and hospitals are prone to conflict in a number of areas. See Greer, supra note 39, at 137. In contrast to physicians who will opt for a closed staff at a hospital at which they have privileges to admit and tend to patients, for example, the hospital itself has an interest in maintaining "open staffs," thereby creating a larger number of physicians to form the hospital's patient-referral pool. See Spivey, The Relation Between Hospital Management and Medical Staff Under a Prospective-Payment System, 310 NEW ENG. J. MED. 984 (1984). Physicians and hospitals also compete with each other, such as by establishing outpatient care facilities. See id.; Relman, Dealing with Conflicts of Interest, 313 NEW ENG. J. MED. 749 (1985).

307. At present, the objective seems to be limited to confronting the doctor with his profigate behavior, and perhaps allowing him to be pressured by his peers into changing his practice habits, but Morreim speculates that hospitals may attempt to revoke admitting privileges of those who are unrepentent or unable to reform. See Morreim, supra note 17, at 34. This could be a powerful threat to a physician, who owes an "economically essential allegiance to the hospital, without which he cannot adequately treat the most seriously ill patients." Id. at 32. Morreim notes that this tactic so far has not been tested in the courts.

308. For a description of such arrangements, see id. at 34. Morreim attributes them to a desire to keep quality-of-care considerations within economic restraints, and suggests that the resulting conflict of interest between physicians and their patients can be avoided by requiring physicians to disclose to their patients the physician's financial interest in the provider. See id. For a critique of this approach, see infra note 334-37 and accompanying text.

309. Physicians also have financial incentives to reduce patient care under capitation systems where the physician is paid a flat rate per patient for a set time period, such as one month or one year. This is the system under which health maintenance organizations (HMOs) operate, and they can be expected to place physicians in the same conflicts of interest with their patients as prospective payment, especially where the HMO is run by the physicians so that they have a direct financial stake in it, or where the physician staff is remunerated in part in proportion to the income or profit of the organization. See Stern, Will the Tort of Bad Faith Breach of Contract be Extended to Health Maintenance Organizations?, 11 LAW, MED. & HEALTH CARE 12, 13 (1983):

It is expected by the members that in the exercise of such judgment [as to which, if any, health care services are vital to the interest of the member at that time] by the physician/agent, the interest of the patient, rather than the costs to the HMO, is the paramount concern of the decision-maker. The plan, on the other hand, perceives that it has a concurrent duty to its overall membership [and possibly its investors] to preserve its resources by avoiding the provision of unnecessary and inappropriate services. . . . How can an interested director (of an HMO) who is also a provider
Unlike alternative methods of controlling the cost of physician care for Medicare patients, such as discounted service arrangements or government-imposed fee-for-service rates, reimbursing physicians under a prospective payment system would create the same conflict-of-interest between physician and patient as between hospital and patient under the present system.

The shortcoming of this result is all the more evident in light of the fiduciary duty traditionally imposed on physicians and hospitals in relations with their patients. The fiduciary relationship tran-

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310. See, e.g., OFFICE OF TECHNOLOGY ASSESSMENT, PAYMENT FOR PHYSICIAN SERVICES: STRATEGIES FOR MEDICARE (1986).

311. Physicians might refuse to accept Medicare patients if the government imposed flat fee-for-service rates, but increased competition between growing numbers of physicians should make corrective steps such as mandatory assignment unnecessary.

312. Warner and Luce observe that the cost of care is irrelevant to physicians paid on a fee-for-service basis to treat well-insured patients, and a "curiosity" to salaried physicians who treat the same type of patients, such as physicians on the staffs of a health maintenance organization. See K. WARNER & B. LUCE, supra note 1, at 178-79: "Only if the physician works within the context of prepayment—that is, if he or she bears financial liability for the use of resources—does the professional concern with cost-effectiveness begin to approach the social concern." Id. at 179. At that point, Warner and Luce observe, the physician is in a hopeless position:

A physician's primary responsibility is to weigh all the costs and benefits of a procedure to the patient. If a particular test has a small probability of improving the diagnosis that could affect case management, the physician's responsibility to the patient is to compare that potential benefit with the cost to the patient—out-of-pocket costs, time lost, pain, and so on. . . . From society's perspective, social costs may exceed social benefit; but asking the physician to adhere to the social standards of desirability requests him or her to deviate from the patient's best interests. In effect, the physician is placed in the untenable position of violating either the patient's or society's interests.

Id. (emphasis in original).

313. Many cases have recognized the fiduciary relationship between physicians and their patients. See, e.g., Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) cert. denied, 409 U.S. 1064; Hammonds v. Aetna Casualty & Surety Co., 237 F.Supp. 96, 102 (N.D. Ohio 1965); State ex rel. McCloud v Seier, 567 S.W.2d 127, 128 (Mo. 1978). Cases recognizing a fiduciary relationship between hospitals and their patients include Gopaul v. Herrick Memorial Hosp., 38 Cal. App. 3d 1002, 1005, 113 Cal. Rptr. 811, 813 (1974) and Grodjesk v. Jersey City Med. Center, 135 N.J. Super. 393, 413, 343 A.2d 489, 500 (1975). Hospitals are also held to have a fiduciary duty to the public to maintain competent staff; the issue arises in challenges by physicians to denials of staff privileges. See, e.g., Rutledge v. Gulian, 93 N.J. 113, 459 A.2d 680 (1983). In Nutty v. Jewish Hosp., 571 F. Supp. 1050 (S.D. Ill. 1983), the only federal court that appears to have considered the issue stopped short of clearly recognizing a fiduciary relationship between a hospital and a patient—in Nutty, a patient complaining of malpractice on the part of hospital nursing staff and interns—on the ground that the physician-patient relationship differs from that of a nurse- or intern-patient relationship. Nutty, 571 F. Supp. at 1052-53. "While physicians clearly have a fiduciary relationship with their patients," the court stated, "the relationship between a hospital and a patient is more difficult to characterize." Id. at 1052. Nevertheless, due to the "superiority of knowledge of the hospital staff, and the confidence and trust which patients must place in nurses and in-
scends the ordinary duty to act reasonably toward another; it requires the fiduciary to act in the best interests of the beneficiary, and to avoid placing the fiduciary’s interests above those of the beneficiary. Yet that is precisely the provider behavior that is encouraged by prospective payment systems. To draw an analogy with corporate directors, who owe a fiduciary duty to shareholders to maximize the value of shareholder equity in the corporation, it

314. The fiduciary need not elevate the beneficiary’s interests above all others, however. For example, despite owing a fiduciary duty to the patient, a physician may be liable if, in upholding the confidentiality of the physician-patient relationship, he fails to disclose information necessary to protect the health of third parties. See, e.g., Tarasoff v. Regents, 551 P.2d 334, 131 Cal. Rptr. 14 (1976).

Similar issues of fiduciary duty arise in the case of publicly held corporations, where the issue is whether the corporate directors may divert funds to philanthropic causes without violating their fiduciary duty to shareholders. Some courts have held the directors’ action to be protected by the so-called “business judgment rule,” on the ground that, although the value of shareholder equity thereby may have been reduced in the short term, the action was calculated to produce long-term maximization of equity value by enhancing the corporate image or the political and social climate in which the corporation does business. See, e.g., Shlensky v. Wrigley, 95 Ill. App. 2d 173, 237 N.E.2d 776 (1968); A.P. Smith Mfg. v. Barlow, 13 N.J. 145, 98 A.2d 581, appeal dismissed per curiam, 346 U.S. 861 (1953). Other courts have refused to permit diversion of corporate wealth under these circumstances. See, e.g., Dodge v. Ford Motor Company, 204 Mich. 459, 170 N.W. 668 (1919). The issue is unsettled, with the American Law Institute and some state statutes adopting the view that philanthropic types of corporate activity do not violate fiduciary obligations of directors. See American Law Institute, Principles of Corporate Governance: Analysis and Recommendations § 2.01 (Tent. Draft No. 2 1984); Pa. Bus. Corp. Law § 408B, Pa. Stat. Ann. tit. 15, § 1408B (Purdon Supp. 1984-85). This view may be justified insofar as disgruntled shareholders can vote out a board of directors that takes action contrary to the shareholders’ interests, and insofar as the value of shares in states with pro-philanthropy statutes can be discounted appropriately, although this only benefits future investors. (I am indebted to Ronald Coffey for these observations.)

would be as if directors were compensated in proportion to the diminution of the value of shareholders’ equity that they achieved.\(^{315}\)

In line with the recent rise of the doctrine of informed consent, it might be argued that the fiduciary obligation of health care providers is merely a misguided relic of paternalism that should be discarded under the new regime of patient autonomy. Patients are entitled to be treated as intelligent, choosing adults, rather than as incompetents for whom health care choices must be made by professionals. A fiduciary relationship between patient and provider, it might be said, undermines the patient’s independence and freedom of choice.

This argument fails for several reasons. First, a fiduciary obligation on health care providers requires them to act in the best interests of the patient, not instead of or in derogation of the patient’s wishes. Advocates of patient autonomy would no doubt insist that informed health care choices made by patients are in the patient’s best interests. The provider’s fiduciary duties would therefore require it to respect and facilitate this patient decisionmaking. Furthermore, the fiduciary obligations on health care providers, like those on corporate and other fiduciaries, are not mere historical artifacts. These special duties are mandated by factors inherent in the circumstances that give rise to the fiduciary relationship. First, the fiduciary is necessarily invested with a substantial degree of discretion,\(^{316}\) and must exercise it in a manner that precludes active supervision by the beneficiary.\(^{317}\) Thus, corporate officers and directors must make day-to-day management decisions without consulting corporate shareholders. Similarly, due to the complexity, variety and uncertainty of diseases and their treatment, it is not possible for patients and providers to agree in advance to all of the details of the treatments that will be provided.\(^{318}\) The fiduciary ob-

\(^{315}\) In contrast to shareholders of a corporation who can vote out of office directors whose policies they reject, patients are often not in a position to replace their health care providers with others who might be more willing to provide better care. Even if patients possessed sufficient information to realize that they were being denied proper care, those in extremis would not have the time to shop around, and only the wealthy might be able to afford to pay extra to induce another provider to supply more care. In other respects, furthermore, patients are at a disadvantage in dealing with conflicts of interest on the part of hospitals and physicians compared to corporate shareholders; for example, patients lack an effective watchdog such as the Securities and Exchange Commission, and the elaborate system of rules that govern corporate activity in the shareholders’ interest.


\(^{317}\) See Anderson, supra note 311, at 757-61.

\(^{318}\) The fiduciary relationship is the product of assent between the parties, here mani-
ligation on the provider mandates that he act in the patient's interest in regard to the aspects of treatment that must be left up to provider discretion.

Fiduciary obligations also derive from the inherent inability of the beneficiary to possess the knowledge and expertise of the fiduciary. Physicians and other health care professionals have undergone years of specialized training to prepare them for the subtleties, complexity and diversity of modern medicine. Their judgments cannot be duplicated by laymen; even if the provider and patient discussed every step of treatment, the patient would still be handicapped in guiding the behavior of the physician by a lack of knowledge and expertise.\footnote{319} A reimbursement system that disturbs the traditional

\footnote{319. See Greenberg, Demand, Supply, and Information in Health Care and Other Industries, in Incentives Versus Controls in Health Policy: Broadening the Debate 96 (J. Meyer ed. 1985). This is a serious problem with efforts to control health care costs by relying on consumer behavior under market-like conditions. It might be suggested that, if patients feel that providers are encouraged to withhold patient benefits under prospective payment, patients may bargain with providers for greater benefits. But this presupposes that patients are in a position to observe and accurately evaluate provider behavior, which is not the case. Furthermore, third-party insurers, rather than patients, typically are in the bargaining position. Yet as discussed earlier, see supra note 69 and accompanying text, their assessment of costs and benefits, hence their bargaining behavior, is based on a different perspective than the patient's. Thus, there is no reason to believe that the "price" agreed upon by third-party payors and providers will be the same that would be arrived at by providers and patients.}

One approach to giving patients a greater economic stake in their health care purchases in order to encourage more prudent buying is to increase their insurance premiums. See Sisk, Effects of Increased Competition in Health Care on the Use and Innovation of Medical Technology, 9 Health Care Mgmt. Rev. 21, 22-23 (1984). Another suggestion for reducing the discrepancies between patient/provider and third-party payor/provider bargaining outcomes is to require patients to pay for a substantial portion of the cost of care before the third-party payments begin. See id. at 22-23. See generally A. Enthoven, supra note 67; U.S. General Accounting Office, A Primer on Competitive Strategies for Containing Health Care Costs (1982); OTA Competition, supra note 66; Feldstein, A New Approach to National Health Insurance, 23 Public Interest 93 (1971).

Co-payment is already a feature of the Medicare system and of most insurance plans. See, e.g., 42 U.S.C. § 1395e (1983); 50 Fed. Reg. 39,940 (1985). In fiscal year 1986, for example, Medicare beneficiaries will be required to pay an annual deductible of $492, and a daily coinsurance amount for each day they are hospitalized beyond 60 days. 50 Fed. Reg. 39,940 (1985). The coinsurance rates are $123 per day for each day of hospitalization between 61 and 90 days, and $246 per day for each day between 91 and 100 days. \textit{Id.} These rates have increased substantially in recent years. In fiscal year 1976, for example, the deductible was only $104. 42 C.F.R. § 409.82(b) (1985). Nevertheless, they do not appear to have had a significant impact on health care costs, in part because Medicare beneficiaries often purchase
fiduciary relationship by introducing a conflict of interest between provider and patient must therefore be viewed with considerable misgivings.320

H. Pressures To Hold the Line At Waste

1. Professional Ethics

The extent, if any, to which providers submit to the pressures to deny patients nonwasteful, cost-increasing care depends on whether these pressures are outweighed by counterpressures to act strictly in patients’ interests. One of the most important of these counterpressures is the ethics of the medical profession, inculcated in physicians by their medical training.321 The Principles of Medical Ethics of private insurance to cover their deductible and coinsurance payments. Further increases in these amounts might be more effective at inducing patients to control their own health care costs, but perhaps not without undermining the fundamental objectives of the Medicare program, which include protecting patients against the costs of health care without impoverishing them. See S. Rep. No. 404, 89th Cong., 1st Sess. 23, reprinted in 1965 U.S. CODE CONG. & AD. NEWS 1943, 1964.

Even if patients were motivated to seek cheaper health care alternatives, it is questionable whether they possess sufficient bargaining power to affect prices significantly. In Tunkl v. Regents, 60 Cal. 2d 92, 383 P.2d 441, 32 Cal. Rptr. 33 (1963), the court refused to uphold a release from liability signed by a patient in part on the ground that the patient lacked equal bargaining power with the provider: “As a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possess a decisive advantage of bargaining strength against any member of the public who seeks his services.” Id. at 60 Cal. 2d at 99-100, 383 P.2d at 445-46, 32 Cal. Rptr. at 37-38.

Finally, one commentator notes that the growth of technology’s role in medicine is due in part to the growth of a better-informed public with higher expectations. See Schroeder, supra note 16, at 19. This suggests that an increase in patient information, without countervailing cost pressures such as increased first-party financial responsibility, would actually increase health care costs.

320. Some approaches to health care cost containment do not create a conflict of interest between providers and patients. CON laws which limit technology acquisition by providers, for example, do not reward providers for acquiring less technology than would benefit their patients. For a discussion of CON laws, see supra notes 276-79 and accompanying text. Coverage decisions, whereby a third-party payor declares in advance of treatment that it will not reimburse providers for a particular technology, create a conflict only if the provider regards the technology as non-wasteful for a patient. In this case, the provider has a conflict between doing what it believes to be in the patient’s interest and avoiding the risk of having to absorb the cost of the technology if the patient is unable to pay. The same is true of rate-setting systems in which payors limit the amounts they will reimburse providers for a particular technology, except that the risk to the provider is the risk of having to absorb only the marginal difference between the set rate and the provider’s normal price. While providers may not have a conflict of interest with patients under these approaches, this is not true of the agencies administering the CON law, the rate setters and the coverage decisionmakers, who may have to choose between nonwasteful technologies and fiscal imperatives. See, e.g., Blumenthal, supra note 129, at 603 (HCFA has a conflict of interest in assessing technologies because of its cost control mission).

321. See 50 Fed. Reg. 24,366, 24,443; Mamana, Ethics and Technology: Crossroads in
the American Medical Association reflect the physician's primary duty to the patient:

A physician has a duty to do all that he can for the benefit of his individual patients without assuming total responsibility for equitable disbursement of society's limited health resources. To expect a physician in the context of his medical practice to administer governmental priorities in the allocation of scarce health resources is to create a conflict with the physician's primary responsibility to his patients that would be socially undesirable.\(^{322}\)

The Principles also state that the physician's duty to his patients takes precedence over cost concerns:

While physicians should be conscious of costs and not provide or prescribe unnecessary services or ancillary facilities, social policy expects that concern for the care the patient receives will be the physician's first consideration.\(^{323}\)

It is particularly noteworthy that the Principles direct physicians to avoid providing patients with "unnecessary" services. While this term is not defined, it is safe to assume, in light of the emphasis on the physician's responsibility to his patients, that it is consistent with the approach to wasteful technology discussed in Section III.\(^{324}\)

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\(^{322}\) Dolenc & Doherty regard the ethics of the medical profession as so compelling that they insist that "[s]urely physicians will not act against a patient's best interests." Dolenc & Doherty, supra note 261, at 25. They admit, however, that, as a result of cost control pressures, physicians may withhold technology from patients where the patients' interests are unclear, or where the benefits of the technology are marginal. See id.

\(^{323}\) AMERICAN MEDICAL ASSOCIATION, CURRENT OPINIONS OF THE JUDICIAL COUNCIL: PRINCIPLES OF MEDICAL ETHICS 2.03 (1984) [hereinafter cited as PRINCIPLES].

\(^{324}\) See supra notes 240-43 and accompanying text. The Statement of Patient Rights and Responsibilities of the Joint Commission on Accreditation of Hospitals is much more ambiguous, stating simply that "[i]ndividuals shall be accorded impartial access to treatment or accommodations that are available or medically indicated, regardless of . . . sources of payment for care." JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, AMH/86: ACCREDITATION MANUAL FOR HOSPITALS xi (1985). While this arguably prohibits a hospital from refusing to provide an indigent patient with a medically indicated technology that it furnishes to those who have insurance or other means of payment, the statement would seem to allow a hospital to deny all patients a technology that was medically indicated but that did not result in a net benefit to the hospital.
2. Legal Pressures

Legal constraints constitute another major impetus for practitioners and providers to furnish nonwasteful but cost-increasing technology and otherwise to minimize the adverse impact of the conflict of interest between providers and patients under prospective payment. The body of law that protects patients and other subjects in medical experimentation, for instance, exemplifies legal reaction to conflicts of interest between providers and patients. These laws are arguably necessary because of potential conflict of interest between what is best for the researcher's patient and what will best attain his research objective.

No laws appear to have been enacted as yet specifically in response to the conflict of interest created by prospective payment. While some states are beginning to enact laws prohibiting physicians from engaging in certain activities that create conflicts of interest, these efforts appear to be aimed at fraud and abuse in connection with state assistance programs rather than at denials of nonwasteful technology. Conceivably, criminal laws aimed specifically at the conflict of interest between providers and patients

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326. See Relman, Editorial: Dealing With Conflicts of Interest, 313 NEW ENG. J. MED. 749, 750 (1985). Specifically, Michigan law now prohibits referrals to facilities in which the practitioner has a financial interest, while a similar statute has been adopted in Pennsylvania but applies only to patients receiving medical assistance from the state. Id. California law requires disclosure of a financial interest in a free-standing diagnostic facility to which a patient is being referred, and the legislature is considering enacting a ban on such referrals. Id. These provisions resemble the general anti-fraud and anti-abuse provisions of Medicare and Medicaid. See Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (codified in scattered sections of 42 U.S.C.).

No reported cases appear to have been brought under these federal provisions against providers accused of denying nonwasteful technology to Medicare or Medicaid beneficiaries. This may be due to the fact that such denials have not occurred or are difficult to detect. But see Guillot v. Cherry, No. 79-4371-F, slip op., (E.D. La. 1979) (suit by 7-year-old Medicaid patient with leukemia against state for denying bone marrow transplant on grounds technology was experimental alleged that state cannot override physician's prescribed treatment regimen; suit settled by state agreeing to pay for technology), cited in Necheles, supra note 230, at 17. The federal provision that comes closest to reaching the conduct in question is the prohibition against giving or receiving remuneration for referring a patient to a facility where Medicare or Medicaid services are provided or for ordering a Medicare or Medicaid service. See 42 U.S.C. § 1395nn(b) (1982). A court might hold that the statute had been violated if a referring physician were compensated by a provider for helping to hold costs down. However, if the physician were deemed an employee, such as a salaried physician on an HMO staff, the statutory exemption for payments to employees of the provider might apply. See id.
could be enacted,\textsuperscript{327} but since they parallel the civil liabilities already imposed by malpractice law,\textsuperscript{328} they may not be worth their transaction costs.\textsuperscript{329}

\begin{itemize}
\item \textit{Malpractice Actions}. The fear of malpractice suits is probably the most effective pressure on providers to refrain from denying nonwasteful technology to patients. Under general standards of malpractice, a provider may be liable in tort if it fails to give the patient the care that should be furnished under generally accepted medical standards.\textsuperscript{330} Moreover, malpractice law essentially takes a patient point of view: no reported cases have denied a plaintiff's claim for relief on the ground that, although generally accepted practice called for a technology to be provided to the patient, the interests of that patient were overridden by the interests of other patients or of society. Nor has any case upheld a denial of care on the ground that the patient's interests were overridden by the interests of providers or of payors. Historically, the law has also been unsympathetic to the defense to a claim of malpractice that generally accepted practice was not followed because it was too costly for the provider or payor,\textsuperscript{331} although the defense has yet to be ad-
\end{itemize}

\textsuperscript{327} For example, a federal or state law could prohibit providers from withholding technology from patients for reasons other than those in the patient's direct interest.

\textsuperscript{328} For a discussion of the role of malpractice law in addressing denial of nonwasteful technology resulting from a conflict of interest under prospective payment, see infra notes 330-32 and accompanying text.

\textsuperscript{329} The major advantage criminal laws would offer over patient-initiated damage actions would be enforcement by government agencies, such as state health departments. These agencies can be expected to possess greater expertise and information than patients, and therefore to be in a better position to detect improper provider behavior. It is unclear whether they would be more likely to take a patient perspective than other "watchdog" entities—such as peer review organizations (PROs). See infra notes 375-84 and accompanying text. If the agency entrusted with enforcing an anti-conflict law is also the agency responsible for maintaining the fiscal integrity of a health care budget, such as a state health department or HCFA, it is not likely to consistently take a patient perspective on technology. Even if the agency does not have a formal budgetary or cost-control function, as an executive government agency it may be responsive to pressure from cost-conscious government officials. To avoid a conflict of interest, a separate bureaucracy to oversee patient care might be created, but is likely to be expensive to run, inefficient and difficult to insulate from cost pressures. Nevertheless, if data show that patients are being denied nonwasteful technology, such a governmental entity may need to be established.


\textsuperscript{331} See Meiselman v. Crown Heights Hosp., 285 N.Y. 389, 34 N.E.2d 367 (1941) (hospital liable for injuries to plaintiff after discharging him prematurely due to his inability to pay); Becker v. Janinski, 15 N.Y.S. 675 (1891) (jury instructed that physician owes indigent and wealthy patients same degree of care); Ricks v. Budge, 91 Utah 307, 64 P.2d 208 (1937) (complaint against physician who refused to continue treatment of patient who could not pay old bills).
dressed by the courts since the beginning of the current cost containment movement. Malpractice law therefore would be a strong incentive to a provider to afford patients technologies that had become generally accepted, even if they increased provider costs.

It might be argued that malpractice law is not the bulwark against the undesirable effects of cost containment described above, since the basic standard of care applied to providers in malpractice actions is the standard of care generally accepted by the medical profession. What is to prevent the medical profession, as a result of cost containment pressures and the resulting changes in health care delivery practices, from recognizing the denial of beneficial technologies to patients as accepted practice? In other words, what is to prevent physicians from concluding that ordering a particular cost-raising technology for their patients can no longer be justified because, although it provides a net benefit to patients and is the most cost-effective treatment available, its costs outweigh its benefits from a non-patient perspective? If this view became sufficiently widespread to be deemed the generally accepted attitude of the profession, which is certainly the objective of some cost containment enthusiasts, malpractice law would not ordinarily hold providers liable for denying the technology to patients.

Erosion of generally accepted standards of practice must be prevented in the first instance by the ethics of the medical profession. The profession will continue to provide patients with non-wasteful technology so long as physicians practice medicine in the best interests of their patients, and so long as they retain the power to do so. It is also possible, albeit unlikely, that if this notion of ethical practice changed within the profession, the courts nevertheless would hold providers to a patient-based standard of care on the theory that the customs of the profession do not establish an appropriate standard of care.332

332. See Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (1974) (malpractice claim for damages resulting from ophthalmologic practice consistent with generally accepted standard should not have been dismissed, since generally accepted practice may not be synonymous with reasonable care). See also The T.J. Hooper v. Northern Barge Corp., 60 F.2d 737, 740 (2nd Cir. 1932) ("Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required"). This judicial approach may be subject to the charge of overreaching, however.

In theory, the legislature can reverse the courts, as long as the standard of the patient's perspective is not deemed to be constitutionally mandated. The legislative effort is not always successful, however. One year after the Helling case, for example, the Washington State legislature passed a law apparently intended to protect health care practitioners from mal-
One aspect of malpractice law that may exert a particularly powerful pressure on providers to furnish patients with nonwasteful technology is the principle of informed consent. Under this principle, providers are required to inform patients of all material alternative technologies and their relative risks, and must obtain the patient's consent to the specific alternative that is provided.\textsuperscript{333}

Two main issues arise in connection with informed consent under cost control systems such as prospective payment. First, is it required, or even appropriate, to inform patients of the cost of alternate technologies? Second, should providers inform patients of alternate technologies that the provider does not regard as material because of their cost?

As to the first issue, it would seem that patients are entitled to be told the cost of a technology as one of the factors that may influence their choice of treatment. This is rather obvious when the patient is paying for the care; it is less obvious when care is paid for by a third party, such as by Medicare. When third-party payors and providers are themselves at financial risk, cost information may be used contrary to the direct interests of the patient. Providers or payors may try to pressure patients into accepting less costly technology, even though the third party payment scheme in which the patient is entitled to participate by statute or by contract arguably was purchased by the patient or was enacted in part in order to insulate patients from such cost pressures. It is therefore imperative that, when cost information is furnished to patients as part of the informed consent process, patients concurrently be informed of the extent of their financial obligation, if any, for the various technology alternatives.

\textsuperscript{333} See, e.g., Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972) ("We now find, as a part of the physician's overall obligation to the patient, a similar duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved."); Sard v. Hardy, 281 Md. 432, 379 A.2d 1014 (1977) (duty to disclose requires a physician to reveal to his patient the nature of the ailment, the nature of the proposed treatment, the probability of success and any alternatives available). Another type of legal response to a provider refusing to furnish a nonwasteful technology might be an action by the patient for breach of contract or for breach of fiduciary duty by the provider. See Stern, \textit{supra} note 309, at 15 (discussing breach of contract). Breach of fiduciary duty of an HMO to patients—in essence an action in tort—has been suggested by Binford. See Binford, \textit{Malpractice and the Prepaid Health Care Organization}, 3 \textit{Whittier L. Rev.} 337, 340 (1981).
The doctrine of informed consent can only be an effective pressure on providers to provide patients with nonwasteful technology if it is construed further to require providers to inform patients of all material alternate technologies, including those for which the provider believes it would not be reimbursed or that should not be provided because of their cost. The provider would be liable if it failed to provide this information and the patient could show that he was injured as a result of not receiving the alternate technology. This would preclude in this country the British practice whereby, in line with cost control objectives, certain classes of patients such as the elderly, in need of certain expensive technologies such as kidney dialysis, are not told that the technology exists or that it would keep them alive.

Morreim recommends that the conflict between patient and provider be mitigated by requiring the provider to disclose the existence of the conflict to the patient. She does not discuss what a patient should do when told: "You should be aware that financial pressures on me create a conflict of interest in which I may not always act in your best interests." Only a persistent, highly intelligent and probably medically trained patient might be able to discover when the provider was in fact acting contrary to the patient's interest; the average patient is more likely merely to be unnerved and confused by the provider's disclosure.

A better approach is to place the burden on the provider to identify and to disclose precisely when and in what way it is failing to act in the patient's interest. This would help relieve the patient of the need to detect such instances on his own. It would also serve several important practical functions. First, it would give those patients who could afford it the option of paying for the technology themselves. Second, it would facilitate patient challenges to prospective denials of treatment or of reimbursement by third-party providers.


336. Even if, in an excess of cost containment zeal, the government attempted to prevent beneficiaries of government programs from purchasing such technologies themselves (and this effort survived constitutional challenge), patients should still be entitled to be informed of the existence of these technologies so that they can purchase the technologies elsewhere if they so desire.
payors. Third, disclosure would encourage providers to recognize when they are proposing to deny patients nonwasteful technologies because of the conflict of interest in which they are placed by prospective payment. This in turn would aid in preventing inappropriate denial of technologies and in identifying patterns of practice that compromise quality-of-care so that they could be brought to public attention.

b. Administrative Processes. A further type of legal constraint that may affect a Medicare provider's decision to withhold nonwasteful technologies from beneficiaries is the administrative process by which claims and coverage decisions can be disputed. In theory, a generous opportunity to contest the denial of technologies to patients might be afforded beneficiaries and other interested parties. As noted earlier, under prospective payment the coverage system is no longer necessary as a measure to contain costs, except perhaps as a means of generating technology assessment data for providers. But the coverage system could be turned into a potent weapon with which patients could discourage providers from withholding nonwasteful technologies.

Under this approach, a coverage determination would no longer be an indication that Medicare would or would not pay for a specific technology, since reimbursement would be governed by payments under the DRG system on the basis of the patient's diagnosis. Instead, a coverage decision would be an affirmation that a particular technology was reasonable and necessary for a patient under certain circumstances, and could not lawfully be withheld by a Medicare provider. The provider would still be free to reduce care to patients to create a greater difference between the cost of the care it provided and the amount of the DRG payment that it received, but it could not deny a patient a technology that was the subject of

337. In Heckler v. Ringer, the Supreme Court precluded a declaratory judgment action by the patient prior to receiving the technology and having a claim for reimbursement denied. 104 S. Ct. 2013 (1984). See infra notes 360-63 and accompanying text. In light of this decision, it is important that patients be given the right to have a peer review organization or provider conduct a prospective review of a proposed denial of technology and for a negative result to trigger the Medicare appeals process, including, ultimately, judicial review. Provider disclosure to the patient of its intention to withhold a technology on grounds of cost is a crucial prerequisite to this right of review.

338. Interested parties other than beneficiaries themselves might include next of kin, providers who disagreed with a claims denial by a contractor or by the Health Care Finance Administration, sponsors of technologies such as manufacturers, and interest groups such as patient advocacy and professional organizations.

339. See supra notes 270-75 and accompanying text.
such an affirmative coverage decision by the government. Providers caught between an affirmative coverage determination and a skimpy DRG could press for an increase in the payment for that particular DRG. In fact, HCFA and the Prospective Payment Commission could be required automatically to assess the adequacy of all DRG payments affected by an affirmative coverage decision.

Coupled with a robust administrative and appeals procedure, such a coverage system could be a significant deterrent to denying non-wasteful technologies to patients. In a number of respects, however, the procedural process afforded patients under the current system is inadequate to achieve this result.

In the first place, the statutory provisions governing which technologies beneficiaries are entitled to receive under Medicare are not clearly defined. The basic governing provision of law is section 1862(a)(1) of the Social Security Act, which prohibits payment for items or services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part." The key phrase, "reasonable and necessary," is not further defined in the statute, in the legislative history of the statute, or in the copious Medicare regulations.

Presumably, technologies with only marginal net benefit would not be required to be provided under such coverage determinations, since it would not be worth the effort to secure a coverage decision in their respect.

Some patients who are entitled to specific technologies under a coverage policy might qualify as cost or day outliers, thereby earning the provider an additional payment beyond the normal DRG amount.

The law also limits payment for certain specified services, such as dental care, id. § 1395y(a)(10).

The key Senate report, S. Rep. No. 404, 69th Cong., 1st Sess. 1989 (1965), merely repeats the language of section 1395y(a). It then classifies the rental of a special hospital bed as an item that might be covered, depending on the circumstances, and describes personal comfort items and services such as massages and heat lamp treatments, and custodial care, as items or services that would not be covered.

Letter from Peter Bouxsein, Counsel, Subcommittee on Health and the Environment, House Committee on Energy and Commerce (Sept. 11, 1985). The regulations merely restate the language of the statute. See 42 C.F.R. § 405.310(k)(e) (1985); Breeden v. Weinberger, 377 F. Supp. 734, 737 (M.D. La. 1974) ("reasonable and necessary" not defined in regulations). A 1977 communication from HCFA to a fiscal intermediary interprets the statutory phrase to mean that the item or service is generally accepted as safe and effective and not experimental, or is so proven by authoritative evidence. See HCFA, Part A intermediary Letter 77-4/Part B intermediary Letter 77-5, MEDICARE & MEDICAID GUIDE (CCH) 128, 152 (1977). In addition, the term is interpreted to mean that the item or service is medically necessary in the particular case and is furnished in accordance with accepted standards of medical practice and in an appropriate setting.

At one point in 1980, HCFA considered adopting a formal interpretation of the "reasonable and necessary" language of the Social Security Act that would have permitted national
Nor has the phrase substantially been interpreted by the courts. Therefore, even if there were adequate procedures by which patients could challenge technology decisions, the lack of clear statutory standards might preclude patients from successfully contesting the withholding of nonwasteful technologies.

This could be remedied by defining the governing term "reasonable and necessary" in section 1862(a) of the Social Security Act to mean, along the lines suggested in Section III, items or services that are unsafe, ineffective, less safe or effective than alternate items or services, or not cost-effective from the patient's standpoint. This definition could be adopted by the Department of Health and Human Services as an interpretive rule or general statement of policy, or as a formal regulation. It could also be enacted by Congress as an amendment to the Act, although an amendment does not seem necessary since this interpretation does not conflict with provisions of the Act and is arguably within the broad rulemaking authority vested in the Secretary of Health and Human Services.

Once adopted, this definition would apply to all coverage determinations—including those at the contractor and peer review organization (PRO) levels—to all quality-of-care review programs, and to all reimbursement decisions.

Even if the statutory standard were interpreted in this fashion,
however, the current procedures for challenging technology decisions under Medicare limit the effectiveness of an affirmative coverage system. This presumably results from the original cost control thrust of the Medicare coverage system.

The most effective affirmative coverage system would inform the patient in the hospital that the hospital is proposing to deny the patient a particular technology on grounds of cost and would then allow a Medicare beneficiary (or his doctor) immediately to challenge the hospital’s proposal. Under current procedures, this challenge would be made, if it could be made at all, to the PRO, which is staffed in part by health professionals such as doctors and nurses, and which contracts with the Health Care Finance Administration (HCFA) to perform certain review functions, including determining if a technology is reasonable and necessary. It is not clear if a PRO would entertain such a challenge by a patient or his physician. HCFA regulations require a PRO to monitor patient discharges to determine if they are premature, and a patient may obtain immediate PRO review of a hospital’s decision to discharge him before actually being forced to leave the facility. But there is no formal procedure for obtaining immediate PRO review of a hospital decision to deny a particular technology to a patient unless the hospital’s position, if sustained, would entail the patient’s discharge.

Assuming the PRO reviewed and affirmed a prospective chal-

348. See 42 U.S.C. §§ 1320c-1-1320c-3. Providers may not obtain Medicare reimbursement unless they have entered into a written agreement of cooperation with a peer review organization to have this review performed. See 42 C.F.R. § 466.78.

349. See DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCE ADMINISTRATION, PEER REVIEW ORGANIZATION MANUAL § 2060.2 (Feb. 1985) [hereinafter cited as HCFA PRO MANUAL].

350. See id. § 3000. HCFA defines a premature discharge to occur “when a patient is discharged even though he should have remained in the hospital for further testing or treatment, or was not medically stable at the time of discharge.” Id.

351. See id. at § 2080. Medicare has recently proclaimed that beneficiaries must be notified upon admission of their right to obtain PRO review of a discharge request by the hospital. See HEALTH CARE FINANCE ADMINISTRATION, MEDICARE FEDERAL INTERMEDIARY BULLETIN No. 86.18 (Feb. 18, 1986).

352. The PRO itself can decide to review a proposed use of a technology for a particular patient in what is called a “pre-procedure review.” See HCFA PRO MANUAL, supra note 349, at § 2050.5. Reflecting the original cost control function of this review, it is limited to certain specified technologies, such as permanent cardiac pacemaker implantation, that are thought to be overused. See id. at § 2080. But there is no formal procedure whereby a patient or physician, rather than the PRO itself, can obtain a preprocedure review, and PRO’s do not ordinarily provide an opportunity for such a review. Telephone interview with Barbara DeCaeser, R.N., Professional Affairs Staff, University Hospitals, Cleveland, Ohio (Dec. 20, 1985).
challenging the withholding of a technology, the beneficiary may request a reconsideration by the PRO. If upon reconsideration, the PRO's decision is still adverse to the beneficiary, he can obtain an administrative review by an administrative law judge (ALJ) if the controversy involves an amount in excess of $200. If the ALJ's decision is adverse, the beneficiary may obtain a review by an Appeals Council.

This would seem to be a generous, multilevel appeals procedure. However, only limited relief for beneficiaries should be expected from PRO's or from the HCFA Appeals Council. The outcome of an appeal is likely to favor the provider's position, since both PRO's and HCFA are obligated in the main to control health care costs. Given this mission, they are more likely to view the relationship between costs and benefits of a technology from the provider's rather than the patient's perspective, even if technically forbidden from doing so by a redefinition of "reasonable and necessary" in the Medicare statute. Thus it becomes important for ben-

353. Under Medicare, the hospital itself is made a party to the beneficiary's appeal. See 42 U.S.C. § 1395pp. The hospital therefore would automatically have an opportunity to defend its proposed denial of the technology in question.

354. See 42 C.F.R. § 473.16.

355. See 42 U.S.C. § 1320c-4. The administrative law judge (ALJ) has subpoena powers. See 42 U.S.C. § 405(d); 20 C.F.R. § 404.950. He is bound by regulations and published rulings of the HCFA, but not by publications in HCFA manuals. See 42 C.F.R. § 401.108; telephone interview with Henry Goldberg, Office of the General Counsel, HCFA (Nov. 8, 1985). Thus, HCFA coverage determinations, which are published in the manuals but are neither formal rulings nor regulations, are not binding on ALJ's.

356. See 42 C.F.R. §§ 473.40, 405.701(c), 405.724; 20 C.F.R. § 404.967. The beneficiary should be able to satisfy the amount-in-controversy requirement by the cost of the disputed technology to the provider. If the beneficiary ultimately wins, the provider will have to provide the technology and absorb the cost within the amount it will be paid under the prospective payment system; unless the additional cost makes the patient a cost-outlier, see supra notes 263-64 and accompanying text, HCFA will not increase the amount it pays the provider for the beneficiary. Nevertheless, the fact that the provider will have to absorb the cost of the technology should qualify to establish an amount in controversy, so that the beneficiary should be able to appeal the PRO reconsideration if the cost of the technology to the provider, if it is ultimately ordered to provide it, would exceed $200. Similarly, the provider should be entitled to appeal a PRO's decision that the technology is reasonable and necessary, but only when the delay created by the appeal would not adversely affect the beneficiary's health status.

357. See 42 C.F.R. §§ 473.40 405.701(c), 405.724; 20 C.F.R. § 404.967. The Appeals Council has jurisdiction to review an ALJ decision when there is an abuse of discretion by the ALJ, the ALJ has committed an error of law, the ALJ's decision is not supported by substantial evidence, new evidence is submitted with the request for review, or the ALJ's decision raises broad issues of policy that may affect the general interest of the public. See 42 C.F.R. § 473.46; 20 C.F.R. § 404.970.

358. See Blumenthal, supra note 129, at 603 (discussing bias of HCFA); see also infra notes 378-84 and accompanying text.
ficiaries to be able to obtain judicial review of an adverse decision of the Appeals Council, since the courts are likely to be more neutral with regard to the conflict between patient and fiscal interests.

Under current Medicare law as interpreted by the Supreme Court, however, judicial review of the proposed withholding of a technology from a beneficiary is precluded. Normally, review of an adverse decision by the Appeals Council may be had in a United States district court if the amount in controversy exceeds $2,000. But in 1985 the Court ruled in Heckler v. Ringer that judicial review is only available when a claim for Medicare reimbursement is denied, and that such a claim can only be presented after a technology has been provided to a beneficiary, thus preventing prospective challenges.

Unless Congress or the Court overrules the Heckler case, judicial review would only be available to a beneficiary if, when faced

359. See 42 U.S.C. §§ 1320c-4. The beneficiary's appeal procedure is more limited under Part B of Medicare, which covers physician and outpatient services and is not governed by prospective payment. See supra note 305. A beneficiary whose Part B claim is denied by a contractor is entitled to a hearing before a hearing officer (not an ALJ) if the amount in controversy is at least $100. See 42 C.F.R. §§ 405.820, 405.823. The hearing officer's decision is final. See 42 C.F.R. § 405.835.

360. See 104 S. Ct. 2013 (1984). Plaintiffs challenged a ruling by the Secretary of Health and Human Services that a surgical technology known as bilateral carotid body resection was not reasonable and necessary and therefore was not covered under Medicare. Id. at 2018. The procedure involves removal of the small carotid bodies in the neck, which its proponents claim will reduce symptoms of asthma, bronchitis and emphysema. Id. at 2018 n.3. The Secretary had originally issued a nonbinding guideline recommending noncoverage of the technology, but the guideline was ignored by many ALJ's who overturned contractor denials of claims. Id. at 2018. The Secretary then replaced the guideline with a ruling, which is binding on ALJ's and on the Appeals Council. Id. at 2018.

By a six to three majority, the Court held that sections 405(g) and (h) of the Social Security Act, 42 U.S.C. §§ 405(g), (h), deprived the courts of subject matter jurisdiction over the action. 104 S. Ct. at 2022. Section 405(g) states in pertinent part that an individual may obtain judicial review of "any final decision of the Secretary made after a hearing to which he was a party." 42 U.S.C. § 405(g). Section 405(h) states that "[n]o findings of fact or decision of the Secretary shall be reviewed by any person, tribunal or governmental agency except as herein provided," and that no action may be brought under § 1331 or 1346 of title 28 of the United States Code "to recover on any claim arising under this title." 42 U.S.C. § 405(h).

The Court noted that there were two groups of plaintiffs—one that had had the operation and that sought to challenge the ruling before completing the Medicare appeals process, and an additional individual, Ringer, who had not had the operation and who contended that, since he could not afford to pay for it himself, the result of the ruling was that no provider would furnish it to him. 104 S. Ct. at 2020-21, 2024. The Court held that, insofar as all plaintiffs were essentially seeking a prospective determination of their right to be reimbursed for the technology, their challenge was a "claim arising under" the Medicare Act and could not be brought until they had exhausted their administrative remedies. Id. at 2023. The Court also held that a mandamus action against the Secretary also would not lie because of plaintiffs' failure to exhaust their administrative remedies. Id. at 2022-23. Ringer, who had not received the operation, was likewise barred from suit because, having no claim for reim-
with a provider decision to withhold a technology under Medicare, the beneficiary proceeded to obtain the technology by offering to pay for it himself. (As a practical matter, unless the beneficiary offered to pay for the technology, his medical condition might not allow enough time for the beneficiary to contest the provider’s position before the technology or an alternate form of treatment or diagnosis had to be obtained). Once the beneficiary had paid for the technology himself, he might then seek to have Medicare reimburse him on the theory that the technology was covered and should have been provided by the hospital. This would afford him the same

As Justice Stevens, joined by Justices Brennan and Marshall, stated in dissenting to that portion of the opinion that barred Ringer from suit, the majority’s holding with regard to Ringer makes it impossible for a beneficiary to challenge a coverage ruling (or a guideline, for that matter) until a claim for reimbursement for the procedure is denied and the appeals process is exhausted; the beneficiary must therefore be able to afford to pay for the technology to perfect such a challenge. “[The majority’s] one-eyed procedural analysis frustrates the remedial intent of Congress as plainly as it frustrates this litigant’s plea for a remedy,” Justice Stevens asserted, adding: “The cruel irony is that a statute designed to help the elderly in need of medical assistance is being construed to protect from administrative absolutism only those wealthy enough to be able to afford an operation and then seek reimbursement.”

Technically the beneficiary would be challenging a determination that he knew or ought to have known that the technology was not covered, and that he was therefore financially liable for the technology after he received it. See supra note 272. One problem that would arise is how to set the amount that Medicare will reimburse the beneficiary if the technology ultimately is found to be covered. The hospital’s charge would not necessarily be the correct amount, since it might be unreasonably high. Prior to the adoption of the DRG prospective payment system, hospitals were paid on the basis of their reasonable costs as calculated by Medicare. This would presumably be an appropriate amount for the patient to have to pay the hospital, and thus the amount the patient should be reimbursed by Medicare if the technology was paid for out of the patient’s pocket.

This would necessitate establishing the reasonable cost in cases where beneficiaries successfully challenged a provider’s initial determination that the technology was not covered. It would also require that the hospital be limited in the amount it could charge the patient to the amount the patient would be reimbursed. Note that as an artifact of the former fee-for-service system, if a PRO determines that a patient has received a non-covered technology along with a covered technology, Medicare will exclude from the DRG payment for that patient an amount corresponding to the non-covered technology. See HCFA PRO MANUAL, supra note 349, at § 2050.3. Thus there must be some method by which Medicare can calculate the proper charge for a particular technology under the DRG payment system.

This raises the further question of whether Medicare or the hospital ought to absorb the cost of the covered technology. The hospital would seem to be the more appropriate cost-bearer, since otherwise it would be paid both a DRG-based Medicare amount for the patient’s care and an additional amount by the patient for a technology that, if ultimately determined to be covered, it should have provided to the patient in return for the DRG-based payment alone. An alternative to making the hospital refund the amount it collected from the patient would be for Medicare rather than the hospital to reimburse the patient so long as the hospital’s initial denial of the technology was in good faith and was a reasonable interpretation of
appeals procedure as in the preprocedure context described above, with the added availability of judicial review. However, as Justice Stevens noted in his dissent in *Heckler v. Ringer*, only those patients wealthy enough to afford a technology would be able to take advantage of this retrospective appeals procedure, including availing themselves of the potentially critical protection of the courts.

As an alternative to relying on individual patients to press for a coverage decision upon being told that a provider proposes to withhold a technology from them, patient groups and others might petition HCFA directly for a prospective coverage determination. If HCFA granted the request, it could issue a guideline or a formal ruling. The process of formulating a coverage guideline is not governed by any specific statutory or administrative procedures under its Medicare obligations. One method of determining the reasonableness of the hospital's actions would be to monitor the frequency of beneficiary affirmative coverage challenges for that hospital. Excessive challenges could create a presumption of unreasonableness or bad faith on the part of the hospital that could subject it to sanctions, such as being disqualified from being reimbursed for serving Medicare patients. See 42 C.F.R. §§ 474.32-.58.

362. If the beneficiary is able to obtain judicial review, it may not be too difficult for him to prove that he is entitled to the technology. The burden of showing that a technology merits Medicare reimbursement is on the claimant. See, e.g., Psychiatric Hosps. of Florida, Inc. v. Heckler, 4 MEDICARE & MEDICAID GUIDE (CCH) ¶ 34,811 (M.D. Fla. June 18, 1985). The burden is not a difficult one to meet, however. Under the current Medicare system, if the government denies a claim for reimbursement and the beneficiary (or provider) appeals, the claimant has the burden of coming forward with evidence why the claim should be allowed. If the claim is denied on the basis that the technology provided is not covered under Medicare, the few decided cases suggest that the claimant can meet this burden merely by showing that the technology was ordered by the attending physician. See, e.g., Breedon v. Weinberger, 377 F. Supp. 734, 737 (M.D. La. 1974).

The burden then appears to shift to the government to show that the technology is inappropriate notwithstanding the physician's order. Ultimately, the government will be sustained if its decision is supported by substantial evidence, see id. at 738, but the courts have taken a hard look at the government's interpretation of what is "reasonable and necessary" for Medicare patients under 1862(a)(1)(A). See Kuebler v. Secretary of the U.S. Dep't HHS 579 F. Supp. 1436, 1438 (E.D.N.Y. 1984); Westgard v. Weinberger, 391 F. Supp. 1011, 1019 (D.N.D. 1975). Cf. Hultzman v. Weinberger, 495 F.2d 1276, 1281 (3rd Cir. 1974) (rejecting government's interpretation of section 42 U.S.C. § 1395y(a)(1)). The burden on the claimant could be relaxed even further by creating a presumption that technology is reasonable and necessary and placing the burden on the government to defeat the presumption in order to deny a claim for a specific technology.


364. Section 553(e) of the Administrative Procedure Act, 5 U.S.C. § 553(e), mandates an opportunity for persons to petition a federal agency to initiate rulemaking proceedings. While section 553(a)(2) of the Act exempts "benefits" programs from the requirements of section 553, and Medicare has been held to be such a program, see, e.g., Humana of South Carolina, Inc. v. Califano, 590 F.2d 1070, 1082-84 (D.C. Cir. 1978), the Department of Health and Human Services waived this exemption in 1971. See 36 Fed. Reg. 2532 (1971); Humana of South Carolina, Inc. v. Califano, at 1084.
the Social Security Act, and has not been the subject of any reported case. By virtue of their nonbinding nature, guidelines would most likely be regarded as interpretive rules or general statements of policy under the Administrative Procedure Act. They would therefore be exempt from any procedural requirements under the act. Neither notice nor an opportunity for public comment, much less a hearing or judicial review, would have to be provided. Since HCFA routinely affords notice and an opportunity for comment to members of the public, the agency in fact extends greater procedural protections to those potentially adversely affected by the guidelines than are required by law.

Formal rulings would qualify as informal rules, and, under the Administrative Procedure Act, require public notice and an opportunity for comment prior to being issued, but no formal hearing. Nor would a party adversely affected by a ruling be entitled to judicial review, since none is provided in the Medicare statutes, and none is mandated under the Administrative Procedure Act for informal rulemaking.

In short, greater rights for participation by interested parties, including rights to a hearing, to review by the Secretary of Health and Human Services, and to judicial review, may become necessary to augment other pressures to avoid denying nonwasteful technologies to beneficiaries.

A final method by which affirmative decisions on coverage might be made is in the course of establishing and recalibrating

365. See 5 U.S.C. § 553(b) (1982). In Bond Hosps., Inc. v. Heckler, 587 F. Supp. 1268, 1273 (D.D.C. 1984), aff'd 762 F.2d 137 (D.C. Cir. 1985), the court held that the Health Care Finance Administration's PROVIDER REVIEW MANUAL, which is similar to the MEDICARE COVERAGE ISSUES MANUAL in which coverage guidelines are published, is an interpretive rule under the Administrative Procedure Act and thus exempt from formal rulemaking requirements. See also American Bus. Ass'n v. United States, 627 F.2d 525 (D.C. Cir. 1980) (agency action is general statement of policy where it is not a binding norm, is prospectively applied, and leaves decision makers free to exercise discretion). Cf. Roberts v. Weinberger, No. C-74-49, (W.D. Tenn. 1975), reported in [1 Transfer Binder] Medicare and Medicaid Rptr. (CCH) ¶ 27,396 (Medicare coverage guidelines excluding technologies from coverage may not be applied retroactively).


367. See id.

368. See id. at §§ 553(b),(c). The Social Security Act does not mandate a hearing before such rulings may be issued, and therefore no hearing is required under the Administrative Procedure Act. See id. at § 553(c).


370. See id.

DRG's under the prospective payment system.\textsuperscript{372} In its first annual report, for example, the Prospective Payment Assessment Commission (PROPAC) noted that it was reviewing several new technologies, such as cochlear implants, to determine if they merited the creation of technology-specific DRGs—that is, DRGs providing Medicare reimbursement for using a particular technology.\textsuperscript{373} In the absence of technology-specific DRGs, providers might not have an adequate incentive to provide a new technology under existing DRG payment levels if the technology substantially increased provider costs. A refusal to establish a technology-specific DRG for such a technology would then have the same discouraging effect on its availability to beneficiaries as a negative coverage determination.\textsuperscript{374} It is therefore discouraging to note that Congress exempted the entire DRG process from administrative and judicial review.\textsuperscript{375}

3. Peer Review Organizations

Another potential source of pressure to provide nonwasteful technologies is the peer review organization (PRO). As discussed earlier,\textsuperscript{376} these are organizations of health professionals and others under contract with Medicare to perform certain oversight functions. One of these functions, mandated by statute, is to review the "completeness, adequacy, and quality of care provided."\textsuperscript{377} HCFA interprets this to require PROs to reduce unnecessary readmissions due to substandard care during a previous admission; assure that technologies avoid a "significant potential for causing serious patient complication;" and reduce avoidable deaths, unnecessary surgery and avoidable complications.\textsuperscript{378} PROs are authorized to invoke a number of sanctions against providers who fail to provide adequate care to beneficiaries, including recommending to the Of-

\textsuperscript{372} See supra notes 261-64 and accompanying text.
\textsuperscript{373} See PROPAC 1985, supra note 1, at 50-51; see also OTA MEDICARE, supra note 2, at 27.
\textsuperscript{374} On the other hand, if the new technology were cost-saving, providers may be reaping an unwarranted windfall under existing DRG payment levels. See PROPAC 1985, supra note 1, at 43-44 (discussing percutaneous transluminal coronary angioplasty).
\textsuperscript{375} See 42 U.S.C. § 1395ww(d)(7) (Supp. I 1983) ("[t]here shall be no administrative or judicial review . . . of the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof . . . .")
\textsuperscript{376} See supra notes 348-58 and accompanying text.
\textsuperscript{378} See Health Care Finance Administration, Request for Proposal, RFP No. CFA-84-015, Operation of Utilization and Quality Control Peer Review Organizations (1984), 2 MEDICARE & MEDICAID GUIDE (CCH) ¶ 12,872.03 (Feb. 29, 1984) [hereinafter cited as RFP No. HCFA-84-015].
Office of the Inspector General of the Department of Health and Human Services that the provider be denied payment for a specific admission or procedure, be fined, or be excluded from serving Medicare patients.379

The PROs' watchdog responsibilities and sanctions potentially make it a powerful source of pressure on providers. However, quality control is not the PROs' only, and perhaps not its prime, objective.380 In addition, it has a major cost containment role. The contract between the HCFA and the PRO must include a specific target for reducing Medicare admissions; the PRO in Kentucky, for example, is obligated to achieve an 8.1% reduction in Medicare admissions between 1983 and 1986.381 If the PRO fails to achieve its target, it may lose its contract or risk nonrenewal.382 Moreover, the PRO is responsible for validating the providers' DRG assignments and assuring the legitimacy of outlier claims.383 The PRO's satisfactory fulfillment of its contract depends not only on achieving specific contract targets, but on producing net dollar benefits to the government (savings resulting from PRO review minus the cost of the PRO contract to the government).384

In short, the PRO is caught between the conflicting goals of insuring quality of care and reducing costs. The logical resolution of this conflict would be for the PRO to adopt the approach to technology waste advocated herein, recouping the cost of providing nonwasteful, cost-increasing technologies through savings from not providing wasteful technologies. Nevertheless, the PRO may well conclude that it can protect its contract better by concentrating on its cost control objectives than by achieving quality-of-care objectives.385 Administrative and judicial patient challenges to PRO determinations should therefore be anticipated and facilitated.

381. See 2 Medicare and Medicaid Guide (CCH) ¶ 12,872.
382. See RFP No. HCFA-84-015, supra note 379.
384. See RFP No. HCFA-84-015, supra note 379.
385. The solution might be to create two separate review entities, one with cost control targets and the other with quality-of-care objectives, in effect placing them in an adversarial position. This would require the creation of another administrative body to resolve disputes between the two PROs.
4. Competitive Pressures

A final source of pressure on providers to provide nonwasteful technologies to patients is competition with other providers. This is a relatively new phenomenon; until recently, the health care system has not been highly competitive. Now, however, there is an oversupply of hospital beds and physicians, a scarcity of patients, and a growing militancy on the part of third-party payors to bring costs under control. This is leading providers to attempt to attract patients—either as individuals or as members of group health care plans—by a variety of competitive methods, including competition on the basis of price and services. 386

To some extent, providers are beginning to compete on the basis of the quality of their care. So far this seems to be limited to promoting the types of services offered. Providers thus extol their newest technology acquisitions but do not emphasize other potential quality-of-care parameters, such as low malpractice claims frequency, mortality rates and readmission frequencies. Nevertheless, these quality aspects of health care may receive greater attention as patients and third-party payors attempt to purchase the best care for the money. To the extent that these parameters would be negatively affected by a practice of denying patients nonwasteful technologies, increased competition between providers might therefore become a potent source of pressure to maintain quality of care.

One major limitation on its effectiveness, however, is the degree to which patients are given and can act upon accurate quality-of-care information about providers. Currently, although patients may be receiving greater information on health care prices, there is virtually no information available to patients on the relative performance of different hospitals, let alone on that of hospitals compared to alternative delivery systems such as health maintenance organizations, or on that of different physicians. 387 Even if this in-

386. See, e.g., Punch, Publicity on Prices Has Little Impact, in HEALTH CARE MARKETING 243 (P. Cooper ed. 1985) (hospital administrations believe consumers will start paying more attention to public disclosure of hospital charges).

387. A number of efforts are now underway to increase the information available to health care consumers. On the federal level, recent Peer Review Organization (PRO) regulations require the PRO to disclose nonconfidential information to "any person upon request." 42 CFR § 476.120(a). Nonconfidential information includes information that either explicitly or implicitly identifies a hospital or institution, aggregate statistical data collected by the PRO, quality review study data, and routine reports submitted by the PRO to the Health Care Finance Administration (HCFA). Id. Confidential information is defined as "information that explicitly or implicitly identifies an individual patient, practitioner or reviewer." 42 CFR § 476.101. In addition, the PRO "may disclose to the public PRO interpretations and
formation were available to patients, it is questionable that they would use it to make informed choices in view of their lack of expertise and the time and effort that would be required. Third-party payors are in a better position both to obtain (and if necessary generate) this information and to use it to choose providers for their subscribers, but, as noted earlier, third-party payors do not have the same perspective on waste as patients, and therefore may make different health choices than subscribers who possessed and processed the necessary information. Pending improvements in both the quality and quantity of provider performance data available to patients, and in methods for assisting patients in making health care choices on the basis of those data, therefore, competition remains a promising but uncertain pressure on providers to maintain the quality of their care.

Generalizations on the quality of health care that identify a particular institution.” 42 CFR § 467.141. This includes information on the length of stay, surgical mortality rates, and the percentage of patients with post-operative infections, for particular institutions. See Wolfe, As Hospital Ratings Go Public, Let’s Rate Doctors, Too. Los Angeles Times, May 6, 1985.

The significance of the PRO-disclosure requirements are based, in part, on two factors: the amount of information the PRO has access to and the ability of some entity to translate the PRO's data into meaningful and accessible information for consumers. With regard to the former, the PRO has access to all records on Medicare patients and other patients whose care they are authorized by contract to review, and to records on other non-Medicare patients if authorized by the institution or provider. See 42 CFR § 476.111. In addition, the PRO can access records or data held by intermediaries or carriers as necessary. See 42 CFR § 112. In regard to the latter, at least one consumer group, founded by Ralph Nader, has announced its intention to collect, process and disseminate PRO data to its subscribers. See Public Citizen Health Research Group, Health Letter, July-Aug. 1985, at 8. The Nader group also advocates that physician-specific data be released by PROs, which is currently prohibited by the regulations. See supra. It responds to objections by the American Medical Association that these data would be misleading due to factors such as variations in patient mix (some doctors see a sicker group of patients than other doctors) by arguing that statistical corrections can be made for such variables, and that even imperfect data are better than nothing. See Public Citizen Health Research Group, Comments on Proposed Rule of Acquisition, Protection and Disclosure of Utilization and Quality Control Peer Review Organization Information 4 (July 5, 1984).

Bills have also been submitted to Congress to establish a health data clearinghouse. See H.R. 2882, S. 1367, 98th Cong., 2nd Sess. (1985) (introduced by Ron Wyden, D. Ore., and Albert Gore, D. Tenn., respectively). The clearinghouse would be located within the Department of Health and Human Services, would collect information on and provide technical assistance to individuals or organizations engaged in gathering, processing and disseminating aggregate health care information, and would make this information public. See id.


388. See infra note 69 and accompanying text.
I. Evidence on Waste Curtailment

The data are not yet available to show if the financial pressures exerted by the prospective payment system are sufficient to overcome the foregoing counterpressures in favor of providing non-wasteful technologies to patients. The Medicare prospective payment system has not been in effect long enough to allow evaluation of its effect on the overall quality of patient care, much less on the development, acquisition and use of technology.\(^{389}\) It is known that during the first year of prospective payment, the average hospital length of stay for Medicare beneficiaries declined, at least in part due to the new system.\(^{390}\) Moreover, the number of Medicare hospital admissions declined by over 4% from the previous, pre-prospective payment year.\(^{391}\) While it has been reported that Medicare patients are being discharged prematurely and in poorer health than before prospective payment,\(^{392}\) no systematic quality-of-care studies have been completed, and the Health Care Finance Administration denies that quality of patient care has decreased.\(^{393}\) Data demonstrating no decline in quality-of-care under prospective payment, despite reductions in variables such as length of stay, might mean that providers are resisting pressures to cut beneficial care or merely that there is still waste in the present system.\(^{394}\) In any event, in view of the lack of definitive data, the issue remains to be resolved.\(^{395}\)


390. See id. at 37-39.

391. See id. at 40.

392. See id. at 39-40.

393. See 50 Fed. Reg. 24,439 (to be codified at 42 C.F.R. pts. 405, 412) (proposed June 10, 1985) ("We do not at the present time have objective data demonstrating that the quality of or access to care has declined. We have noted a significant decrease in average length-of-stay, a slight decrease in admissions, and an increase in average case mix.").


395. Some data on the impact of conflict of interest on patient care has emerged from prepaid health delivery systems such as health maintenance organizations (HMOs), which are vertically integrated providers that combine an insurance function with the delivery of care. See OTA Competition, supra note 67, at 36. An HMO has the incentive to withhold nonwasteful technologies from its patients except insofar as this will require additional care, presumably from the same HMO provider, in the future. In one respect, the impact of the provider's conflict of interest on the quality of patient care may be more adverse in the case of an HMO than in the case of Medicare prospective payment: when a third-party payor like Medicare refuses to reimburse a provider for a technology, the quality of care to the patient in question may not directly be affected, since the patient may have received the technology before the claim for reimbursement is submitted. See supra note 275.

In the case of an HMO (other than one reimbursing another provider, such as an out-of-
V. Conclusion

Cost-containment initiatives intensify public and private efforts to identify and control wasteful technology. Although these efforts are prone to a host of technical and conceptual difficulties, some form of technology assessment is inevitable. Technology assessment must adopt approaches that avoid these difficulties as much as possible, while methodological refinement continues.

The two most serious problems in technology assessment are the choice of perspective and the valuation of intangible benefits. These problems arise most conspicuously in performing cost-benefit analysis. Accordingly, cost-control efforts should be focused on technologies that are wasteful in terms of being unsafe, ineffective or not cost-effective. Curtailing these sorts of wasteful technologies has

town hospital, for care for one of its subscribers), on the other hand, the decision to refuse to pay for the technology precludes the patient from obtaining it—at least from that HMO. See Stern, Will the Tort of Bad Faith Breach of Contract be Extended to Health Maintenance Organizations?, 11 LAW MED. & HEALTH CARE 12, 13 (1983). In other respects, however, HMO patient care may be less prone to suffer from the provider's conflict of interest than non-HMO care, since the HMO has an incentive to maximize patient welfare when doing so will prevent the need for future care by the HMO, while the non-HMO provider has an opposite incentive to encourage the patient to return as another prospectively-paid admission. In any event, HMO patients appear to have lower rates of hospitalization and surgery than non-HMO patients, but the same or higher rates of office or ambulatory visits. See OTA COMPETITION, supra note 67, at 37-39. As of 1982, however, the lower rates of care did not appear to result in lower quality-of-care, nor was there any clearcut evidence that HMOs denied their subscribers needed hospitalization or surgical treatment. See id. at 64-65. This may have been due to the need for HMOs to compete on a quality-of-care basis with non-HMO providers. See OTA IMPLICATIONS, supra note 73, at 123.

There is some indication that patients will sacrifice the quality of their own care when they are financially responsible for health care. For example, in a major study by the Rand Corporation on the effect of varying degrees of patient co-payment on frequency and quality of care, RAND CORPORATION, THE EFFECT OF COINSURANCE ON THE HEALTH OF ADULTS (1984), a direct correlation was found between the level of co-payment and consumption of services. The highest co-payment population consumed about 30% less care than the population whose care was free (no co-payment or insurance premiums). Id. at 25. Reduced consumption did not affect five general health status measures (physical health, role functioning, mental health, social contacts and health perceptions) for the average person. Id. at 26. Nor was there any effect on risk factors for cardiovascular disease or cancer like smoking, weight and cholesterol. Id. at 25-26. But those subjects whose health care was free had significantly less myopia and hypertension. Id. at 26. Insofar as hypertension is a risk factor for death, the Rand investigators calculated that, in the population of 50-year-old men, there would be eleven fewer deaths per thousand if care were free rather than if a high co-payment were required. Id. at 27. In interpreting the significance of this study, it is important to note that there was an income-related ceiling on health care expenditures for poor subjects, and that the study excluded those over 60 and the disabled. Id. at 27-28. Thus, the study may have underestimated the impact of co-payment on the most vulnerable populations: the elderly and the poor.
the additional advantage of allowing cost-containment objectives to be consistent with patient interests.

Cost-containment methods such as Medicare's prospective payment system, while presenting certain advantages over other methods of controlling technology waste, create incentives for providers and third-party payors to deny patients not only technologies that are wasteful but also technologies that provide net benefit to the patient but that increase provider costs. Insofar as the relationship between patient and provider is concerned, these incentives introduce a conflict of interest between provider and patient, a situation that is especially troubling in view of the factors that have led the duties that the provider owes to the patient to be characterized as fiducial. At the same time, providers are under a variety of pressures to act strictly in the patient's interest. Whether cost-control incentives or these counterpressures will be the stronger determinant of provider behavior is not yet known.

In any event, greater assurance is needed that Medicare's prospective payment system will limit its control of wasteful technologies to those that are wasteful both from a patient and a cost-control perspective. This requires both greater clarity in the standards by which Medicare determines which technologies to reimburse for, and increased assurance that these standards are being adhered to. At the same time, the methodology for assessing technologies should continue to be improved so that more cost-effective methods of identifying wasteful technology can be developed. This will facilitate extending cost controls, if necessary, to more marginal technologies.

This approach to waste is suggested as a first, but not necessarily last step in reconciling cost controls with technical assessment capabilities and with social goals. If insufficient reductions in technology costs result, the impetus will grow for more severe cost-control measures, including measures dependent on assessment techniques that are presently of questionable value. At that point, it may be necessary to come more starkly to grips with the basic question of how much health care is worth.