

# Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach

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The news is depressingly familiar: Health care costs in the United States continue to rise at an alarming rate. As a consequence, private health insurance has become unaffordable to tens of millions of Americans.

Federal and state governments could extend coverage to those currently uninsured,<sup>1</sup> but estimates indicate that such coverage would cost at least twenty-four to twenty-seven billion dollars annually.<sup>2</sup> Given present efforts to curtail rather than to expand health care programs,<sup>3</sup> it is highly unlikely that governments will opt to incur these costs. If governments are unwilling either to provide or to mandate insurance coverage, private sector initiatives—perhaps with some governmental involvement—may present the only path to reform. Without entering the debate over whether public or private reform is preferable, this Note proposes a private sector cost-containment initiative that emphasizes controlling the use of medical technologies as a means of controlling health care costs and analyzes the legal implications of such an initiative.<sup>4</sup>

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1. Governments could provide health insurance directly to the uninsured. *See, e.g.*, Himmelstein & Woolhandler, *A National Health Program for the United States: A Physicians' Proposal*, 320 *NEW ENG. J. MED.* 102 (1989) (proposing federal funding for all health care). Alternatively, governments could mandate that all employers provide health benefits for their uninsured employees. This approach has been advocated—thus far unsuccessfully—at the Federal level by Senator Kennedy, S. 768, 101st Cong., 1st Sess. (1989), and has been adopted or proposed in several states. *See* GEORGE WASHINGTON UNIV. INTERGOVERNMENTAL HEALTH POL'Y PROJECT, *MAJOR CHANGES IN STATE MEDICAID AND INDIGENT CARE PROGRAMS 17-18* (1988) (summarizing recent initiatives in Massachusetts, California, New York, West Virginia, Wisconsin, and Maine). Most states, however, have not sought to extend health insurance coverage to the uninsured.

2. *See, e.g.*, Tolchin, *Turning to the Biggest Gap in U.S. Health Coverage*, *N.Y. Times*, Dec. 25, 1988, § 4, at 4, col. 1.

3. *See, e.g.*, *Budget Office Proposes \$8 Billion Medicare Cut*, *N.Y. Times*, Dec. 1, 1989, at A26, col. 4.

4. There is an emerging consensus that technologies must be controlled if health care costs are to be controlled. *See, e.g.*, NATIONAL LEADERSHIP COMM'N ON HEALTH CARE, FOR THE HEALTH OF A NATION (1989); Leaf, *Cost Effectiveness as a Criterion for Medicare Coverage*, 321 *NEW ENG. J. MED.* 898 (1989); Roper, Winkenwerder, Hackbarth & Krakauer, *Effectiveness in Health Care*, 319 *NEW ENG. J. MED.* 1197 (1988); Califano, *Billions Blown on Health*, *N.Y. Times*, Apr. 12, 1989, at A25, col. 2. As a result of this consensus, a number of public and private programs have been established to assess technologies, *see infra* note 21, and the Federal Government has recently reorganized its technology assessment efforts and created the Agency for Health Care Policy and Research. *See*

Section I briefly describes the structure of health insurance in the United States and the problem of the uninsured. It then explores the causal relationship between medical technologies and health sector cost increases and argues that many technologies are wasteful. Section I also discusses the process of technology assessment by which wasteful technologies can be identified. Section II describes how most private health insurance contracts not only fail to exclude wasteful technologies from coverage but actually promote their overuse. This Section also describes how the failure to exclude wasteful technologies raises the price of health insurance, decreases access to care, and leads to the inefficient use of individual resources. Section III contends that prevailing judicial attitudes and legal rules that favor broad insurance coverage exacerbate the problems of price, access, and inefficiency. Section IV contains a proposal for private sector reform. It suggests that technologies should be routinely assessed and that beneficiaries should have the option to select a coverage plan that excludes wasteful technologies in return for a lower premium. Section IV also assesses the implications of such reform. Finally, Section V argues that the legal rules governing the interpretation of insurance contracts would need to be modified for such reform to be successful and suggests how the rules should be modified.

## I. THE RELATIONSHIP BETWEEN TECHNOLOGY AND HEALTH CARE COSTS

Health care costs in the United States consume an ever-increasing percentage of our Gross National Product. In 1987, for example, we spent \$500 billion or 11.1% of the GNP on health care,<sup>5</sup> and it is estimated that by the year 2000 we will spend over \$1.5 trillion, or 15% of the GNP, on health.<sup>6</sup> Since 1950, the rate of inflation in the health care sector has exceeded the general inflation rate in every year but three.<sup>7</sup>

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Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103(a), 103 Stat. 2106 (1989). Because estimates of the potential savings from more rational use of technology range as high as \$22 billion per year, NATIONAL LEADERSHIP COMM'N ON HEALTH CARE, *supra*, at 59, the debate has shifted in recent years from the question of whether we should assess and control technologies to the question of how best to approach the task. See, e.g., Fuchs, *What is CBA/CEA, and Why Are They Doing This to Us?*, 303 NEW ENG. J. MED. 937 (1980) ("We do not . . . have an option between evaluating and not evaluating. The only option is whether to evaluate explicitly, systematically, and openly . . . or whether to evaluate implicitly, haphazardly, and secretly, as has been done so often in the past."). Unlike other proposals that focus on controlling technology as a means of curtailing either public sector spending or health care costs in general, this Note suggests a mechanism by which information about technologies could be used in the private market to enhance access to care.

5. Levit & Freeland, *National Medical Care Spending*, 7 HEALTH AFF., Winter 1988, at 124, 125. Official figures for 1988 are not yet available.

6. Division of National Cost Estimates, Health Care Fin. Admin., *National Health Expenditures, 1986-2000*, 8 HEALTH CARE FIN. REV. 1, 2, 25 (1987).

7. Renn, *The Structure and Financing of the Health Care Delivery System of the 1980s*, in HEALTH CARE AND ITS COSTS 45 (C. Schramm ed. 1987). The health sector inflation rate between 1950 and 1985 averaged 10.4% and outpaced general inflation in every year except 1973, 1978, and 1984. *Id.*

Total expenditures on health care may be divided into three roughly equal parts. Private insurers (including Blue Cross/Blue Shield) pay about thirty percent; self-insured companies, private individuals, and charities pay another thirty percent;<sup>8</sup> and the Federal and state governments, which provide insurance for the elderly, the disabled, and the indigent, contribute the remaining forty percent.<sup>9</sup>

In the private sector, the high cost of health care is reflected in expensive insurance premiums. Although expensive health insurance greatly affects the business community<sup>10</sup> and those individuals who pay for their own insurance,<sup>11</sup> the most important consequence of expensive health insurance is that a large number of people cannot afford coverage. Some of those who cannot afford private health insurance are eligible for governmental coverage, but there are now at least thirty-one million Americans without health insurance for at least part of each year.<sup>12</sup>

8. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH UNITED STATES 160 (1988).

9. *Id.* Medicare, funded by the Federal Government, provides insurance for those over the age of 65 and the disabled. Medicaid, funded jointly by the Federal and state governments, provides insurance for the indigent. Renn, *supra* note 7, at 29-30.

10. In addition to funding some care directly through self-insurance and contributing to Medicare through FICA taxes, the business community pays about 75% of all private insurance premiums. Wing, *American Health Policy in the 1980's*, 36 CASE W. RES. L. REV. 608, 672 (1986). Employers that pay for their employees' health insurance typically provide a choice among various traditional commercial insurance plans and one or more Health Maintenance Organizations. Renn, *supra* note 7, at 39.

The cost of health care to the business community is startling. In 1984, for example, Blue Cross/Blue Shield was Chrysler's single largest supplier. J. CALIFANO, AMERICA'S HEALTH CARE REVOLUTION: WHO LIVES? WHO DIES? WHO PAYS? 30 (1986). In 1987, the amount U.S. companies spent on health care was equal to 94% of their after-tax profits. Levit, Freeland & Waldo, *Health Spending and Ability to Pay: Business, Individuals, and Government*, 10 HEALTH CARE FIN. REV. 1, 9 (Spring 1989).

11. This group includes those who are self-employed, unemployed, or who work for an employer that does not provide health insurance as a benefit. Although the bulk of private insurance premiums are paid by employers, *supra* note 10, many employers do not pay for or provide insurance for their employees.

12. Moyer, *A Revised Look at the Number of Uninsured Americans*, 8 HEALTH AFF., Summer 1989, at 102, 102. Because Medicaid pays for care for the truly indigent, those without health insurance are typically the almost-indigent or members of the lower middle class. Over half of the uninsured are full or part-time workers, and more than one fifth are children. *Id.* at 105-06.

The uninsured suffer for two reasons. First, they may not have access to adequate care. They are, for example, less likely to obtain medical care, use preventive services, or receive prenatal care. Braverman, Oliva, Miller, Reiter & Egerter, *Adverse Outcomes and Lack of Health Insurance Among Newborns in an Eight County Area of California, 1982-1986*, 321 NEW ENG. J. MED. 508, 508 (1989). When ill, they may be forced to use public hospitals which are frequently underfunded and understaffed. See French, *General Hospital, New York City Style*, N.Y. Times, Jan. 15, 1989, § 4, at 7, col. 1. ("You can't help wondering if Dickens's world was not a kinder place, and the tragedy is we know how to do better; we just can't get our act together to do it."); *Hospitals Overwhelmed as Poor in New York City Search for Care*, N.Y. Times, Dec. 4, 1988, at A1, col. 5. Others may be denied care altogether or may be forced to leave the country to seek care. See *American Health Care: Paying More and Getting Less*, ECONOMIST, Nov. 25-Dec. 1, 1989, at 17-18 (250,000 Americans denied care last year because of inadequate insurance); *Health Care on the Border: Poor Go To Mexico*, N.Y. Times, Oct. 17, 1988, at A1, col. 2. Second, even when the uninsured do receive the care that they need, they are billed directly for that care.

In addition to those who are totally uninsured, there are tens of millions of Americans with inadequate protection against the possibility of large medical bills. See Farley, *Who Are the Underinsured?*, 63 MILBANK MEMORIAL FUND Q. 476, 499 (1985).

Medical technologies, defined as "drug[s], device[s], or medical or surgical procedure[s] used in medical care,"<sup>13</sup> are widely believed to be one of the major causes of rising health care costs.<sup>14</sup> Examples of medical technologies include pharmaceutical drugs, devices such as CAT scanners and artificial hearts, and procedures such as dialysis and organ transplants. Medical technologies, broadly defined, may be responsible for as much as fifty percent of health sector inflation.<sup>15</sup>

Not all technological innovation is good. Some technologies are unsafe and others are ineffective.<sup>16</sup> Moreover, some technologies that are effective are not "cost-effective." A cost-effective technology is one that is as effective as an alternative but less expensive.<sup>17</sup> If no equally effective alternative is available, then a technology is cost-effective regardless of its cost. Technologies that are unsafe, ineffective, or not cost-effective can be defined as "wasteful" technologies.<sup>18</sup>

13. OFFICE OF TECHNOLOGY ASSESSMENT, STRATEGIES FOR MEDICAL TECHNOLOGY ASSESSMENT 3 (1982).

14. See H. AARON & W. SCHWARTZ, THE PAINFUL PRESCRIPTION: RATIONING HOSPITAL CARE 117-18 (1984); R. EVANS, STRAINED MERCY: THE ECONOMICS OF CANADIAN HEALTH CARE 163-64 (1984); see also Altman & Wallack, *Is Medical Technology the Culprit Behind Rising Health Costs? The Case For and Against*, in MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS? 35 (S. Altman & R. Blendon eds. 1979) (health care costs also driven by general inflation, growing and aging society, and increase in real income).

15. See, e.g., Cooper & Gaus, *Controlling Health Technology*, in MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS?, *supra* note 14, at 244-45 (20-40% of all hospital cost increases due to technological change); Schwartz, *The Inevitable Failure of Current Cost-Containment Strategies*, 257 J. A.M.A. 220, 221 (1987) (more than 50% of real cost increases in hospital sector due to increased intensity of services, resulting mainly from technological change). The effect of technology on prices is most pronounced in the hospital sector where technology is most concentrated, but the effect is not limited to this sector.

16. "Safety" is defined as "a judgment of the acceptability of risk in a specified situation." OFFICE OF TECHNOLOGY ASSESSMENT, ASSESSING THE EFFICACY AND SAFETY OF MEDICAL TECHNOLOGIES 18 (1978). "Efficacy" is "[t]he probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use." *Id.* at 16. Of course, no technology is ever safe or unsafe, effective or ineffective, under all circumstances. Classifying technologies therefore requires that some arbitrary lines be drawn.

17. Doubilet, Weinstein & McNeil, *Use and Misuse of the Term "Cost Effective" in Medicine*, 314 NEW ENG. J. MED. 253, 254 (1986); Fuchs, *supra* note 4, at 937. A cost-effective technology is not necessarily one that is inexpensive or unsophisticated; it is simply one that is less expensive than an equally effective alternative. Because no two medical technologies produce precisely the same results, to be "equally effective" two technologies need not produce the same results, only results that are very similar. A number of techniques have been developed to aid in comparing technologies that produce similar but not identical results. See Eisenberg, *Clinical Economics: A Guide to the Economic Analysis of Clinical Practices*, 262 J. A.M.A. 2879, 2880 (1989).

There are alternative definitions of "cost-effective," including "more effective and more costly, [with the] additional benefit being worth [the] additional cost," Doubilet, Weinstein & McNeil, *supra*, at 254, and "less effective and less costly, [with] the added benefit of the rival strategy not being worth its extra cost," *id.* These alternative definitions, however, blur the distinction between cost-effectiveness analysis and cost-benefit analysis, and are therefore not as easily applied. See *infra* note 18.

18. Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RES. L. REV. 778, 835 (1986). This definition is a practical one. Identifying wasteful technologies under this definition requires only that two safe and equally effective technologies be identified and that their costs be compared; benefits need not be monetized. The process of comparing the costs of equally effective technologies is called "cost-effectiveness analysis."

The term "wasteful" as used in this Note is not equivalent to the classical economic definition of

Wasteful medical technologies can be identified through technology assessment,<sup>19</sup> a process in which the safety, efficacy, or cost-effectiveness of a technology is evaluated.<sup>20</sup> Currently, in the United States, most drugs and medical devices are assessed for safety and efficacy but not cost-effectiveness, and most medical and surgical procedures are not formally evaluated at all.<sup>21</sup>

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wasteful. In economic terms, a wasteful technology is one whose costs outweigh its benefits or one that is more expensive than an equally beneficial alternative. Although technically more precise, identifying wasteful technologies under this definition would require a direct comparison between costs and benefits. Such comparison, called "cost-benefit analysis," is extraordinarily difficult in the health care setting in which benefits cannot easily be monetized.

An unknown number of technologies that fall outside the more practical definition of "wasteful" would be captured by the broader definition. For example, a technology that is less expensive than an equally effective alternative (and which is therefore cost-effective) may nonetheless have costs that outweigh its benefits. See generally R. EVANS, *supra* note 14, at 252-59 (comparing cost-effectiveness and cost-benefit analysis); *infra* text accompanying notes 51-52 (distinguishing health from welfare).

19. Technology assessment is, at a minimum, the systematic evaluation of the important properties of a technology through randomized clinical trials, consensus conferences, or literature reviews. INSTITUTE OF MEDICINE, *ASSESSING MEDICAL TECHNOLOGIES 2* (1985). More broadly, technology assessment includes evaluation of approaches to specific illnesses that involve the use of more than one technology. Historically, technology assessment focused only on safety and clinical efficacy, not on cost-effectiveness. Over the past 15 or 20 years, however, as health care costs have soared, there has been a growing recognition that the economic consequences of new technologies should be evaluated as well, despite imperfections in the techniques for analyzing economic impact. See *id.* at 141-43.

20. Studies suggest that several widely used technologies are not cost-effective, and, as noted, many others have not been formally evaluated. See, e.g., Braunwald, *Effects of Coronary-Artery Bypass Grafting on Survival*, 309 NEW ENG. J. MED. 1181 (1983) (medical therapy for coronary disease may be just as effective but less costly than bypass grafting for some patients); Charig, Webb, Payne & Wickham, *Comparison of Treatment of Renal Calculi by Open Surgery, Percutaneous Nephrolithotomy, and Extracorporeal Shockwave Lithotripsy*, 292 BRIT. MED. J. 879 (1986) (ESWL at least as effective but less costly than surgery); Hayashida, Alterman, McLellan, O'Brien, Purtill, Volpicelli, Raphaelson & Hall, *Comparative Effectiveness and Costs of Inpatient and Outpatient Detoxification of Patients with Mild-to-Moderate Alcohol Withdrawal Syndrome*, 320 NEW ENG. J. MED. 358 (1989) (outpatient detoxification for alcoholics as safe and 1/9-1/20th as costly as inpatient treatment); Houston, Sanders, Little, Griffith, Clericuzio & Balducci, *Staging of Lung Cancer: A Cost-Effectiveness Analysis*, 8 AM. J. CLINICAL ONCOLOGY 224 (1985) (gallium scanning more costly than other equally effective staging techniques); Kinoshian & Eisenberg, *Cutting Into Cholesterol: Cost-effective Alternatives for Treating Hypercholesterolemia*, 259 J. A.M.A. 2249 (1988) (dietary modification may be as effective and less costly than pharmacological therapy); Ramirez & Javid, *Cost Effectiveness of Chemonucleolysis Versus Laminectomy in the Treatment of Herniated Nucleus Pulposus*, 10 SPINE 363 (1985) (non-surgical technique for treating lumbar disc disease equally effective and less costly than surgery); see also Pascale, *Comparative Efficacy and Safety of Histamine-2 Antagonists in the Treatment of Stress-Related Mucosal Disease*, 12 DRUGS IN PATIENT CARE 1 (Aug. 1989) (Yale-New Haven Hospital substituting Cimetidine for Ranitidine because it prevents ulcers as effectively and will save hospital \$100,000 annually); *Less Prenatal Care Urged for Most Healthy Women*, N.Y. Times, Oct. 4, 1989, at A1, col. 3 (reporting results of study finding that "many procedures and tests performed on healthy pregnant women were expensive and time-consuming and provided no real benefit").

21. In the United States, both the Federal Government and private organizations perform technology assessment, and efforts are being made to coordinate public and private research. The National Leadership Commission on Health Care, for example, called for a "National Quality Improvement Initiative" to coordinate nationwide public and private assessment activities. NATIONAL LEADERSHIP COMM'N ON HEALTH CARE, *supra* note 4, at 58.

Currently, the Food and Drug Administration (FDA) evaluates drugs and medical devices for safety and efficacy. The FDA, however, is not charged with evaluating either costs or cost-effectiveness. INSTITUTE OF MEDICINE, *supra* note 19, at 41.

Both the Government and private groups evaluate some medical and surgical procedures, although there is no statutory requirement that such procedures be routinely assessed. It is estimated that about 10-20% of procedures have undergone randomized trials for safety and efficacy. *Id.* at 5. In the public

Despite the fact that wasteful technologies can be identified, private insurance contracts do not categorically exclude them from coverage.<sup>22</sup> If these technologies were excluded from coverage, health insurance, in theory, would be less expensive and therefore more accessible to some of those who cannot currently afford insurance.

## II. PRIVATE INSURANCE AND THE PROBLEMS OF COST, ACCESS, AND INEFFICIENCY

### A. *Private Insurance Covers Wasteful Technologies*<sup>23</sup>

Most private health insurance contracts attempt to limit coverage to care that is "reasonably necessary" or "medically necessary."<sup>24</sup> These terms, however, are generally construed very broadly, and contracts are

sector the newly created Agency for Health Care Policy and Research is responsible for both assessment of individual procedures and patient outcome research. The Agency is under a statutory mandate to consider "the safety, efficacy . . . and, as appropriate, the cost-effectiveness" of technologies. See Omnibus Budget Reconciliation Act of 1989, *supra* note 4, at § 6103. In the private sector, a loose network of academic centers, insurers, and professional societies evaluates medical and surgical procedures. See INSTITUTE OF MEDICINE, *supra* note 19, at 35. In recent years private sector evaluations have increasingly focused on costs in addition to safety and efficacy. *Id.* at 137-39. Cooperation among private assessors of medical technologies may be limited, however, by potential antitrust liability, especially if assessments are linked to decisions by insurers to restrict coverage. Cf. Vest v. Waring, 565 F. Supp. 674 (N.D. Ga. 1983) (antitrust suit by private ophthalmologists unable to obtain reimbursement for radial keratotomy surgery); Rose & Leibenluft, *Antitrust Implications of Medical Technology Assessment*, 314 NEW ENG. J. MED. 1490 (1986).

22. Private contracts do exclude *some* wasteful technologies, particularly unsafe and ineffective drugs and devices. See *infra* note 24. However, technologies are rarely excluded because of cost considerations per se.

23. Section II of this Note addresses the relationship between the *extent* of coverage and prices, arguing that broad coverage raises prices. The *mechanism* of reimbursement also influences prices.

Private insurance has traditionally been retrospective. Under a classical regime of retrospective insurance, patients and providers make decisions about which technologies are necessary, and insurers reimburse them for their costs (or charges). This system provides maximum decisionmaking discretion to patients and providers, but it also causes prices to rise for two reasons. First, because consumers do not pay for most care directly, they tend to ignore price. As a result, they use resources inefficiently, and as demand increases, so do prices. Second, because providers of care are reimbursed for their costs (or charges), there are few incentives for them to use cost-effective technologies. See C. HAVIGHURST, *DEREGULATING THE HEALTH CARE INDUSTRY* 83-84 (1982).

To control the inflation resulting from retrospective insurance coverage, some private insurers have begun to reimburse some care, particularly inpatient hospital care, on a prospective basis and pay hospitals a predetermined amount for each hospital admission. The amount of payment varies with the patient's diagnosis or "diagnosis-related group" (DRG). This mechanism of reimbursement is also used by Medicare. See Renn, *supra* note 7, at 32-33. Prospective payment is not more widespread in the private insurance industry because individual insurers generally lack the market power to bargain for this type of reimbursement and the antitrust laws prohibit collective efforts by insurers to impose such reimbursement on hospitals. *Id.* at 33.

Cost-consciousness has also stimulated the development of alternatives to traditional retrospective insurance such as Health Maintenance Organizations which provide beneficiaries all care for a given period of time for a flat fee. See P. STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 393-419 (1982).

24. See Address by Joel Miller, *The Private Insurer Response to Advanced Health Care Technology: The Challenge of Costly Therapeutics*, delivered at the Conference on Critical Issues in Organ Transplantation 5-7 (May 30, 1986) (transcript on file with author). Care that is "not part of generally accepted medical practice," "unnecessary or inappropriate," "experimental," or "investigational" is typically excluded. Greenberg & Derzon, *Determining Health Insurance Coverage of Technology: Problems and Options*, 19 MED. CARE 967, 972 (1981).

typically interpreted to cover any non-experimental technology generally accepted by the medical community which has not been affirmatively deemed unsafe or ineffective.<sup>25</sup> Moreover, private insurers virtually never consider the costs of a technology when determining whether it is reasonable or necessary.<sup>26</sup> Contracts as they are currently written and interpreted therefore cover two types of wasteful technologies: (1) those that are presumed to be safe and effective but which in fact are not,<sup>27</sup> and (2) all non-cost-effective technologies.

### B. *Insurance Coverage Drives Utilization and Price Increases*

If there is a need for a medical technology which appears to be safe and effective, the rate at which that technology is utilized depends almost entirely upon whether it is covered by insurance.<sup>28</sup> In a world with inadequate technology assessment, coverage, rather than evidence of safety, efficacy, or cost-effectiveness, drives utilization.<sup>29</sup>

Insurance that covers and thereby promotes wasteful technologies, especially those that are not cost-effective, raises the price of medical care (and therefore the price of health insurance) for two reasons. First, by definition, technologies that are not cost-effective are more expensive than equally effective alternatives, so coverage of these technologies is more expensive than coverage of cost-effective technologies. Second, coverage of technologies that are not cost-effective creates an incentive for the development of new technologies without regard for cost-effectiveness, and this leads to additional increases in the cost of health care and health insurance. As noted, access to care declines as prices increase.

Because of the close relationship between insurance coverage and utili-

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25. Greenberg & Derzon, *supra* note 24, at 974. Lack of FDA approval generally constitutes strong evidence for lack of safety or efficacy of drugs and devices. However, coverage of technologies is not typically linked expressly to approval by the FDA.

26. Joel Miller, *supra* note 24, at 13. In contrast, public agencies have begun to consider costs when defining reasonable or necessary care. The Health Care Finance Administration, for example, recently proposed adding cost-effectiveness as a criterion for Medicare coverage decisions. 54 Fed. Reg. 4302, 4308 (1989) (to be codified at 42 C.F.R. §§ 400 & 405) (proposed Jan. 30, 1989).

27. The history of medicine is full of technologies that were widely believed to be safe and effective but were not. Examples include the sedative thalidomide, internal mammary artery ligation for relief of angina pectoris, fracture gluing, induction of insulin coma to treat schizophrenia, and stomach freezing to cure ulcer disease. See E. LAMBERT, *MODERN MEDICAL MISTAKES* (1978).

28. Other factors that influence utilization to a lesser degree include prevailing attitudes about how an illness should be treated, the nature of the technology, its clinical utility, and advertising. INSTITUTE OF MEDICINE, *supra* note 19, at 178-81. Expensive technology in turn may stimulate demand for insurance coverage. Goddeeris & Weisbrod, *What We Don't Know About Why Health Expenditures Have Soared: Interaction of Insurance and Technology*, 52 MOUNT SINAI J. MED. 685, 688 (1985).

29. The enormous influence of insurance coverage can best be seen in the case of dialysis, where the number of patients more than quintupled in the three years after coverage was provided to virtually all patients with end-stage renal disease. Hellinger, *Controlling Costs by Adjusting Payment for Medical Technologies*, 19 INQUIRY 34, 35 (1982); see also Katz, *Genies in the Medicine Bottle*, ESQUIRE, Dec. 1989, at 74 ("'MRIs will completely take over from CAT scans,' one radiologist quipped. 'I know, because they're more expensive.'").

zation, insurers, responding to pressures from premium payers, have attempted in recent years to restrict coverage to control health care costs.<sup>30</sup> With rare exceptions, however, none of the programs aimed at restricting the extent of coverage has focused on the control of technology per se.<sup>31</sup> Specifically, private insurers have not attempted to contain costs by systematically excluding wasteful technologies from coverage.<sup>32</sup>

### C. *Private Insurance Promotes Inefficiency*

Insurance policies as they are currently structured promote the inefficient use of individual resources in addition to promoting wasteful technologies. Because the language of most policies is so broad,<sup>33</sup> consumers have a choice only between buying insurance that covers many wasteful technologies or buying no insurance at all. Those who would prefer less inclusive coverage in return for a lower premium are forced to overinsure—if they can afford to. Specifically, those who would prefer not to have coverage for wasteful technologies must nonetheless pay for coverage of many such technologies.<sup>34</sup> A more efficient system would allow them to buy less expensive coverage that excludes wasteful technologies, and would allow them to spend the money saved on competing goods of greater marginal value.<sup>35</sup>

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30. Private insurers have used several strategies to limit the extent of coverage. First, most have raised deductibles and co-payments. See *Companies Shift Bigger Share of Health Costs to Employees*, N.Y. Times, Nov. 22, 1988, at A1, col. 1. There is conflicting evidence about the efficacy of this approach. See Marmor, *Coping With a Creeping Crisis: Medicare at Twenty*, in SOCIAL SECURITY: BEYOND THE RHETORIC OF CRISIS 177, 194 n.37 (T. Marmor & J. Mashaw eds. 1988). Second, most insurers have instituted managed care programs to reduce the utilization of insured services. Examples of managed care include pre-admission approval for elective hospitalization, second opinions prior to elective surgery, and ongoing or retrospective evaluation of the reasonableness of or the necessity for services covered by the insurer. See Renn, *supra* note 7, at 18–19. Utilization review may reduce total medical expenditures by as much as 8.3%. Feldstein, Wickizer & Wheeler, *The Effects of Utilization Review Programs on Health Care Use and Expenditures*, 318 NEW ENG. J. MED. 1310 (1988). Third, on rare occasions, some insurers have excluded specific technologies from coverage because of cost considerations. Blue Cross/Blue Shield, for example, suspended coverage for routine preoperative chest x-rays and electrocardiograms because cost-benefit analysis suggested that these procedures, expensive in the aggregate, produced few benefits. Blue Cross and Blue Shield Association, *Guidelines on Diagnostic Testing Will Lead to Cost Savings, Better Patient Care* (press release, Apr. 2, 1987). See generally Frech & Ginsberg, *Competition Among Health Insurers, Revisited*, 13 J. HEALTH POL., POL'Y & L. 279 (1988) (providing overall review of private sector cost-containment efforts).

31. They aim instead to shift costs away from insurers or to control the utilization of all health services. Deductibles and co-payments, for example, primarily shift costs from insurers to beneficiaries, while utilization review primarily controls hospitalization rates.

32. See *infra* Section IV(B).

33. See *supra* note 24 and accompanying text.

34. See *supra* text accompanying note 27.

35. The rational consumer will only buy insurance to the point where an additional dollar spent on insurance will yield the same satisfaction as a dollar spent on competing needs. To the extent that poorer people have greater competing needs (for basic goods such as housing and food), they may want to buy less health insurance, especially if the coverage offered is broader than they want. See Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis*, 97 YALE L.J. 353, 362–63 (1988).



### III. LAW, TECHNOLOGY, AND INSURANCE CONTRACTS

The legal rules governing interpretation of health insurance contracts exacerbate the problems of cost, access, and inefficiency. Although there are few reported cases involving disputes over coverage for technologies, these cases show that the legal rules exacerbate these problems by extending coverage for technologies even beyond the expansive wording of the typical contract.

Courts expand the scope of coverage either by relying on the maxim that all ambiguities should be interpreted against the insurer or by stretching the definition of "reasonable" or "necessary" care.<sup>36</sup> In the first instance, courts simply construe the terms of the contract in the light most favorable to the beneficiary.<sup>37</sup> In the second instance, rather than relying on scientific evidence of safety, efficacy, or cost-effectiveness to determine what care is reasonable or necessary, courts rely instead either on evidence that the individual beneficiary benefited (or might benefit),<sup>38</sup> or on evidence that the technology was prescribed by a physician.<sup>39</sup> Either of these general strategies can be used to extend coverage for almost all technologies, including wasteful ones.<sup>40</sup>

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36. See *supra* text accompanying note 24.

37. See, e.g., *McLaughlin v. Connecticut Gen. Life Ins. Co.*, 565 F. Supp. 434 (N.D. Cal. 1983) (coverage for holistic cancer therapy mandated on ground that absence of FDA approval did not unambiguously imply that drug was not reasonable or necessary); *Aetna Life Ins. Co. v. Sanders*, 127 Ga. App. 352, 193 S.E.2d 173 (1972) (classifying exogenous obesity as "disease" so that beneficiary could get coverage for expensive surgery, despite acknowledged possibility of successful, less expensive alternative); *Van Vactor v. Blue Cross Ass'n*, 50 Ill. App. 3d 709, 365 N.E.2d 638 (1977) (ordering coverage for dental surgery because contract ambiguous about whether dentist or insurer should determine medical necessity); *Fassio v. Montana Physicians' Serv.*, 170 Mont. 320, 553 P.2d 998, 1000 (1976) (ordering coverage for unproven therapy for Down's Syndrome, stating that "if [the insurer] wishes to exclude or limit the risk contracted for, then let them do so in words that leave no doubt"); *Wilson v. Travelers Ins. Co.*, 605 P.2d 1327, 1329 (Okla. 1980) (extending coverage for Laetrile, stating that "[t]he contract could have precluded payment for illegal drugs, experimental drugs, or provided that all drugs must have been declared safe and effective by the FDA before they would be covered expenses under the contract. It did not do so.").

38. See, e.g., *Dallis v. Aetna Life Ins. Co.*, 768 F.2d 1303 (11th Cir. 1985) (extending coverage for holistic cancer therapy because of testimony by individual patients that they had benefited from therapy, despite absence of scientific support); *DiDomenico v. Employers Coop. Indus. Trust*, 676 F. Supp. 903 (N.D. Ind. 1987) (enjoining insurer from refusing to cover liver transplant because insurer's classification of technology as experimental focused on general guidelines rather than on patient himself); *Shumake v. Travelers Ins. Co.*, 147 Mich. App. 600, 383 N.W.2d 259 (1985) (requiring coverage for Laetrile despite general recognition that it was ineffective), *appeal denied*, 425 Mich. 859 (1986). See generally *Cline & Rosten, The Effect of Policy Language on the Containment of Health Care Costs*, 21 *TORT & INS. L.J.* 120 (1985) (describing how broad policy language frustrates insurers' cost-containment efforts).

39. See, e.g., *Breeden v. Weinberger*, 377 F. Supp. 734 (M.D. La. 1974) (physician's judgment should be given great weight in determining whether treatment is reasonable or necessary); *Fassio*, 170 Mont. at 320, 553 P.2d at 1000-01 (if services are "prescribed and performed" by physician, that "should be and is sufficient" to satisfy contractual requirement for "necessary" care).

40. Some ambiguity can be found in most insurance contracts, and in most cases it is relatively easy to adduce some evidence either that the patient did (or might) benefit or that the technology was prescribed by a physician. The mere fact that a patient benefited (or might benefit) from a technology, however, should not determine whether that technology was reasonable or necessary. Because of coincidence or the placebo effect, for example, a patient might improve after administration of an unsafe or ineffective technology. Likewise, the actions of individual physicians should not define reasonable

The judicial bias favoring those seeking coverage for medical technologies is just one example of a more general phenomenon. Most insurance contracts are interpreted in favor of the beneficiary because they are considered to be contracts of adhesion.<sup>41</sup> When interpreting contracts of adhesion, courts frequently intercede to protect the party that has less bargaining power; in the case of insurance contracts, they protect beneficiaries.<sup>42</sup> Courts generally intercede either to honor the reasonable expectations of the beneficiary or to deny insurers unconscionable advantages.<sup>43</sup>

Judicial intervention on behalf of a beneficiary can clearly be justified on fairness grounds where the *ex ante* expectations of the beneficiary were truly reasonable or where the insurer exercised some unconscionable advantage. However, where courts extend coverage to beneficiaries who, by the terms of the contract, clearly had *unreasonable* expectations *ex ante* (or no expectation of coverage at all), they do more than simply fulfill the insured's reasonable expectations or compensate for the insurer's bargaining power advantage. In those instances, courts essentially mandate insurance coverage by creating rights that are beyond the scope of the insurance contract itself.<sup>44</sup> Extra-contractual insurance rights have been labeled "judge-made insurance."<sup>45</sup>

Judge-made insurance raises the price of health insurance premiums because it requires insurers to pay for additional care.<sup>46</sup> This type of ex-

or necessary care. Many physicians, for example, prescribed Laetrile for cancer patients prior to a definitive study proving its ineffectiveness. See Moertel, Fleming, Rubin, Kvols, Sarna, Koch, Currie, Young, Jones & Davignon, *A Clinical Trial of Amygdalin (Laetrile) in the Treatment of Human Cancer*, 306 NEW ENG. J. MED. 201 (1982). More generally, studies now show that there are enormous variations in the rates at which various procedures are used in similar communities, suggesting that at least some technologies are probably used inappropriately. See, e.g., Wennberg, *Dealing With Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF., Summer 1984, at 6.

41. A. CORBIN, CORBIN ON CONTRACTS: A COMPREHENSIVE TREATISE ON THE RULES OF CONTRACT LAW § 559 (1960). Contracts of adhesion are those in which "the terms of a written contract have been chosen by one of the parties and merely assented to by the other." *Id.* They are written in settings where there is a disparity in the bargaining power of the two parties, and where the terms of the contract are dictated by the stronger party. See Kessler, *Contracts of Adhesion—Some Thoughts About Freedom of Contract*, 43 COLUM. L. REV. 629, 632 (1943).

42. See Keeton, *Insurance Rights at Variance with Policy Provisions*, 83 HARV. L. REV. 961, 961 (1970); Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1536 (1986).

43. Keeton, *supra* note 42, at 961–68. Underlying these two justifications for intervention are the equitable doctrines of waiver, estoppel, election, reformation, and rescission. *Id.* at 962. At times, however, neither of these justifications is articulated and, as noted, courts simply resort to the maxim that all ambiguities should be resolved against the insurer. *Id.* at 972; see also *supra* note 37 (examples of courts relying on this reasoning).

44. See Abraham, *Judge-Made Law and Judge-Made Insurance: Honoring the Reasonable Expectations of the Insured*, 67 VA. L. REV. 1151, 1154–55 (1981). Abraham describes "mandated coverage" cases as those where "[t]he policy language denying coverage is relatively clear; it is unrealistic to suppose that the insured would actually or reasonably expect the coverage in question; and the policy's denial of coverage does not appear unfair. . . . The opinions speak of expectations without satisfactorily pointing to their source." *Id.* at 1162–63; see also Keeton, *supra* note 42 (discussing and providing examples of extra-contractual insurance rights).

45. Abraham, *supra* note 44, at 1151.

46. Judge-made insurance has a particularly strong impact on prices because it tends to extend coverage only for the most expensive technologies; disputes about inexpensive technologies are not

pansive coverage is beneficial to those insureds who want the additional coverage and can afford higher premiums, but detrimental to those who cannot afford the higher premiums.<sup>47</sup>

#### IV. PRIVATE INTERESTS, SOCIAL GOALS, AND INSURANCE REFORM

##### A. *Conflicts in Private Cost-Containment*

Limiting insurance coverage to those technologies that have been demonstrated to be safe, effective, and cost-effective would enhance social welfare by making adequate health insurance less expensive and more accessible.<sup>48</sup> Limiting insurance coverage in this manner would require the exclusion of both categories of wasteful technology presently covered by private insurance contracts: those that are presumed to be safe and effective but which in fact are not, and those that are not cost-effective.<sup>49</sup>

Although eliminating wasteful technologies from private insurance coverage would enhance social welfare, some beneficiaries would prefer to retain coverage for the types of wasteful technology that are currently covered and would be willing to pay a higher premium to retain access to

litigated as frequently. The magnitude of the price increase depends on whether insurers elect to continue coverage for the technology at issue. If they elect to continue coverage, they must raise the price of insurance to reflect the cost of the technology and the likelihood that it will be used. If they specifically exclude the technology at issue from all future contracts, they must nonetheless raise the price of all future contracts at least enough to recover the cost of providing the technology to the successful plaintiff and others in similar situations with similar contracts.

47. Abraham, *supra* note 44, at 1185-89.

48. In a world of finite resources, widespread access to an adequate level of health care is a greater social good than narrow access to a higher standard of care. See generally J. RAWLS, *A THEORY OF JUSTICE* 152-61 (1971) (under conditions of uncertainty, resource allocation should be guided by "maximin" strategy, which requires that worst possible outcome should still be acceptable). In the United States, therefore, where some have access to enormously sophisticated care and many others have access to only the most rudimentary care, social welfare would be enhanced by expanded access to adequate care.

The definition of "adequate" care has proven to be elusive. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, for example, concluded that an adequate or "equitable" level of care implied access to "enough care to achieve sufficient welfare, opportunity, information, and evidence of interpersonal concern to facilitate a reasonably full and satisfying life." 1 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *SECURING ACCESS TO HEALTH CARE* 20 (1983). The Commission added that "[p]rovided that [this] level is available to all, those who prefer to use their resources to obtain care that exceeds that level do not offend any ethical principle in doing so." *Id.* The Commission also stated that "[a]ny pursuit of equity entails some limitations on choice. However, limitations that occur in pursuit of equity are more ethically acceptable than those that occur when no principle of comparable importance is being advanced." *Id.* at 47. Although the plan proposed here would not meet the goal of adequate access for all, it would represent a step in that direction.

49. See *supra* text accompanying note 27. To exclude all untested technologies that are presumed to be safe and effective but which actually are not, all untested technologies would need to be excluded from coverage because, prior to testing, unsafe and ineffective technologies cannot be identified. Of course, if all untested technologies were excluded, some technologies that *are* safe and effective would be excluded inadvertently. This problem would disappear, however, if technologies were routinely evaluated for safety and efficacy. See *infra* note 55 and accompanying text. As noted, currently marketed insurance policies generally exclude technologies demonstrated to be unsafe or ineffective. See *supra* note 24 and accompanying text.

them. Some beneficiaries, for example, would be willing to pay a higher premium for coverage of untested technologies that are presumed to be safe and effective in the hope that they are indeed safe and effective.<sup>50</sup> Similarly, some individuals would be willing to pay a higher premium to retain access to technologies that are not cost-effective because such technologies may provide greater comfort or convenience than equally effective, less expensive, technologies.<sup>51</sup>

Underlying the willingness of some individuals to pay more for technologies that are not cost-effective is the distinction between health and welfare. Such "extras" as comfort and convenience may enhance welfare even if they do not enhance health. After satisfying their demand for health care, individuals must decide whether any welfare-enhancing "extras" provided by a non-cost-effective technology are worth the additional price. If they derive greater satisfaction from these "extras" than from an equally expensive competing good, they will demand the non-cost-effective technology. If, on the other hand, they derive greater satisfaction from the alternative good than from the "extras," they will demand the less expensive cost-effective technology instead and spend the money saved on the alternative good. After determining, for example, that two medicines are equally safe and effective, individuals must decide whether they are better off spending an additional ten dollars on the more convenient of the two medicines or on a competing good such as food or books. If they believe that they will be better off with the more expensive but more convenient medicine they will demand it; if they prefer one of the competing goods they will demand the less expensive medicine and spend the ten dollars on pasta or Plato.

Because some consumers are willing to pay a higher price for insurance that covers wasteful technologies, profit-maximizing private insurers will not exclude these technologies from all contracts. However, social welfare will not be maximized if wasteful technologies are not excluded. The only way in which the private insurance system can accommodate these conflicting goals would be to offer more than one coverage option.<sup>52</sup>

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50. Empirical evidence for this point exists in the demand for unapproved cancer treatments and AIDS therapies. See, e.g., *Best Cancer Drugs Often Not Covered*, U.S.A. Today, June 26, 1989, at A1, col. 5; *Group Will Import Unapproved Drugs for Treating AIDS*, N.Y. Times, Mar. 6, 1989, at A1, col. 5.

51. If, for example, Technology A requires only one visit to the doctor while equally effective Technology B requires several visits, A will clearly generate some demand even if it is more expensive. Similarly, some would prefer a more expensive, twice-daily medicine to a cheaper medicine that must be taken four times a day.

Airline travel may provide the best analogy to this point. Although flying tourist class is less expensive but as safe and effective as flying first class, many travelers prefer first class because it is more comfortable and convenient.

52. The provision of insurance by the Federal and state governments, of course, is governed by statutes and not contracts. Governments therefore need not negotiate the limits of coverage with beneficiaries; they can dictate coverage, subject only to statutory language and political pressures. If the Government wished to cut Medicare costs, it *could* transform that program into a multi-tiered system

## B. *Proposal for Private Cost-Containment*

To satisfy different levels of demand for technology, private insurers could segregate technologies according to their degree of wastefulness and offer a series of progressively more expensive insurance options covering progressively more wasteful technologies.<sup>53</sup> Beneficiaries could then select among the various options and, if they chose, voluntarily contract to limit their coverage to certain classes of technologies.<sup>54</sup>

A system of voluntary contractual limits on coverage for technologies would require that technologies first undergo routine technology assessment for safety, efficacy, and cost-effectiveness.<sup>55</sup> Routine technology as-

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in which beneficiaries wishing top-tier coverage paid a premium, but it need not do so. So long as the governing statute allows, the Government could simply ignore the preferences of beneficiaries and exclude all wasteful technologies. *See supra* note 26.

53. There may be several reasons why private insurers have not already adopted plans such as the one proposed here. First, any individual insurer wishing to offer insurance based on distinctions among technologies would be faced with the problem that technology assessment is, with few exceptions, too expensive to be performed without collective efforts. Second, because information, once generated, is very inexpensive, collective technology assessment efforts are impeded by the free-rider problem: There is an incentive for each insurer to wait for another insurer to generate information and then to use it once it becomes public. Third, because insurers must share part of any efficiency gain with beneficiaries to achieve that gain, their incentive to search for efficiency-saving measures is attenuated. Insurers, in other words, would be more likely to search for wasteful technologies if they could exclude them from contracts without then being required to lower the price of the contract to induce beneficiaries to buy the narrower coverage. *See* Hanson & Logue, *The First-Party Insurance Externality: An Economic Justification for Enterprise Liability* 75 CORNELL L. REV. (forthcoming 1990) (manuscript at 24-27; on file with author). Fourth, insurers may simply be unaware of the potential for profit inherent in a multi-tiered system such as the one proposed in this Note. *See infra* note 61.

In addition to the economic disincentives to private technology assessment, insurers have probably been dissuaded from offering multi-tiered insurance by the current legal environment. As noted in Section III, *supra*, this environment is not conducive to limited insurance coverage.

54. The cost-containment proposal offered here is novel in that it focuses specifically on the private contractual control of technology. Other authors have proposed a similar private strategy for controlling malpractice costs. *See, e.g.,* Epstein, *Medical Malpractice, Imperfect Information, and the Contractual Foundation for Medical Services*, 49 LAW & CONTEMP. PROBS. 201 (1986) (patients should be allowed to contractually limit their tort rights in return for lower charges); Havighurst, *Private Reform of Tort-Law Dogma: Market Opportunities and Legal Obstacles*, 49 LAW & CONTEMP. PROBS. 143, 156-72 (1986) (outlining approaches and legal obstacles to such reform); *see also* Havighurst & Hackbarth, *Private Cost Containment*, 300 NEW ENG. J. MED. 1298, 1300-02 (1979) (advocating greater selectivity in benefits as cost-containment mechanism). This Note's proposal is more strongly paternalistic than the private contractual approaches to malpractice. *See infra* note 59.

For proposals to contain technology and health care costs by means of government regulation, as opposed to private initiatives, *see* Cooper & Gaus, *supra* note 15, at 245-50; Mehlman, *supra* note 18, at 838-47. As mentioned, this Note does not address the relative merits of private and public solutions, but simply outlines one solution that relies primarily on the private market. *See supra* text accompanying note 4.

55. *See supra* note 4. "Routine" technology assessment would require that the FDA or another group evaluate the cost-effectiveness of the drugs and devices that the FDA now tests only for safety and efficacy. It would also require a concerted effort by both the Government and the network of private assessors to evaluate fully many of the medical and surgical procedures that are now not evaluated at all. "Routine" technology assessment would not require, however, that all technologies be evaluated. Initially, to maximize savings, technology assessment might focus on those "big ticket" technologies such as cesarean sections and the treatments for breast cancer and myocardial infarctions that appear to be the major stimuli for increasing health care costs. *See* Scitovsky, *Changes in the Costs of Treatment of Selected Illnesses, 1971-1981*, 23 MED. CARE 1345 (1985) (demonstrating that few "big ticket" technologies have substantially greater impact on health care costs than multitude of "little ticket" technologies such as laboratory tests and x-rays). *But see* Moloney & Rogers,

assessment could be performed either by the Government or by private assessors, but ideally would be handled jointly, with one organization coordinating efforts and certifying results.<sup>56</sup>

Once evaluated, technologies could be segregated into two or three classes, and insurance could be arranged accordingly. Basic insurance—a “tourist class” policy—would cover only those technologies demonstrated to be safe, effective, and cost-effective.<sup>57</sup> A second, more expensive, insurance option might cover all those technologies covered by the basic insurance option plus all safe and effective technologies that are *not* cost-effective. A third option, more expensive and broader still, might cover all technologies covered by the second option as well as experimental technologies that have not been formally evaluated.<sup>58</sup>

In such a multi-tiered system of health insurance, the lowest priced option would probably be the most popular because it excludes only wasteful and untested technologies.<sup>59</sup> However, a market for the more expensive

*Medical Technology—A Different View of the Contentious Debate Over Costs*, 301 NEW ENG. J. MED. 1413 (1979) (arguing, prior to Scitovsky, that thousands of small tests and procedures are more inflationary than “big ticket” items).

Technology assessment should certainly not be performed on those technologies where it is estimated that the cost of assessment would outweigh any potential savings. Such technologies should be exempt from the assessment requirement. See generally Smits, *The Clinical Context of Technology Assessment*, 9 J. HEALTH POL., POL'Y & L. 31 (1984) (discussing need for, and suggesting scheme for, prioritizing technology assessments).

56. The insurance reform proposed in this Note would work best if there were one body responsible for classifying technologies as wasteful or non-wasteful. A centralized organization would circumvent the collective action problem that has prevented more substantial technology assessment activities to date, and the Government's imprimatur would lend credibility to the classifications. See *supra* note 21 (discussing proposed National Quality Improvement Initiative); *supra* note 53 (describing obstacles to private technology assessment). Regardless of the identity of the assessor, however, beneficiaries and insurers would need to agree *ex ante* to accept the classifications of the technology assessor for the system to function properly.

57. This option should also include technologies exempted from the technology assessment process because they are not worth testing. See *supra* note 55. Basic insurance would also need to cover any sort of care administered in “emergencies,” that is, in those situations in which time constraints prohibit determination of the limits of a patient's coverage.

58. The third option might cover the cost of either experimental or non-mainstream therapies for which there clearly appears to be some demand. See *supra* notes 37–39 (examples of cases in which experimental or non-mainstream technologies were demanded). This option would probably be very expensive because the demand for such coverage would stem only from those who want coverage for “one-in-a-million” cures, and the financial risk would be difficult for insurers to estimate.

59. As noted, basic insurance would cover every technology proven to be safe and effective, no matter how complex or expensive, in the absence of a less expensive and *equally effective* alternative. It would exclude only technologies demonstrated to be wasteful and untested or experimental technologies. Thus, even if beneficiaries have imperfect information or evaluate risk poorly and mistakenly choose the basic package rather than one of the more expensive ones, they would be covered adequately.

An insurance system that allows beneficiaries to opt out of coverage for *non-wasteful* technologies could also be designed. Such a system would be based on the idea that some beneficiaries would prefer not to have access to some costly but effective technologies (or would prefer to bet that they would never need those technologies) in return for a lower premium. A beneficiary, for example, might decide that she would never want neurosurgery, or at least would prefer to bet that she would never need that technology, in return for a lower insurance premium.

A system allowing beneficiaries to opt out of *nonwasteful* technologies would engender at least two major problems. First, imperfect information or the inability to evaluate risk accurately might lead a beneficiary to opt out of coverage that she later needs. This is especially problematic because many

packages would be maintained by individuals wishing to preserve access to either cost-ineffective or untested technologies.

A system providing beneficiaries some choice over the classes of technology they want covered would have numerous advantages over the current system. Access to insurance would be enhanced because basic insurance would be less expensive than the insurance that is currently marketed and would be affordable to some of those who are currently uninsured.<sup>60</sup> System-wide cost reductions would result because cost-ineffective technologies would be excluded from some policies and because the existence of a market limited to cost-effective technologies would encourage the development of such technologies.<sup>61</sup> Efficiency would increase because beneficiaries would not be forced to choose between overinsuring and foregoing insurance altogether.<sup>62</sup>

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consumers of medical care are very young, elderly, or incompetent. Second, enormously troubling ethical dilemmas would arise when patients who opted out of coverage for certain useful technologies nonetheless became ill. See G. CALABRESI & P. BOBBITT, TRAGIC CHOICES 121 (1978) (envisioning desperate man who failed to insure adequately lashing himself to lamppost in front of hospital with chest placard stating, "Give me another chance"); Atiyah, *Medical Malpractice and the Contract/Tort Boundary*, 49 LAW & CONTEMP. PROBS. 287, 295-98 (1986) (raising these issues in context of private malpractice reform).

The insurance system proposed by this Note does not engender either of these problems except to the extent that beneficiaries with basic coverage would not have access to experimental technologies. These problems would generally be avoided because, in Calabresi and Bobbitt's terms, while the choice between additional discretionary money and nonwasteful health care is a "tragic" one, no tragedy is inherent in the choice between additional discretionary money and wasteful health care. See G. CALABRESI & P. BOBBITT, *supra*.

Although this analysis suggests that individuals should not be allowed to opt out of coverage for non-wasteful technologies even where the benefits are small in proportion to the costs, it does not suggest that governments should be precluded from excluding such technologies from coverage. Governments with limited resources should allocate those resources as efficiently as possible and should consider not covering technologies whose costs far outweigh their benefits.

60. The extent to which access would be enhanced would depend upon the extent to which the price of insurance could be decreased. It is beyond the scope of this Note to estimate either figure.

61. Although technology assessment and more selective insurance coverage could potentially cut enormous sums from the overall health care bill, *supra* note 4, it is not clear whether the multi-tiered insurance system envisioned by this Note would be profitable for *insurers*. However, it is quite possible that it would be.

In general, insurers can increase profits by segregating insureds into risk pools and charging lower premiums to those at lower risk. By doing so, insurers can sell insurance to low-risk individuals who otherwise would not have bought insurance because the price was too high relative to their risk. As sales increase, so do profits. See generally Abraham, *Efficiency and Fairness in Insurance Risk Classification*, 71 VA. L. REV. 403, 407-08 (1985) (describing how risk classification allows insurers to capture protection dollars). The new beneficiaries would be "low-risk" not because they would be any less likely, on average, to make claims than current beneficiaries, but rather because the value of the claims they could make would be lower, on average, than the value of claims that could be made by beneficiaries with coverage for wasteful technologies.

Overall profitability would be determined not only by the profits that would result from greater risk-segregation but also by the costs that insurers would incur in assessing technologies and administering the more complex system. Because an estimate of both the profits and the costs of the proposed system are beyond the scope of this Note, this Note cannot state with certainty whether insurers would profit from the proposed system.

62. In addition to these advantages, a joint public/private effort to assess technologies would have spillover effects in that the information generated would be available to governments as well as to private insurers, and thus could be used in the Medicare and Medicaid coverage determination processes. See *supra* note 26.

Finally, and perhaps most significantly, the increased access, lower costs, and gains in efficiency might be achieved without a decrease in the quality of health care available to those who select the lowest-priced option. Indeed, consumers buying the lowest-priced option might receive better care than they do under current insurance contracts because all technologies would be *proven* safe and effective.<sup>63</sup>

An insurance scheme based on technology assessment and offering a range of options covering different classes of technology would also engender certain social and financial costs. Social costs would result from the inequalitarian nature of the system,<sup>64</sup> from the chilling effect on the development of new technologies,<sup>65</sup> and from decreased professional autonomy for physicians.<sup>66</sup> The financial costs would include the cost of performing technology assessment<sup>67</sup> and the costs of administering the system.<sup>68</sup> Some of these costs might be mitigated,<sup>69</sup> but even if they could not be, they would likely be outweighed by the benefits of the proposed system.

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63. Consumers would therefore not be exposed to the potential dangers of untested technologies, particularly untested medical and surgical procedures. *See supra* note 27 and accompanying text.

64. It is likely that the proposed system would lead to differential access to technology based on differences in wealth. Although the various levels of coverage would be offered as options, the less expensive option would probably be more attractive to poorer people and the more expensive options would likely be bought by wealthier people. Because those who opt for the lowest-priced option would have fewer technologies available to them, the system would be inequalitarian. This system, however, would be more egalitarian than the existing system in which so many have no insurance.

Closely related to this cost is the cost of making explicit the fact that access to health care in the United States is a function of wealth. Even though access to care is now largely a function of wealth, the fact that currently marketed insurance is not *explicitly* inequalitarian masks some of the system's inequities. Some of these inequities would be unmasked by an insurance system explicitly offering different levels of insurance at different prices. In Calabresi and Bobbitt's terms, this is the cost of being honest rather than engaging in subterfuge. *See G. CALABRESI & P. BOBBITT, supra* note 59, at 23-26. This cost could be mitigated by emphasizing that some health insurance is better than none.

65. The proposed system might have a chilling effect on the development of new technologies because of the requirement that all technologies be found non-wasteful prior to coverage. Such a requirement could create some overall disincentive to invest in initial research and would also lengthen the lag time between initiation of research and approval of coverage. The proposal might also decrease the availability of those technologies that offer only minimal comfort or convenience because the benefits of such technologies may be unmeasurable.

66. Physicians would lose autonomy to the extent that insurers gain a heightened role in determining what medical technologies can be used.

67. Presumably, however, the benefits of technology assessment would outweigh the costs. *See supra* note 55 (technology assessment should not be performed where it is estimated that the costs of assessment would outweigh any potential savings); *see also* Detsky, *Are Clinical Trials a Cost-effective Investment?*, 262 J. A.M.A. 1795 (1989) (finding clinical trials cost-effective).

68. The proposed system might increase administrative costs because of the need to explain the various policy options to beneficiaries and because patients or providers of care would be obligated to keep track of which technologies are covered by each patient's insurance. However, substantial new bureaucracies would not be required to perform either of these tasks. As discussed, *supra* note 10, most private insurance is provided as a benefit of employment, and employers generally already offer and explain a variety of health plans to their employees. Moreover, providers of care must currently seek approval from insurers for many types of care. *See supra* note 30.

69. Procedures could be designed, for example, to expedite approval of "breakthrough" technologies. Such procedures could be modeled on the procedures recently adopted by the FDA for expedited marketing of lifesaving drugs such as those for the treatment of AIDS prior to full testing for safety and efficacy. *See* 21 C.F.R. §§ 312.80-312.88 (1989).



## V. IMPLEMENTING PRIVATE COST-CONTAINMENT

For a multi-tiered private insurance system to function as envisioned, not only would there need to be better coordination of technology assessment, but the courts would need to cease favoring coverage for wasteful technologies.<sup>70</sup> If informed beneficiaries agree to contract to certain coverage limitations, courts should not disregard those limitations.

To protect such a system, courts would need to abandon the presumption that all health insurance contracts are adhesive.<sup>71</sup> Instead, they would have to recognize that some coverage limitations, such as the ones envisioned in this Note, are selected voluntarily and with adequate information by beneficiaries *ex ante*.

Interpreting insurance contracts as mutual contracts rather than as contracts of adhesion would by no means require that courts abandon their equitable responsibilities. It would require, however, that they refuse to honor unreasonable expectations and refuse to find advantages where none exist. It would require, in short, the curtailment of judge-made insurance.<sup>72</sup>

Specifically, courts would need to accept the conclusions of the technology assessor specified in each contract regarding the safety, efficacy, and cost-effectiveness of each technology.<sup>73</sup> Courts would not be free to second guess these conclusions in light of evidence, for example, that the beneficiary herself improved from a technology classified as ineffective.<sup>74</sup>

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70. Section V argues that the legal rules governing the interpretation of insurance contracts would need to be altered for the system proposed in this Note to survive. In addition, the legal rules governing medical malpractice might also need to change.

Physicians are currently held to the same standard of care for all patients; economic constraints do not legally justify care that does not meet the community's standards. Patients are free to refuse care, however, and doctors are not liable for harms that result from informed refusals. Under the system proposed here, physicians would continue to recommend treatment in much the same manner that they do now, but more patients would be forced to decline therapy because of restrictive insurance coverage. Theoretically, harms would be no more likely than under the current system (because only wasteful technologies would be excluded), and if a harm occurred, existing malpractice law would adequately protect physicians who fully inform their patients. Reality does not always follow theory, however, and if doctors are held liable for harms that befall patients consequent to informed rejections of therapy, the rules governing liability would need to be clarified to delineate the relative responsibilities of patients, doctors, and insurers under the new legal regime. *See generally* Morreim, *Cost Containment and the Standard of Medical Care*, 75 CALIF. L. REV. 1719, 1757-63 (1987) (physicians under economic constraints should be allowed to rebut presumption that they owe all patients same standard of care).

71. The California Supreme Court has already abandoned this presumption, holding that an insurance contract which was negotiated by the beneficiary's union representative, and which was one of several options offered to the beneficiary, was not a contract of adhesion and therefore should be interpreted as a mutual contract. *Madden v. Kaiser Found. Hosps.*, 17 Cal. 3d 699, 552 P.2d 1178, 131 Cal. Rptr. 882 (1976).

72. *See supra* text accompanying notes 44-47.

73. Such deference would be consistent with the well-established administrative law principle that courts should be deferential to the judgments of administrative bodies making technical or scientific judgments. *See generally* J. MASHAW & R. MERRILL, *ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM* 374-85 (2d ed. 1985) (discussing varying degrees of judicial deference in cases involving complex, technical issues).

74. In other words, courts would need to rely on formal technology assessment which minimizes

Moreover, courts would need to abandon the rule that all ambiguities be interpreted against the insurer. They would instead need to strive to interpret contracts in light of the reasonable expectations of the parties *ex ante*. In so doing, they would need to assume that a reasonable person would not want coverage for most wasteful technologies.<sup>75</sup>

If courts did not voluntarily alter the way in which they interpreted insurance contracts, legislation might be required. Legislation might establish, for example, a rebuttable presumption that insurance contracts of the type envisioned here are mutual contracts rather than contracts of adhesion. Such a presumption would permit the development of the proposed insurance system but would preserve for courts their traditional equitable powers where there has been a substantial abuse of bargaining power by the insurer.<sup>76</sup>

## VI. CONCLUSION

The language of most health insurance contracts is overly broad and covers many wasteful technologies. Coverage of such technologies raises the price of health insurance and leads to inadequate access to health care and inefficient spending by individuals. The current legal rules exacerbate these problems.

An insurance system that allows individuals to exclude wasteful and untested technologies from their coverage in return for lower premiums would represent an improvement over the existing system. For such a system to be successful, the legal rules that govern courts' interpretation of insurance contracts would need to be changed—perhaps by legislation—to discourage unprincipled judicial expansion of coverage.

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the influence of coincidence or the placebo effect. *See supra* note 40.

75. Courts seeking to limit coverage to those technologies proven to be safe and effective and seeking to honor only reasonable expectations could rely upon two lines of precedent. First, several courts have already recognized the problems inherent in providing coverage for unproven technologies. *E.g.*, *Shumake v. Travelers Ins. Co.*, 147 Mich. App. 600, 383 N.W.2d 259, 263-64 (1985) ("rubber stamp approach to a physician's unfettered exercise of discretion could result in coverage for inane treatments"), *appeal denied*, 425 Mich. 859 (1986); *Zuckerberg v. Blue Cross and Blue Shield*, 67 N.Y.2d 688, 490 N.E.2d 839, 499 N.Y.S.2d 920 (1986) (overturning decision extending coverage for holistic cancer therapy because it did not meet contractual definition of medical, surgical, or obstetrical care).

Second, several courts, including the Supreme Court, have narrowly interpreted the meaning of "safe and effective" in statutory contexts. *E.g.*, *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (Food, Drug, and Cosmetic Act requires "general recognition among experts, founded on substantial evidence" that drug produces claimed results before it can be considered effective, and that "the expected therapeutic gain [must] justify the risk entailed" by use of drug before it can be considered safe); *United States v. Articles of Food and Drug Coli-Trol 80 Medicated*, 372 F. Supp. 915, 921 (N.D. Ga. 1974) ("what is required [by Food, Drug, and Cosmetic Act for proof of safety and efficacy] is more than belief, even by an expert; it is a general recognition based on substantial scientific evidence"), *aff'd*, 518 F.2d 743 (5th Cir. 1975).

76. There are numerous examples of legislative modification of the common law of contracts. The most familiar example is the Uniform Commercial Code, which has been adopted by all states except Louisiana. *J. CALAMARI & J. PERILLO, THE LAW OF CONTRACTS* 15 (3d ed. 1987).