

1986

### Commentary: Health Care Cost Containment and Technology Assessment

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#### Recommended Citation

Seymour Perry and Flora Chu, *Commentary: Health Care Cost Containment and Technology Assessment*, 36 Case W. Rsrv. L. Rev. 884 (1986)

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# COMMENTARY: HEALTH CARE COST CONTAINMENT AND TECHNOLOGY ASSESSMENT

*Seymour Perry\* & Flora Chu\*\**

## INTRODUCTION

**N**EW FORCES IN the delivery and financing of health care, namely the pressures of cost containment and market competition, have led to an increasing demand for rational, formalized mechanisms to assess new and existing technologies. Professor Mehlman has set out to address comprehensively the question of how to determine which technologies are wasteful, and how to translate these findings into cost savings. He explores the scope of technology-assessment activity, the observed and potential impacts of such activity on the acquisition of technology, and its use by regulatory bodies in an effort to control costs. He identifies and describes the important parties responsible for technology-assessment activities and delineates the inherent problems in performing assessments, emphasizing two dilemmas: the problem of perspective and of determining the value of intangible benefits. He details the legal precedents and implications of a cost-conscious approach to the diffusion of technologies, particularly in the unique fiduciary relationship between the provider and the patient.

In a field spanning various disciplines and encompassing the interests and well-being of many different parties, Professor Mehlman has very capably grasped the essential issues which continue to complicate technology-assessment efforts. The author outlines the many incentives and disincentives in the current medical-legal climate to adopt costly, beneficial technologies, and concludes that it is yet uncertain which pressures will prevail. He demonstrates a comprehensive grasp of the structure and workings of the Prospective Payment System (PPS), instituted three years ago in an effort to control costs in the Medicare hospital program.

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In his conclusion, Professor Mehlman proposes an approach to technology assessment which emphasizes patients' interests and focuses on the safety, effectiveness, and cost-effectiveness of technologies. In this Commentary, we would like to address a few of the issues identified by Professor Mehlman in his discussion, providing some elaboration and perhaps complementing his views with our own perspectives.

## I. THE CONTEXT: THE ROLE OF PUBLIC PERCEPTION AND TECHNOLOGY

### A. *Public Opinion On Health Care Cost Containment*

There is virtual universal agreement that health care costs must be brought under control, and this conviction has constituted the basis for the cascade of recent cost-containment initiatives. Nevertheless, it is interesting to note that public opinion has not clearly evidenced a rise in concern to a level justifying revolutionary reforms. Although public opinion surveys have repeatedly indicated that the public regards rising costs as the most important problem in health care today, they also reveal that the public does not wish to significantly change their own arrangements for care.<sup>1</sup> Even with the spectre of the federal deficit looming large, two out of three Americans think that federal health care expenditures should be increased. Only twenty-one percent wish to limit the use of new, costly technologies, but seventy-four percent do support the regionalization of very expensive equipment.

Health care cost-control measures should take into account the public's opinion, high expectations, and valuation of health care services in order to maintain public trust and confidence.<sup>2</sup> Thus, as Professor Mehlman has highlighted in his article, the assessment of technologies, within the system of checks and balances, should be based in large part on patient-centered values, and the patient should have reasonable opportunities for appeal and review if a technology is denied or not covered. In particular, Professor Mehlman has suggested that the public is entitled to three things: clarification of the extent of Medicare coverage for technology, adequate public recourse to appeal, and assurance that quality standards will be enforced.

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1. See Blendon & Altman, *Special Report: Public Attitudes About Health-Care Costs: A Lesson in National Schizophrenia*, 311 NEW ENG. J. MED. 613 (1984).

2. *Id.* at 614.

### B. *Factors Contributing to the Technological Imperative*

Professor Mehlman describes the "technological imperative" as a phenomenon leading to the inappropriate and excessive development, acquisition, and use of technology. In addition to the cited contributing factors, such as the cost-based reimbursement method, lack of adequate incentive to abandon a new technology, and increasing specialization in medicine, public and media demands also significantly contribute toward feeding the "technological imperative." The American public is quite sophisticated and aware of up-to-date technologies and promising therapeutic breakthroughs, often demanding the use of these resources for reassurance or in support of the conventional array of physician expertise and clinical tools. Some doctors have noted that the use of an electroencephalogram is not always needed in the diagnosis of brain death but is useful in reassuring relatives of the certainty of death.<sup>3</sup> Many patients welcome the intervention of so-called high technology and place great value on its potential benefits, even if only for assurance that disease is absent or has not progressed.

The media has also played a significant role in whetting the public appetite for newer and better technologies. Both print and electronic news media have increasingly focused attention on health care issues, responding to reports of new advances in therapies quickly and, at times, in an almost sensationalistic manner. The recent publicity surrounding the reports of interferon trials with cancer patients unleashed a flood of inquiries from patients seeking treatment. Unfortunately, as exemplified by this case, the media focused more on the potential benefits and advances than on the stark appraisal of its risks and limitations. Dramatic stories about doctors and hospitals often highlight the latest in life-saving technologies and may be quite influential in shaping public attitudes.<sup>4</sup> In the medical literature as well, studies demonstrating the positive results of a technology's effectiveness appear to be chosen for publication more often than studies showing no changes or benefits—so-called "negative" studies. Consequently, expectations and demands for medical technology can be heightened by these influences.

In addition, cost-based reimbursement has encouraged the use of technologies, as noted by Professor Mehlman. It also has provided no incentives to adopt simpler or cost-saving technologies.

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3. See Jennett, *High Technology Medicine: How Defined and How Regarded*, 63 MILBANK MEMORIAL FUND Q. 141, 159 (1985).

4. See *id.* at 153.

As it stands now, third-party reimbursement mechanisms provide more generous remuneration for the use of medical and surgical technologies than for the use of physician services, such as completing a complicated physical diagnosis, eliciting a thorough patient history, or educating or counseling a patient. For example, an internist could triple his net income just by increasing the use of such technologies as blood tests, electrocardiograms, and sigmoidoscopies, which are usually not time-intensive services.<sup>5</sup> All these attitudes towards technology have contributed to the "technological imperative."

### C. *The Contribution of Technologies to Rising Health Care Costs*

Professor Mehlman names expensive or "big-ticket" items as attracting the blame for rising costs. Indeed, the readily recognizable, high-priced technologies have been assumed to be one of the major culprits behind rising hospital costs. It may be useful to attempt to describe in more detail the factors contributing to rising costs. In turn, the definition of these factors may be helpful in choosing which technologies may be more fruitfully targeted for assessment and cost-control efforts.

The Office of Technology Assessment (OTA) found that thirty percent of the growth in costs for each Medicare enrollee was due to both increased services as well as increases in costs for these services above general inflation.<sup>6</sup> The increase in services per enrollee could be attributed to a number of factors, also alluded to by Professor Mehlman, including the introduction of new technologies, the role of defensive medicine in escalating the use of technologies, the greater use of either "little-ticket" or "big-ticket" items, and the increased use of intensive treatments for critically ill patients.<sup>7</sup> One recent study found that "big-ticket" imaging technologies, such as CT scans, generally substituted for older, invasive methods, while "little-ticket" laboratory procedures did not account for a substantial portion of the increase in costs. The addition of more intensive treatments, such as surgery for patients with heart attacks, and critical care treatment for babies with respiratory distress syndrome,

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5. See Schroeder & Showstack, *Financial Incentives to Perform Medical Procedures and Laboratory Tests: Illustrative Models of Office Practice*, 16 MED. CARE 289, 297 (1978).

6. See OFFICE OF TECHNOLOGY ASSESSMENT REPORT, *Health Care Costs and Access to Technology for Older Persons*, in TECHNOLOGY AND AGING IN AMERICA 254 (1984).

7. See Showstack, Stone & Schroeder, *The Role of Changing Clinical Practices in the Rising Costs of Hospital Care*, 313 NEW ENG. J. MED. 1201 (1985).

were also responsible for much of the rise in costs.<sup>8</sup> It is interesting to note that a study of the use and costs of Medicare services found that a total of twenty-eight percent of all Medicare payments was spent for the last year of life, almost half spent in the last sixty days.<sup>9</sup>

## II. DEFINITION OF WASTEFUL TECHNOLOGIES AND WASTEFUL USES OF TECHNOLOGY

The main thrust of Professor Mehlman's presentation is that the identification and elimination of wasteful technologies, or wasteful uses of technologies, can both help curb health care costs and enhance quality of care. We would definitely agree with this premise, and we think that the analytical tools of technology assessment are well suited for identification of waste. We would also add that technologies which are clearly recognizable as unsafe or ineffective are more readily discarded or used sparingly by physicians. The more recalcitrant but frequently occurring situation arises when a technology appears safe and effective, but there is insufficient knowledge about the proportion and characteristics of the patient population for which it can be successfully applied. Without a sufficient foundation, the technology is then applied on a routine basis rather than selectively.

This spread in the use of technologies to less effective uses has been labeled "technology creep."<sup>10</sup> Some examples studied include the routine admission chest X-ray<sup>11</sup> and the routine admission electrocardiogram,<sup>12</sup> with results indicating a low yield in terms of new information in the majority of hospitalized patients. Benefits from treating mildly hypertensive patients with drugs have been shown to be important but uncertain or infrequent, and the routine use of such therapy would add considerably to health care costs.<sup>13</sup> In these situations, however, physicians may feel more secure and productive by extending the use of therapies known to be effective in

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8. See *Id.* at 1206.

9. See Lubitz & Prihoda, *The Use and Costs of Medicare Services in the Last 2 Years of Life*, 5 HEALTH CARE FIN. REV., Spr. 1984, at 117, 129.

10. See Fineberg, *Technology Assessment: Motivation, Capability, and Future Directions*, 23 MED. CARE 663, 666 (May 1985).

11. See Hubbell, Greenfield, Tyler, Chetty & Wyle, *The Impact of Routine Admission Chest X-Ray Films on Patient Care*, 312 NEW ENG. J. MED. 209 (1985).

12. See Moorman, Hlatky, Eddy, Wagner & Duke Medical House Staff, *The Yield of the Routine Admission Electrocardiogram*, 103 ANNALS INTERNAL MED., Oct. 1985, at 590.

13. See Freis, *Should Mild Hypertension be Treated?*, 307 NEW ENG. J. MED. 306 (1982).

selected patients to more generalized populations, especially when the risks appear to be absent or minimal.

Professor Mehlman describes an ineffective technology as one that produces no discernible benefit to the patient or no positive change in a patient's condition. In preventive medicine, of course, it is the absence of disease or of deterioration in well-being which is the measure of success and effectiveness. A benefit may not be "discernible" to the individual patient, yet be an important contribution to improvement of health. One example is the polio vaccine, which can very effectively prevent disease and disability. But in the United States, a nonimmunized individual generally faces little risk of exposure to the wild viral agent, and has only a very small chance of developing the illness through immunization. Thus, healthy individuals may elect not to be immunized, since future benefits to the individual appear uncertain, even though it is a highly effective strategy to prevent epidemics of this paralytic disease in a susceptible society at large.

### III. DEFINITION OF TECHNOLOGY ASSESSMENT

OTA's definition, which Professor Mehlman adopts, of technology assessment as "a comprehensive form of policy research that examines the technical, economic, and social consequences of technological applications" does not appear to fully address the breadth of operations and objectives of technology assessment. Another definition which was used by the National Center for Health Care Technology (NCHCT) described technology assessment as

a form of research, analysis and evaluation that attempts to examine the various impacts of a particular technology on the individual and society in terms of the technology's safety, efficacy, effectiveness, and cost-effectiveness, and its social, economic, and ethical implications, and to identify those areas requiring further research, demonstrations and evaluations.<sup>14</sup>

Technology assessment encompasses many diverse activities across multiple disciplines of study in a common goal: to provide the highest quality of care possible with optimal use of available resources. It appears that this important objective may be overlooked in the sometimes overriding impetus for cost containment.

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14. Perry, *Efforts in Health Care Technology Assessment in the United States*, in PROCEEDINGS OF A JOINT SYMPOSIUM ON ASSESSMENT OF BIOMEDICAL TECHNOLOGY IN THE HEALTH CARE FIELD: INTERNATIONAL PERSPECTIVES IN METHODOLOGY 100 (1981) (published by the National Center for Health Care Technology, Public Health Service, Department of Health and Human Services).

Clearly, it will be a useful analytical method to target wasteful technologies. But in addition, technology assessment can aid in fostering innovations that enhance quality of care, but that may not be diffusing appropriately under traditional forces because of low visibility or less prominent proponents. Thus, the identification of both wasteful and useful technologies serves to promote cost-effective, quality patient care.

#### *A. Priority System for Technology Assessment*

Professor Mehlman remarks that no widespread system to prescribe priorities for assessing technologies is likely to be feasible. However, it would seem that mutually agreed-upon criteria can be selected. Among the criteria outlined in the article are potential benefits, probability of risks, size of the salient patient population, and the economic impact. Additional criteria may include a threshold level of available evidence for safety and efficacy, thus eliminating from full consideration emerging technologies for which benefits and risks are yet undetermined; presence of important ethical or legal issues; and the likelihood that the diffusion pattern may be distorted by economic or regulatory forces. A relative-value scale could be devised to rank technologies into at least three categories: low-priority, candidate, or high-priority topics.

#### *B. Timing of Assessment Activities*

In terms of the timing of technology assessment in relation to the life cycle of technologies, Professor Mehlman points out the merits and drawbacks of assessing emerging technologies. He notes that although findings may prevent the entrenchment of nonefficacious therapies, the risks, costs, and benefits may change rapidly over time, outdating evaluation results quickly. Nevertheless, early assessment may be useful to identify preliminary impressions of the projected impact on quality of care, to note any troublesome ethical or safety issues, and to make responsible parties aware of these emerging technologies.

Certainly, in the clinical experimentation phase and early diffusion phase, the results of technology-assessment efforts can be quite helpful in determining appropriate practice patterns. Even when a technology has been widely disseminated, findings of a rigorous evaluation coupled with a broad-based effort to alert and inform providers can promote optimal allocation of health care resources.

In addition, the need for technology assessment may vary be-



cause of changes in the alternative choices of therapy, changes in the techniques or applications of an existing technology, or even changes in the character of the disease.<sup>15</sup> For example, with the advent of newer and more efficacious medical treatment of coronary artery disease, the role of coronary artery bypass surgery may need to be reexamined.

### C. *Costs of Technology Assessment*

Professor Mehlman observes that formal technology assessment is extremely costly, with clinical trials running into millions of dollars. In some cases, the costs of assessment exceed the maximum costs of the technology itself. It seems that technologies could be ranked in terms of the size of the affected patient population and overall costs, so as to eliminate these technologies from assessment consideration. Alternatively, smaller-scale assessment procedures could be designed.

Although it may be expensive to undertake full-scale technology-assessment activities, it is estimated that total United States funding for technology assessment in 1984, including industry-sponsored clinical trials, was only \$1.3 billion.<sup>16</sup> Of this total, the major public sector, professional, and third-party payor organizations responsible for technology assessment had an aggregate budget of \$28 million. Compared to the level of total health expenditures of \$424 billion in 1985,<sup>17</sup> and an estimated \$77.7 billion for administrative costs alone,<sup>18</sup> this represents a relatively small amount. In 1985, the Institute of Medicine called for an immediate increase of \$30 million for technology-assessment activities.<sup>19</sup> This would not mean that fewer dollars would be allocated to basic research. Rather, technology assessment research would complement and augment the use of basic research findings.

## IV. MAJOR ENTITIES INVOLVED IN TECHNOLOGY ASSESSMENT

Professor Mehlman describes the major parties at the forefront of formal technology-assessment activities. Of course, as stated in his article, the medical profession has always been involved in infor-

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15. See Fineberg, *supra* note 10, at 669.

16. See INST. OF MED., *ASSESSING MEDICAL TECHNOLOGIES* (1985).

17. See Francis, *U.S. Industrial Outlook 1986 Health and Medical Services*; 3 MED. BENEFITS—THE MEDICAL ECONOMIC DIGEST 6 (Feb. 1986).

18. See Himmelstein & Woolhandler, *Cost Without Benefit: Administrative Waste in U.S. Health Care*, 314 NEW ENG. J. MED. 441, 442-43 (1986).

19. See INST. OF MED., *supra* note 16.

mal technology assessments in the past and will continue to be so involved in the future. These evaluations are based on reviews of the literature, results of clinical trials, case reports, anecdotal experience, information gained at professional meetings, exchanges among peers, and standards for appropriate use developed by various specialty societies. But such evaluations, diverse in nature and of varying scientific validity, do not always provide a coherent picture of a given technology.

Recently, the ever-expanding armamentarium of drugs, devices, medical and surgical procedures, as well as the recognition of the need to control costs and evaluate the broader social implications of technology use, has led to the initiation of formal technology-assessment programs. Synthesizing all the necessary data, analyses, and viewpoints would be overwhelming for an individual physician or policymaker. Thus, one of the functions of technology-assessment activities should be to provide useful, objective information for clinical and public policy decisionmaking responsibilities.

#### A. *FDA Approval of Drugs and Medical Devices*

The Food and Drug Administration (FDA) is the agency responsible for approving the safety and efficacy of new drugs and devices. However, there are important distinctions between the approval process for drugs and for devices. All devices on the market prior to the enactment of the Medical Device Amendments, as well as those appearing later which were substantially equivalent to those pre-1976 devices, were exempted from pre-market approval. For example, the CT scanner was introduced prior to 1976 and was automatically given marketing approval. Only Class III devices, generally considered to be life-supporting or with potentially significant risks for patient injury, must undergo pre-market approval. Recently, the Medical Device Reporting Rule has been implemented, and the Medicare pacemaker registry was expected to be initiated in late 1986.

Amendments to the Food and Drug Act, enacted in 1962, require both pre-market approval and evidence of safety and effectiveness through controlled clinical trials in the case of a new drug application (NDA). As noted above, not all new devices require pre-market approval. In contrast, most new drugs require an NDA. The Orphan Drug Act provides incentives for developing drugs for rare diseases, facilitating the use of investigational drugs in these cases. A "me-too" drug—a new version of a drug that has been previously marketed by another company—can be FDA-ap-

proved with a shorter application and evidence of published studies documenting safety and efficacy.<sup>20</sup> No such procedures exist for medical devices.

The FDA weighs the potential benefits of a drug against its risks, and will accept greater risks if the drug represents a significant advance in treatment. The reporting system for drugs in post-market surveillance was established in 1969, and consists of a data base of adverse reactions submitted by health professionals, and also by manufacturers who are mandated by law to report such incidents to the FDA.

The FDA allows a physician to use an unapproved device or product in two defined circumstances, aside from the exemptions given for use in clinical research (called "investigational new drug exemptions" or "INDs" and "investigational device exemptions" or "IDEs").<sup>21</sup> The first situation arises when a patient has not responded satisfactorily to available therapies, in which case a treatment IND or IDE (or so-called compassionate IND or IDE) may be administered. The second circumstance involves the emergency use of an unapproved product in a life-threatening situation if other therapies are not available. One example of an FDA determination of an appropriate emergency use was the use of an artificial "Phoenix heart" implant in Arizona in March 1985; the device had never been approved for investigational use.<sup>22</sup> The Jarvik-7 heart, the only artificial heart approved by the FDA for investigational use at that point, was not available. It is also worthy to note parenthetically that the FDA pre-market approval process may not even strictly limit access to a device in the investigational phases. Prior to pre-marketing approval, over forty-three Magnetic Resonance Imaging (MRI) devices were installed.<sup>23</sup>

### B. *ProPAC's Role in Technology Assessment*

We would particularly like to expand on Professor Mehlman's discussion of the role of the Prospective Payment Assessment Commission (ProPAC). He notes that ProPAC has not yet exercised its mandate to commission technology assessments. Actually, the

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20. See Pines, *A Primer On New Drug Developments*, in FDA CONSUMER, DHHS (HEW) Pub. No. 81-3021 (rev. ed. July 1981).

21. See Flannery, *Should it be Easier or Harder to Use Unapproved Drugs and Devices?*, 16 HASTINGS CENTER REP., Feb. 1986, at 17.

22. See *id.* at 17-18.

23. See Steinberg, Sisk & Locke, *X-Ray CT and Magnetic Resonance Imagers: Diffusion Patterns and Policy Issues*, 313 NEW ENG. J. MED. 859, 863 (1985).

Commission serves purely in an advisory capacity to the legislative and executive branches of the government on the Prospective Payment System. Its two primary responsibilities are to recommend each year appropriate update factors (the percentage change for inpatient Medicare payments) and necessary changes in DRGs.<sup>24</sup> Its commitment to technology assessment was described as: limited technology assessments and evaluation based on existing information on safety and effectiveness and more extensive analysis of data related to the costs and cost-effectiveness of technologies, focusing on issues of DRG classification and payment amounts. It was not anticipated that ProPAC would ever recommend coverage of a particular technology, but rather it would react to an announcement of coverage, or begin an analysis if a coverage decision was imminent.<sup>25</sup>

In addition, it appears that ProPAC's recommendations are not always approved by the Secretary of the Department of Health and Human Services. For example, ProPAC strongly recommended an adjustment in 1986 for payments to hospitals serving a disproportionate share of low-income patients, but this advice was not accepted by the Secretary. ProPAC also recommended a 1.5% increase in prospective payments for the current year, but the Secretary ruled that PPS rates for inpatient hospital services be frozen for 1986.<sup>26</sup>

## V. PROBLEMS IN TECHNOLOGY ASSESSMENT

### A. *Diagnostic Technologies*

Professor Mehlman discusses the inherent problems associated with assessing specific technologies. He notes that diagnostic technologies are difficult to assess because of both the uncertain and often undetermined links with a therapeutic outcome and the application of a single technology for many different purposes. This heterogeneity of use and results of diagnostic technologies does account for the lack of a single value which indicates the "worth" of

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24. See Prospective Payment Assessment Commission, Report and Recommendations to the Secretary, U.S. Department of Health and Human Services, Apr. 1, 1985, 50 Fed. Reg. 24,456-24,457 (1985).

25. See *The Prospective Payment Assessment Commission's Role in Technology Assessment*, staff paper presented at the ProPAC meeting, Washington, D.C. (July 17-18, 1985).

26. See 1986 ADJUSTMENTS TO THE MEDICARE PROSPECTIVE PAYMENT SYSTEM, REPORT TO THE CONGRESS 1-3 (1985).

many of these technologies.<sup>27</sup> However, there are several ways to measure the usefulness of these diagnostic methods. Each method's efficacy can be measured in terms of detecting a specific disease or condition by asking the question of how well it can predict the absence or presence of a disease.

Another inquiry may be its relative efficacy compared to other available methods—how much additional information does this method provide towards establishing the diagnosis? For example, although CT scanning is the diagnostic method of choice for most diseases of the central nervous system, its value in evaluating occasional headaches is probably minimal when other diagnostic procedures would reveal sufficient information with which to form the diagnosis.<sup>28</sup> Another issue concerns the value of a diagnostic test result in influencing the decision to treat or to modify treatment. Probably the most difficult task is to assess its value in contributing to a patient outcome. For example, even with the benefits of earlier and more precise diagnoses with CT scanning, patients with pancreatic cancer and brain tumors have not evidenced significant increases in five-year survival.<sup>29</sup> On the other hand, major therapeutic breakthroughs may depend on prior evidence provided by diagnostic studies which characterize the nature and progression of the disease.

Another complication arises in determining the costs of the introduction of new diagnostic techniques. As Professor Mehlman describes, there is a tendency for these new technologies to “add on” to older, more established techniques, rather than to fully substitute for older methods. In these cases, only a marginal amount of new information is gained, which may not significantly improve the precision of diagnosis. This tendency to employ a new technology as an “add on” may be attributed to the providers’ promotion of the technology, efforts to refine diagnostic accuracy in comparison with a proven method, and desires to define the anatomical regions or disease categories for effective application. However, perhaps the most important reason may be that the physician is more comfortable with, and has more confidence in, the older technology which he or she has used for a longer period of time.

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27. See Schroeder, *Medical Technology and Academic Medicine: The Doctor-Producers' Dilemma*, 56 J. MED. EDUC. 634, 637 (Aug. 1981).

28. See *Diagnostic Imaging Medical Necessity Guidelines Discourage Routine Ultrasound*, MED. DEVICE & DEVICE INSTRUMENTATION REP. I&W 1 (June 1984).

29. See Abrams, *The Golden Era of Radiology: Is There Enough Gold?*, 141 AM. J. RADIOLOGY, Dec. 1983, at 1335.

As an example of a current "add on," diffusion of MRI has probably been slowed, at least in part, by the uncertainty over its ability to substitute, to augment, or add on to CT scanning. Fully thirty to forty percent of MRI scans may substitute for the use of CT scans in central nervous system imaging,<sup>30</sup> but the extent of MRI's clinical role in other cases in which both CT and MRI scans are used is unclear. Thus, the overall costs of diagnostic imaging for specific medical conditions may be increased in the introductory phases of a new technology. But the cost for a single new imaging method could actually decrease on a cost-per-case basis, as technical capabilities are improved and the service or facility operates at a higher volume and efficiency.

Professor Mehlman also points out that initial assessments of these technologies may be overly optimistic when actually applied to the generalized clinical context. However, this may not always be true. The performance and interpretive skills of physicians, as well as the degree of technical capability of the device or equipment, may evolve to a greater degree of sophistication and accuracy, improving over the initial efficacy. In addition, advances in recent years in the methodology used to assess diagnostic technologies take cognizance of the issues raised when such technologies are applied to a larger population after the initial investigative phase.

### B. *Medical and Surgical Procedures*

Findings indicate, as Professor Mehlman points out, that medical and surgical procedures are significant components of the total costs of patient care, which at present, are not fully addressed by current mechanisms of technology assessment and regulation. He notes that OTA regards this gap in assessment efforts as the "overriding weakness of the nation's technology assessment activities." It was estimated that one-third of the national health care expenditures in 1981, or about \$90 billion, was spent for surgical care.<sup>31</sup> In light of the significant portion of health care costs attributed to procedures largely outside the purview of the Food and Drug Administration and other bodies involved in assessing technologies, more attention should be focused on designing methodologies for their

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30. See PROSPECTIVE PAYMENT ASSESSMENT COMMISSION SUBCOMMITTEE ON DIAGNOSTIC AND THERAPEUTIC PRACTICES MEETING, PANEL PRESENTATION—PAYING FOR COSTLY NEW TECHNOLOGIES—MAGNETIC RESONANCE IMAGING (Nov. 1985).

31. See Moore, *Surgical Streams in the Flow of Health Care Financing—The Role of Surgery in National Expenditures: What Costs Are Controllable?*, 201 ANNALS SURGERY, Feb. 1985, at 132, 134.

evaluation. For example, Professor Mehlman describes the difficulties in detecting significant changes in medical and surgical techniques and the ethical problems associated with performing controlled trials in surgical treatment. However, a few remedies come to mind.

Although it may not be as rigorous a method as a double-blind controlled clinical trial, a trial comparing various technologies and techniques could be performed with common outcome measurements. This would not only provide data on the safety and effectiveness of each method, it would also provide information to guide the appropriate management of particular patient subsets. For example, a trial of antiarrhythmia treatments could compare drug therapies, surgical techniques, closed-chest catheter techniques, and implantable devices.

Another evaluation method involves establishing a data registry on patient outcomes. An international registry has been established to collect data on patients undergoing catheter ablation of the atrioventricular junction: a closed-chest surgical technique to eliminate the focus of arrhythmia origins.<sup>32</sup> In addition, a number of technologies used in psychobehavioral therapy, which do not lend themselves easily to conventional quantitative standards and trials of efficacy, could be subjected to assessment on the basis of outcome measurements on a common health-sickness rating scale.<sup>33</sup> In any case, some disciplines, such as surgery and psychotherapy, have not focused sufficient attention on the need for critical evaluation of the techniques they employ and for developing the appropriate methodology to make such assessments.<sup>34</sup>

### C. *Methods of Assessment*

The controlled clinical trial, as outlined by Professor Mehlman, remains the best tool for determining the safety and efficacy of a technology. He describes the ethical and cost considerations which significantly limit the use of controlled clinical investigations. These problems are linked to both the large patient populations

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32. See Scheinman, Evans-Bell & the Executive Committee of the Percutaneous Cardiac Mapping and Ablation Registry, *Catheter Ablation of the Atrioventricular Junction: A Report of the Percutaneous Mapping and Ablation Registry*, 70 CIRCULATION, Dec. 1984, at 1024.

33. See Luborsky, *Clinicians' Judgments of Mental Health: Specimen Case Descriptions and Forms for the Health-Sickness Rating Scale*, 39 BULL. MENNINGER CLINIC 448-80 (1975).

34. See Perry, *The National Center for Health Care Technology: Assessment of Psychotherapy for Policymaking*, 38 AM. PSYCHOLOGIST, Aug. 1983, at 924.

such investigations require and study designs requiring an internal control—withholding the technology from an appropriately matched group. But the seriousness of these problems may depend on the nature of the disease. For example, the evaluation of analgesics for treatment of mild headaches, arthritis, and back pain would not entail either large study populations or an ethical dilemma in withholding a new and perhaps valuable treatment.

In addition, other study designs can yield statistically valid findings with fewer patients than otherwise required. Externally controlled studies—clinical trials which compare subjects to historical controls or controls in other settings—designed with explicit hypotheses and rationales for data interpretation and generalizability of results can add to scientific knowledge.<sup>35</sup> However, in diseases with fluctuating natural courses (remissions and exacerbations), matched controls are essential, as historical controls may be misleading. Crossover studies—clinical trials in which responses to two or more treatments in sequence are studied—and self-controlled studies can also produce findings which may strengthen clinical inferences.<sup>36</sup> Even if relatively few patients are enrolled in a study, detailed information about each individual, such as serial measurements, may be sufficiently valid to allow for generalization to a larger group.

Another assessment methodology is the consensus development conference.<sup>37</sup> Although it does not generate original data, it provides a mechanism for the synthesis and review of existing data. It results in a summary of the state-of-the-art knowledge and serves to identify gaps in the knowledge base, thus helping to set priorities in research funding.<sup>38</sup> Above all, consensus development provides a forum where conflicting data can be scrutinized and where different disciplines and individuals with differing perspectives can interact.

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35. See Bailar, Louis, Lavori & Polansky, *Statistics in Practice: Studies Without Internal Controls*, 311 NEW ENG. J. MED. 156 (1984).

36. See Louis, Lavori, Bailar & Polansky, *Statistics in Practice: Crossover and Self-Controlled Designs in Clinical Research*, 310 NEW ENG. J. MED. 24 (1984).

37. See Perry & Kalberer, *The NIH Consensus-Development Program and the Assessment of Health-Care Technologies: The First Two Years*, 303 NEW ENG. J. MED. 169 (1980).

38. See Perry, *The Brief Life of the National Center for Health Care Technology*, 307 NEW ENG. J. MED. 1095, 1097 (1982).



## VI. IMPLEMENTATION OF WASTE CONTROL

### A. *Role of Government and the Private Sector in Technology Assessment*

Professor Mehlman outlines the relevant advantages and disadvantages of a system in which the government assumes a major role in technology assessment. One of the points made in his article is that technology-assessment findings are similar to a public utility in that its benefits can be applied generally; they are not restricted to those who pay for the assessment. In light of this consideration, it appears that a combination of public and private sources is both desirable and essential to fund and undertake technology assessment.

Industry is responsible for much of the technological innovation and provides much of the impetus for the use of new technologies. The medical profession often plants the seeds of medical innovation and is responsible for the competent application of technologies for promoting patient welfare. Third-party payors are responsible for overseeing the quality and costs of care for their beneficiaries. These entities should all be willing partners in providing assessments of new and existing technologies.

### B. *Proposals for Roles in Evaluation and Coverage*

Professor Mehlman observes that the large variety of players in health care delivery, each with their own set of priorities for evaluation of technologies, "admit to no ready solutions." However, there have been several proposals aimed at improving medical technology assessment in this country,<sup>39</sup> and these may have stirred Congress in late 1984 to enact legislation<sup>40</sup> that authorized the establishment of a council on health care technology under the aegis of the National Academy of Sciences. As Professor Mehlman indicates, Congress had previously created a federal entity with respect to comprehensive technology assessment: the National Center for Health Care Technology. However, under pressure from the device

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39. See, e.g., Bunker, Fowles & Schaffarzick, *Evaluation of Medical-Technology Strategies: Proposal for an Institute for Health-Care Evaluation*, 306 NEW ENG. J. MED. 687 (1982); Relman, *An Institute for Health-Care Evaluation*, 306 NEW ENG. J. MED. 669 (1982); Perry, *Technology Assessment Proposed*, 1 HEALTH AFF., Fall 1982, at 123; INST. OF MED., A CONSORTIUM FOR ASSESSING MEDICAL TECHNOLOGY PLANNING STUDY REPORT (Nov. 1983).

40. Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, 98 Stat. 2815.

industry and the American Medical Association, the Reagan administration acted to abolish it.

The new legislation, in effect, implements the recommendations of a 1983 report<sup>41</sup> by the Institute of Medicine of the Academy, which proposed that a "consortium" be established as part of the Institute both to serve as an information clearinghouse for medical technology assessment and to foster communication among the principal organizations engaged in technology assessment. The legislation authorized a grant to the Institute for planning purposes on the condition that matching funds were obtained from the private sector. For operational purposes, funding would have to be derived primarily from private sources with some secondary support from the government. The establishment of such an institution should help to address the current deficiencies in technology assessment by facilitating exchange and coordination among the diverse groups involved and by providing funds for necessary research regarding appropriate use of technologies, including clinical trials (assuming that adequate financial support is obtained).<sup>42</sup>

One suggested method of governmental involvement is to make coverage of and reimbursement for the use of technology contingent upon results of technology assessments. Professor Mehlman raises an objection here, arguing that this approach may impose disproportionate burdens on those who cannot afford to pay for treatment. There appear to be a few alternatives to minimize this possibility. During the investigational phase, device manufacturers, but not drug manufacturers, are allowed to recover costs from users. Although this charge may be nominal in relation to actual costs incurred, it can indeed pose financial burdens for the institution or for individual patients. The institutional review board should ensure that no candidates for clinical trials are excluded on the basis of ability to pay. One other recourse may be to reexamine the provision for cost recovery by device manufacturers, since the new devices have not yet been approved as safe and effective.

Another promising approach entails reimbursement by third-party payors for experimental and as yet non-covered procedures and technologies in exchange for submission of data by the provider on the safety, effectiveness, and costs based on a mutually agreed-

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41. INST. OF MED., *supra* note 39.

42. See Perry, *Technology Assessment: Continuing Uncertainty*, 314 NEW ENG. J. MED. 240, 241 (1986).

upon protocol.<sup>43</sup> This policy would be implemented in only selected clinical centers. Such an approach would expedite the acquisition of information about new technologies, replacing the unstructured and inefficient means by which such information is currently obtained. In this manner, valuable information about a technology could be collected and evaluated as it enters the practice setting in order to formulate a permanent coverage decision. In addition, access to these technologies would be more equitable and timely. Too often technology is not subjected to formal evaluation, and data about the experience with technologies in the early stages of clinical acceptance are lacking. Yet, they quickly are widely disseminated and integrated into the practice of medicine.

### C. *Health Planning and Certificate-of-Need Programs*

Another possible role for government is in restricting the acquisition of new technology. Professor Mehlman observes that while Certificate-of-Need Programs (CON) appear to have reduced the number of hospital beds, they have not been effective in reducing the acquisition of new technology. However, in the past several years, the controls employed by CON programs have been eased or even dropped in several states.<sup>44</sup> The current administration budget plan for 1987 calls for an end to federal funding for health planning. Such funding was scheduled to terminate on September 30, 1986 if not reauthorized by Congress.<sup>45</sup> Seven states have already repealed CON programs. Others have deregulated certain facilities or set threshold levels higher than those mandated by the federal rules. And in most states, nonhospital-based outpatient facilities and physicians' offices are exempt from regulation, and thus can freely acquire costly new technologies.<sup>46</sup>

Objections have been raised to health planning and CON programs, probably based on a combination of impressions: 1) the programs are not effective; 2) the government is intruding and hindering competition in the health care delivery system; and 3) other mechanisms are available to control capital expenditures without intrusion into allocation decisions (e.g., proposed Medicare

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43. See Towery & Perry, *The Scientific Basis for Coverage Decisions by Third-Party Payers*, 245 J. A.M.A. 59, 61 (Jan. 1981).

44. See Perry, *Rational and Irrational Diffusion of New Technologies*, 1 J. HEALTH CARE TECH., Fall 1984, at 73.

45. See *Health Planning Faces New Challenges*, WASH. REP. ON MED. & HEALTH—PERSPECTIVES 3 (K. Glenn ed. Feb. 17, 1986).

46. *Id.*

capital prospective payments). However, planning agencies can also serve other functions: collecting and analyzing data, predicting the health needs of the region, and developing plans within the communities to meet those needs. In New York, local health systems agencies target funds for primary care and maternal-child programs, and planning functions are closely linked with health policy development functions. In New Jersey and Maryland, health planning functions are linked to the all-payor, prospective rate-setting system.<sup>47</sup> Thus, it appears that although planning controls have been applied somewhat haphazardly across the nation, health planning in some areas can be used to shape and implement state health policy in accordance with community needs, eliminating wasteful use or duplication of technologies.

#### D. *Regionalization*

In addition to controlling the acquisition of new technologies, health planning entities can establish medically acceptable guidelines for the use of expensive technologies in order to regionalize selected technologies. In regional centers, the necessary resources, equipment, and manpower can be marshalled in order to maintain a high quality standard of care as well as ensure financial responsibility by operating on economies of scale. Regionalization would also counter the inappropriate proliferation of services, with many providers competing to keep their facilities solvent.

The benefits of regionalization have been demonstrated in a number of circumstances. For example, the regionalization of perinatal care has been shown to successfully decrease infant mortality rates by eighteen percent without increasing developmental disabilities.<sup>48</sup> Studies have also shown that complication rates may be linked to the number of procedures performed at a given center. In the case of coronary arteriography, centers performing less than 100 procedures yearly experienced a complication rate ten times that of centers that performed more than 400 per year.<sup>49</sup> Thus, improved safety and effectiveness as well as economies of scale can be achieved through regionalization.

Some services, such as organ transplant centers, require a con-

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47. *Id.*

48. *See Regionalized Perinatal Networks Reduced Infant Mortality by 18% Without Increasing Disabilities*, 1 TECH. REIMBURSEMENT REP.—THE BEIGE SHEET 3 (Nov. 1985).

49. *See* Kennedy, Kennedy, Frye, Giuliani, Pluth, Smith, Ritter & Nobreg, *Use of the Cardiac-Catheterization Laboratory in a Defined Population*, 303 NEW ENG. J. MED. 1273, 1276 (1980).

siderable outlay of resources, institutional commitment, and expert clinical management. A few states, such as Ohio and Massachusetts, have planned consortiums to coordinate various centers' activities in organ procurement and patient selection. This is an example of careful health planning efforts to conserve scarce resources and to use them wisely.

## VII. THE PROSPECTIVE PAYMENT SYSTEM

### A. *Impact on the Diffusion of Technology*

The overall level of PPS and other payments to hospitals may exert the greatest effect on technological advances and adoption. The absence of an adequate allowance for scientific and technological advances is likely to both restrict the diffusion of new technologies and distort patterns of access to technologies, perhaps more than any other provision of the PPS. Historically, the average annual increase between 1968 and 1980 in the intensity of services was between four and five percent.<sup>50</sup> Now, a hospital must fund new acquisitions either from the "profits" left over after providing for the care of Medicare beneficiaries or from the payments derived from other third-party payors. Although hospitals generally reported significant increases in operating profitability in 1984, it is uncertain whether this trend can continue.<sup>51</sup> With the probable implementation of prospective rates or limitations on Medicare capital payments in 1988, disincentives to adopt costly, new technologies will be exacerbated.

Furthermore, since prospective rates do not currently apply to outpatient procedures or physician fees, outpatient clinics and physicians can acquire devices and equipment and yet still collect fees on a reasonable-cost reimbursement basis. This may lead to an inappropriate distribution of technology, with an increased tendency for new technologies to be acquired by outpatient facilities. Such a pattern may be even more costly in the aggregate and may render new technology less accessible to patients. It is estimated that thirty-nine percent of all MRI devices are currently situated in outpatient settings, twice the proportion of CT scanners at a comparable stage of development.<sup>52</sup>

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50. See Anderson & Steinberg, *To Buy or Not to Buy: Technology Acquisition Under Prospective Payment*, 311 NEW ENG. J. MED. 182 (1984).

51. See PROSPECTIVE PAYMENT ASSESSMENT COMMISSION, *Financial Consequences for Hospitals*, in MEDICARE PROSPECTIVE PAYMENT AND THE AMERICAN HEALTH CARE SYSTEM: REPORT TO THE CONGRESS 47-50 (Feb. 1986).

52. See Steinberg, Sisk & Locke, *supra* note 23, at 860.

Another issue affecting the diffusion of and access to new technologies is the timeliness of technology assessment findings. OHTA, the federal entity responsible for providing advice to the Health Care Financing Administration (HCFA) on Medicare coverage, had a 1985 budget of only \$700,000.<sup>53</sup> In addition, FDA approval is a necessary prerequisite for Medicare coverage. A coverage decision may be announced fairly soon after approval, but it may follow a year or more later. For example, OHTA was requested in 1983 to produce an analysis of MRI devices along with a recommendation regarding coverage. The report was not submitted until mid-1985, and Medicare approved coverage in November of 1985—about five years after the first MRI device was installed.<sup>54</sup>

Furthermore, the decision with respect to coverage is only the first step under the Prospective Payment System. The two-step determination establishing the payment level must then be made. First, a new technology must be properly identified for data collection regarding costs and utilization. Until recently, no mechanism for creating new codes existed. Second, a technology may be classified in a particular DRG or DRGs. The resulting payment determination may not reflect the true level of added resources needed for the operating costs of the new technology. An additional problem is that the single payment prescribed for a DRG discourages the use of a more expensive model of a device or drug, even if it may be more appropriate or superior. A current case in point involves the implantation of single chamber pacemakers and dual chamber pacemakers. Even though the dual chamber is a more expensive device and technically more difficult to implant, both pacemaker implantations are reimbursed at the same rate.

Finally, the Prospective Payment System incorporates a long delay time in price adjustment. Currently, DRG recalibration is required every four years at the very least; the 1986 rates will be based on charge data collected in 1984; the next mandated recalibration will not be until 1990. ProPAC has recommended to the Secretary that recalibration occur annually, a proposal subsequently declined by HCFA.

### B. *Impact on Providers*

The Medicare Prospective Payment System and its incentives encouraging providers to utilize cost-effective technologies are ex-

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53. See INST. OF MED., *supra* note 16.

54. See Steinberg, Sisk & Locke, *supra* note 23, at 862.

plicitly described by Professor Mehlman. However, since the system still applies only to Medicare inpatient services, exclusive of outpatient procedures and physician fees, there are implications both for access to care and for overall expenditures, as mentioned above. There may also be a tendency to shift any losses realized from caring for Medicare inpatients to other third-party payors, or to "dump" uninsured and indigent patients on other institutions if no margin from Medicare payments exists for charity care or cross-subsidization. This transfer of uninsured patients not only results in a significant cost shift to public hospitals, it also creates an alarming limitation on the access to health care for the poor.<sup>55</sup> If a DRG payment is significantly inadequate with respect to the true costs of the necessary resource use, an unfair burden is placed on some institutions, which can limit access to care to Medicare inpatients.

PPS rates are based on historical charge and cost data, which tend to reflect the traditional cross-subsidization of expensive procedures with less expensive services within hospital billing patterns.<sup>56</sup> Thus, more complicated technologies tend to be underpriced in DRG rates, and hospitals may benefit by deleting these services and transferring certain patients elsewhere, even if the technology is cost effective in the long run.

Professor Mehlman states that the variation in Medicare reimbursement policy at the contractor level may provide advantages, such as accommodating new technologies in a more flexible manner. It is true that intermediaries may exercise their discretion prior to a national coverage decision. However, this may also have several drawbacks. For instance, the technology may not be safe or effective or truly beneficial, findings which may have been revealed by a formal assessment provided to HCFA by the Public Health Service (PHS). It also creates inequities in access to care for Medicare beneficiaries across the nation. In addition, data accrual on the application of new technologies on a nonsystematic basis is generally minimal, as would be expected if coverage were inconsistently applied. It would appear that HCFA has potential access to enormous amounts of data, but its data collection system is deficient. In any case, the lack of uniformity in coverage creates uncertainty on the part of providers, manufacturers, and patients. It appears to be in the best interests of patients and providers to promulgate clear,

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55. See Schiff, Ansell, Schlesser, Indris, Morrison & Whitman, *Transfer to a Public Hospital: A Prospective Study of 467 Patients*, 314 NEW ENG. J. MED. 552, 556 (1986).

56. See Steinberg, Sisk & Locke, *supra* note 23, at 862.

enforceable rules for Medicare coverage, as Professor Mehlman suggests.

### C. *Impact on Manufacturers*

Professor Mehlman outlines the various forces which may impact on the behavior of manufacturers and others who develop new technologies. Although it is a complicated process, which in some degree is insensitive to market forces, there is evidence that manufacturers are increasingly emphasizing the relative efficacy and cost-effectiveness of technologies. This trend has been more prominent in the marketing approaches for existing devices, since the research and development (R&D) of these devices began several years before the incentives created by the PPS emerged. One medical device manufacturer has established screening mechanisms to evaluate R&D efforts with respect to short-term cost effectiveness, and has attempted to develop short-term cost-effective devices specifically to be used in particular DRG categories.<sup>57</sup> As another example, a drug manufacturer has advertised that the use of a new antibiotic will not be charged to the provider if the patient's hospital stay exceeds the average length-of-stay for the DRG payment level.

In a marked change, the Health Industry Manufacturers Association (HIMA) was focusing on technology assessment as one of its priority areas in 1986, exploring "relative efficacy" criteria and research programs to collect health outcome information, such as survival rates and impact on quality of care.<sup>58</sup> This responsiveness to cost-constraint pressures on the part of industry, coupled with other public and private initiatives, may constructively address the problem of wasteful technologies.

Research and development of technologies may also be negatively affected, potentially altering the rate of innovation. Companies may decide not to pursue costly technological advances because of the uncertainty of demand and reimbursement. This will be beneficial if it results in the production of fewer marginal or inefficient technologies, but it may be harmful if advances in the quality of care are stifled. Greater standardization in product mix is likely, and financially limited small companies may be forced out of the

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57. See Bessey, *Don't Let Cost Containment Stifle Technological Innovation*, presented at the 1985 Harold and Jane Hirsch Symposium at George Washington University.

58. See *Use of "Relative Efficacy" Criteria Is Part of HIMA Study on Technology Assessment and Health Financing*, 2 TECH. REIMBURSEMENT REP.—THE BEIGE SHEET 9 (Feb. 1986).



market due to competitive pressures and uncertainties of reimbursement.

#### D. *Conflict of Interest Embodied in Current Cost-Containment Initiatives*

In his article, Professor Mehlman comments on the shortcomings of the current combination of prospective payment and coverage determination for implementing controls on wasteful technology. He very aptly describes the system as creating distinct incentives for *cost-reducing* technologies, which are not necessarily disincentives for *wasteful* technologies. This bias not only creates a conflict of interest between the provider or investor physician and patient, but also between the primary care provider and institutional administrator. The physician's primary responsibility is to act in the best interests of his or her own patients. The hospital administrator's duty is owed to all the patients receiving care at the hospital, as well as to the financial viability of the institution. In addition, the physician who is an investor in a facility in which he or she is employed or to which he or she can refer patients is in a serious conflict-of-interest situation.

The growth of competition under the PPS can create pressures to lower per-unit costs of technologies, but can also induce providers to unbundle expensive services, generate new services or repeat procedures unnecessarily, and increase the volume of services for which payment is received. In addition, in view of the growing trend and size of corporation-owned hospitals and for-profit institutions, the physician "employee" may begin to lose some of his or her traditional autonomy and influence in placing the patient's interests foremost.

#### E. *Quality of Care Concerns*

Professor Mehlman states that Medicare's PPS has not been in effect long enough to permit evaluation of its impact on quality of care, including the development, acquisition and use of technologies. While it is true that data does not presently exist directly linking reductions in the quality of care to the PPS forces, the studies thus far have not generally focused on the entire episode of care, including post-hospitalization treatment. Outcome may not be adequately determined until a period of time after the inpatient stay has elapsed.

Peer Review Organizations (PROs) have generally focused on

review of admissions, procedures, outliers, and readmissions.<sup>59</sup> The scope of PRO review of quality of care has been restricted to inpatient services, exclusive of outpatient care, home care, and nursing home care. The General Accounting Office Report for the Senate Committee on Aging noted that the number of home health agencies increased and were dealing with more complicated case loads after the implementation of PPS.<sup>60</sup> In addition, surveys of the membership of both the American Medical Association and the American Society of Internal Medicine revealed that a majority of physicians perceived a deterioration in quality of care or pressures to discharge patients prematurely.<sup>61</sup>

Another explanation for the evident lack of complaints about the quality of care is that beneficiaries have perceived that Medicare limits the number of days of care per hospitalization. They have also been unaware of their rights to recourse or appeal if they felt that they had been or were about to be discharged prematurely. Although PPS was implemented in late 1983 and early 1984, HCFA did not have any general information for distribution to beneficiaries until spring of 1985. Only recently has a mechanism been established to routinely distribute fact sheets to beneficiaries at the time of admission aimed at informing them about their rights to appeal a hospital's denial of additional inpatient services before discharge.

The new scope of PRO oversight proposed by HCFA in November, 1985, includes generic quality screens to determine adequacy of discharge planning, stability at discharge, and morbidity and mortality rates during hospitalization. The proposal also provides for assistance in improving information dissemination to beneficiaries regarding PPS and their rights in the appeals process. However, no funds are presently provided for review of services outside the hospital setting.<sup>62</sup>

### F. *Future Implications*

Although it is generally accepted that PPS will have to be modi-

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59. See *DRGs and Quality of Care*, WASH. REP. ON MED. & HEALTH—PERSPECTIVES 3 (S. Williams ed. Nov. 25, 1985).

60. General Accounting Office Letter Report to the Senate Special Committee on Aging—"Information Requirements for Evaluating the Impact of Medicare's Prospective Payment System on Post-Hospital Care" (GAO/PEMD-85-8).

61. See *DRGs and Quality of Care*, *supra* note 59, at 3.

62. See *ProPAC's Report to Congress*, WASH. REP. ON MED. & HEALTH—PERSPECTIVES 306 (K. Glenn ed. Mar. 10, 1986).

fied and the concept probably extended, certain implications of the effects of PPS seem apparent at this time. While hospitals generally profited under Medicare's PPS in 1984, it is predicted that, in the transition to national rates, some large rural hospitals and hospitals located in the East and West-North-Central regions will suffer significant losses. It is not clear that differences in payment distributions to hospitals reflect differentials in operating efficiency.<sup>63</sup> Proposed regulations issued by HCFA specify that reasonable, national ceiling rates may be prescribed for payments for new expensive technology or new efficiencies in the use of existing technology.<sup>64</sup> This would signify a departure from the general policy of basing payments on historical charge data. Factors that might be considered in establishing payment limits could include the price markup in comparison with similar services, a cost-effective utilization rate, and the costs of providing the service. This proposed limit for new technologies could significantly affect diffusion patterns.

For example, ProPAC recently voted to recommend an add-on payment of \$124 for hospitals that possess MRIs and are receiving capital payments, and an add-on payment of \$282 for hospitals contracting with another hospital for MRI services.<sup>65</sup> This payment level is based not only on cost and charge data obtained from hospital experience, but also on a desired level of medium to high efficiency of operation. A 1985 analysis of MRI units in the United States indicated that at the present volume of operation, the break-even economic point would be \$1084 per scan; at a high volume of operation, the break-even point would be \$635 per scan.<sup>66</sup> If the payment level is set significantly below costs, access to these services by Medicare patients could be limited. Such payment levels could even encourage duplication and unnecessary use in order to achieve a high volume of services. Proposed MRI payments would be paid from the general allowance for scientific and technological advances, thus reducing the available funds for other new technologies or for hospitals not utilizing MRI scans.

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63. *Id.*

64. *See New Expensive Technology is Among Cases Where HCFA May Set National Medicare Charge Limits*, 2 TECH. REIMBURSEMENT REP.—THE BEIGE SHEET 3 (Feb. 1986).

65. *See Prospective Payment Assessment Commission, Report and Recommendations to the Secretary, U.S. Department of Health and Human Services* 53-54 (Apr. 1, 1986).

66. *See Evens, Jost & Evens, Economic and Utilization Analysis of Magnetic Resonance Imaging Units in the United States in 1985*, 145 AM. J. RADIOLOGY, Aug. 1985, at 393.

### VIII. LEGAL PRESSURES AS INCENTIVES TO PROVIDE COSTLY TECHNOLOGIES

Professor Mehlman describes the legal pressure which is encouraging providers to furnish non-wasteful but cost-increasing technology, namely the fear of malpractice suits. He also observes that, historically, malpractice law favors the patient perspective over the interests of the providers and payors. Although these legal standards have provided a strong impetus for providers to utilize costly technologies in patient care, they have also led to wasteful use of technologies in order to ensure a defensible stance against any malpractice claim. The American Medical Association estimates that \$15 billion a year is spent on defensive medicine. A 1983 survey of physicians noted that 40.8% of respondents prescribed additional diagnostic tests, and 34.6% prescribed additional treatment procedures in response to pressures of possible litigation.<sup>67</sup>

Another interesting point raised by Professor Mehlman is the possibility that the medical profession may adopt the attitude that a cost-increasing technology can no longer be justified, although it may enhance quality. Would this be sustained in a court of law as an accepted standard of care? It appears unlikely as long as physicians continue to serve the patient's best interests, and society values the patient higher than payor and provider interests. For instance, it is doubtful that Americans would accept the rationing process inherent in the National Health Service (NHS) in Great Britain. Because of economic constraints, physicians in the NHS must allocate scarce resources among patients and among various technologies.<sup>68</sup> Confronted with these decisions, it appears that the physician has, in some cases, incorporated economic restrictions into the medical standards of care.<sup>69</sup> An elderly patient with kidney failure may not be told of the possibilities of treatment with dialysis, and a patient with chest pain may not qualify for the relatively restrictive criteria for coronary artery bypass surgery. It is of interest to note, however, that questions have been recently raised in this circumstance concerning the patient's right to treatment, the doctor's duty to his or her patient, and the possibility that the doctors could be committing a crime by knowingly withholding beneficial

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67. See Zuckerman, *Medical Malpractice: Claims, Legal Costs, and the Practice of Defensive Medicine*, 3 HEALTH AFF., Fall 1984, at 128, 131.

68. See Schwartz & Aaron, *Rationing Hospital Care: Lessons from Britain*, 310 NEW ENG. J. MED. 52 (1984).

69. See *id.* at 54.

treatment.<sup>70</sup>

Medical rationing through the use of socioeconomic criteria would be anathema in the United States. It would generally be regarded as unacceptable for maintaining either the public confidence in medical care or the equal opportunities implicit in the promises of accessible health services. However, in some sense, the cost-control measures in place with prospective rates, capitated systems, and regulation over coverage and acquisition of technologies act as rationing devices, and such devices are being implemented when resources are constrained. For example, bed availability affects the admission and discharge decisions of physicians working in intensive care units (ICU). The most important concern is that when beds are scarce, the physician may have to rely on schemes for risk stratification of patients according to reasonable expectations of and sound information about the safety, effectiveness, and appropriate use of the technologies employed.

Although most people have access to a reasonably high standard of care, there are many who, due to geographical, cultural, and economic barriers, do not have access to some of the more sophisticated services and technologies. A source of increasing concern is the access to care for the poor, disabled, and elderly.<sup>71</sup> The new initiatives in cost containment in the publicly funded programs for Medicare and Medicaid may exacerbate the differentials in access to care for these groups. Under the PPS, a larger proportion of health care costs have been passed on to the beneficiary in the form of higher premiums, higher deductibles, and greater use of outpatient services, including nursing home care (which is not usually reimbursed under Medicare).<sup>72</sup>

## IX. CONCLUSIONS

The impetus for cost containment has led to increased interest and efforts in technology assessment in order to define appropriate and inappropriate uses of technology. It is clear that many new technologies enter the practice arena, some of which involve costs beyond reasonably anticipated benefits, some of which may be applied on a wasteful basis, and some of which have great promise to improve quality of care. It is also clear that current competitive

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70. See Brahams, *End-Stage Renal Failure: The Doctor's Duty and the Patient's Right*, 1 LANCET 386 (1984).

71. See Mechanic, *Cost Containment and the Quality of Medical Care: Rationing Strategies in an Era of Constrained Resources*, 63 MILBANK MEMORIAL FUND Q. 453 (1985).

72. See *ProPac's Report to Congress*, *supra* note 62.

incentives, regulatory controls, and the Prospective Payment System cannot be relied upon alone to foster the appropriate decision-making regarding new and existing uses of technologies. Professor Mehlman concludes that although there exist technical and conceptual difficulties, technology assessment is inevitable and, we would add, desirable to assess the most crucial step in health care delivery: determining how a technology can be best used in patient care. While there are many uncertainties facing the future of our health care system, including questions of how much health care we can afford, there are also new opportunities to influence the delivery of health care with careful planning and evaluation.

Of note is the intensified interest in technology assessment in the private sector, composed of professional organizations, industry, third-party payors, universities, and provider organizations. The establishment of the Council on Health Care Technology at the Institute of Medicine (IOM), a public-private entity charged with assessing health care technologies and with coordinating information exchange and evaluation efforts, could help to fill a much-needed role to form a coherent, formal mechanism for technology assessment.<sup>73</sup> In addition, a system is needed to set assessment priorities among technologies and to fund research projects, including clinical trials to determine safety, effectiveness, and the relative efficacy of technologies. Whether the IOM Council will acquire the requisite resources remains to be seen.

Another step in the systematic assessment of new technologies should be to establish programs for the interim coverage and reimbursement of new technologies as they enter the practice setting. Such a program would fill an important gap in knowledge about medical technologies—the experience in the real world of the practice of medicine. Such programs could target selected study sites and protocols. In exchange for payment, providers would supply data on safety, effectiveness, costs, and cost-effectiveness of a given technology based on a predetermined protocol. This program would augment the process of decisionmaking for third-party reimbursement, as well as provide more equitable access to new technologies.

The results of technology assessment can be used in making appropriate allocation decisions, providing an objective evaluation prior to the routine use of technologies in clinical practice. For example, expensive, new technologies, such as organ transplants,

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73. See Perry, *supra* note 42, at 242.

MRI, or cardiac catheterization procedures, can be regionalized. This would prevent wasteful duplication of services and promote a level of use commensurate with economic feasibility and staff proficiency.

Another result of technology-assessment efforts lies in providing guidance and information to engender more cost-effective and appropriate clinical practice patterns. Wennberg's studies have demonstrated the highly discretionary character of medical care decisions, which correlate with differences among physicians and their practice styles.<sup>74</sup> A broader consensus on the appropriate use of medical technologies can help to determine which practice patterns can be most beneficial for patients. In addition, appreciation of the factors contributing to the process of clinical decisionmaking would appear to reflect a more refined strategy to control per-capita costs when compared to prescribing a price for a hospitalization or for a technology.

Professor Mehlman appropriately views with misgivings the implementation of a Medicare reimbursement system that creates a conflict of interest between patients and providers, thereby encouraging providers to withhold technologies that might be in the patient's interests but that increase provider costs. Indeed, greater vigilance needs to be focused upon the potential inequities of the PPS: the ripple effects felt in the other sectors of the health care system; the unequal burdens it may place on different patient groups or providers; and, in the long run, consequences for the quality of care. A set of new technologies could be studied as case examples of technology diffusion under PPS, and aspects of the system which cause distortions in patterns of diffusion could be identified and reevaluated. In these examples, effects of reimbursement decisions, risks of over or under diffusion, the relationship of demonstrated evidence of safety and effectiveness to clinical acceptance and dissemination patterns could be studied. The scope of quality review by PROs should encompass the entire episode of patient management: diagnosis, treatment, as well as post-hospitalization care.

In summary, there is a recognized need for a rational, coherent system to identify and assess health care technologies, to reduce the use of less efficacious services, and to accommodate the use of proven, effective technologies. Medicine has been a discipline char-

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74. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF., Summer 1984, at 6.

acterized by dynamic scientific development, and the future promises to bring an ever-increasing number of technological advances. Challenges to manage the increased demand in an equitable fashion will have to be met. Technology assessment can be the analytic tool for use by the diverse parties involved in promoting the appropriate and discriminate use of resources in order to enhance both the quality and cost effectiveness of care.