

Assessing Medical Technology Assessment: Past, Present, and Future

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ADVANCES IN MEDICAL TECHNOLOGY—WHICH includes techniques, drugs, devices, and procedures used by health care professionals and the systems in which health care is delivered (U.S. Congress. Office of Technology Assessment 1982a)—have contributed both to the quality of health care and to rising costs of treatment (Altman and Blendon 1979). The proliferation of health care technologies has led to growing pressure to evaluate them, making “technology assessment” an integral aspect of health policy (Banta and Behney 1981). The goal of technology assessment is the examination of the safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness of a particular technology—including social, economic, and ethical consequences—to improve health care decisions (Institute of Medicine 1983). Unlike many health issues, there is a general consensus that some manner of technology assessment is desirable, or at least inevitable, reflecting the possibility that appropriate evaluation may offer higher quality care while moderating or reducing costs (Relman 1980). Indeed, the absence of any evaluative efforts raises the specter of irrational diffusion of technology, allowing adoption and entrenchment of technologies before safety, efficacy, or costs are established.

Despite widespread commitment to the principle of medical tech-

nology assessment, however, there has been little agreement on how to structure the institutions that will undertake assessment activities. Of course, individual physicians and professional organizations have always engaged in informal assessment, but recent sophisticated technical advances as well as the pressures of cost containment make individual decision making impractical and unrealistic. Government involvement in medical technology assessment has been sporadic and modest at best; criticism of public technology assessment efforts abound (U.S. Senate. Committee on Human Resources 1978; U.S. Congress. Office of Technology Assessment 1982a).

Why have efforts at comprehensive medical technology assessment strategies been consistently troublesome? The difficulty is two-fold. First, we have failed to understand both the limits as well as the strengths of a public role in technology assessment. And, second, where government intervention has been appropriate and productive, there have been problems designing institutional structures to accomplish the assessment goals. Breyer's theoretical work on regulation provides a starting point for analysis of past problems and future reforms. Breyer (1982) has argued that the roots of regulatory failure lie in a mismatch between tools and the problem at hand. This mismatch may be avoided if the regulatory objectives are clearly defined, alternatives are examined, and the best methods for achievement of goals chosen. He applied this deceptively simple framework to the intricacies of economic regulation. The concept is equally relevant to an appraisal of medical technology assessment strategies which can be improved if implementing institutions are properly matched with assessment goals.

Breyer cautioned against abstract generalizations in the application of his model. Blumenthal (1983) has devised a useful categorization, dividing medical technology assessment into three distinct layers: (1) *knowledge development* involves clinical trials, analyses of cost effectiveness or cost benefit, and assessments of the social, legal, or ethical effects of particular technologies; (2) *knowledge processing* includes systems for gathering, validating, interpreting, and disseminating information to public and private audiences; and (3) *regulation* directly controls the development, dissemination, and use of health care technologies. Within each of these levels of activity, any institution can address problems related to particular technologies—devices, drugs, procedures, or sys-

tems—and limit inquiries to one or more of the general concerns—safety, effectiveness, cost, or legal, ethical, or social issues.

Once these three layers of assessment are understood, the policy challenge is to apply Breyer's approach: matching these goals to institutional structures. There are many institutional alternatives, including reliance on individual corporations, private sector organizations, public entities, or creative combinations of these forms. Appropriate matches between goals and institutions require an understanding of legal limitations (Breyer and Stewart 1979) and the political environment. While a detailed exploration of the law and politics of regulation is beyond the scope of this article, the discussion will draw upon sources that stress the influence of internal politics on the behavior of institutions (Wilson 1975), as well as those who argue that outside pressures shape institutional outcomes (Dahl 1956; Lowi 1979). Moreover, because internal and external politics are dynamic, preferences for various institutional structures change over time, as does the power of interested stakeholders (Freeman 1984). Political changes are made more complicated in this context because technological advancements constantly present new political challenges. In addition, because it is not likely or necessarily preferable that one centralized assessment institution will emerge, the interrelationship of institutions must be evaluated.

In a broad context, we must ask whether assessment strategies satisfy general political requirements of legitimacy and accountability. Do they protect innovation without compromising other important social interests (Tribe 1973)? And, are our expectations for medical technology assessment realistic? In the search for a coherent, viable system or set of systems, we must not assume that there is one simple answer.

This article consists of four parts. First, it evaluates federal technology assessment efforts in the 1970s, a decade dominated by a preference for government solutions, under Breyer and Blumenthal's framework discussed above. The second part describes the rise and fall of the National Center for Health Care Technology, an agency that illustrates the transition from the 1970s to the 1980s. The third part describes the institutions of the 1980s, an era characterized by private rather than public sector solutions, highlighting recently created assessment entities, including the newly authorized "public-private" partnership

under the auspices of the Institute of Medicine (Public Law 98-551). In the final section, the article evaluates the present institutions for medical technology assessment, with recommendations for the future.

Thirteen years ago, a report from the National Center for Health Statistics quoted Edna St. Vincent Millay's "Huntsman, What Quarry?" (U.S. National Center for Health Statistics 1973). That quotation remains an apt characterization of the elusive search for successful assessment strategies:

Upon this gifted age, in its dark hour,
Rains from the sky a meteoric shower
Of facts . . . they lie unquestioned, uncombined.
Wisdom enough to leech us of our ill
Is daily spun, but there exists no loom
To weave it into fabric.

Round One: Government and Technology Assessment in the 1970s

Congressman Emilio Daddario, chairman of the House Subcommittee on Science, Research and Development, formally developed the concept of technology assessment in 1965 (Banta and Behney 1981). His work recognized that scientific and technological progress has potential social consequences that must not be overlooked (Green 1983). The goal of technology assessment is to engage in conscientious study of technological innovations before they are unquestioningly adopted and diffused into society. Concerns about the social consequences of the burgeoning field of medical technology surfaced at this time, as the proliferation of innovative medical technologies brought questions about new risks and rising health care costs into the public forum.

One of the underlying questions was what role government should play in assessing medical technologies. Successful assessment strategies depend upon information about the technology under study. Public demand for new technology and the economic pressures on producers encourage rapid diffusion. The marketplace, however, does not generate sufficient information to evaluate medical technology for a variety of reasons. Basic information is costly to develop because clinical testing is time-consuming and expensive (Relman 1980). Once information is acquired, it is easy for competitors to become free riders through

observation of others' choices. Additionally, the legal environment for information can be threatening, in that revelations of problems related to technology may increase the possibility of lawsuits.

The federal government had a growing interest in technology assessment both as traditional guardian of the public safety (U.S. Congress. Office of Technology Assessment 1982) and, in 1965, in its newly assumed role as provider under Medicare (Bunker, Fowles, and Schaffarzick 1982) despite market constraints on information. Given the preference for government solutions in the 1970s, it was inevitable that there would be efforts by the government to intervene (Bunker, Fowles, and Schaffarzick 1982).

Expansion of the Traditional Regulatory Role: The Food and Drug Administration

Since the turn of the century, the federal government had promoted public safety through regulation of food and drugs (Temin 1980). Following drug-related crises in 1938 and 1962, Congress expanded the authority of the Food and Drug Administration (FDA) to regulate the safety and efficacy of drugs. The FDA could require that pharmaceutical companies produce clinical evidence of safety and efficacy; this amounted to knowledge-development activities under Blumenthal's assessment categories. In addition, the FDA could control the marketing of drugs pending FDA approval, which is a regulatory function. Crises related to the Dalkon shield and defective cardiac pacemakers led Congress to pass the Medical Device Amendments of 1976 (Public Law 94-295), which authorized the FDA to engage in knowledge development and regulation of devices similar to its power over drugs (Foote 1986). The FDA's role, however, is limited to consideration of safety and efficacy of a particular product. It has no power to weigh cost or cost effectiveness, compare competing technologies, or engage in broader social or ethical health policy issues.

The political climate in the 1970s was ripe for the extension of traditional regulatory forms to emerging health technology. Federal protection of consumers from unsafe products was a popular concept; in this period Congress created a number of other health and safety agencies, including the Occupational Safety and Health Administration (1970) and the Consumer Product Safety Commission (1972). The FDA, while never uncontroversial, was a well-accepted, entrenched

agency. Pharmaceutical companies were accustomed to federal controls. The medical-device amendments were no threat to physicians; in fact, the clinical data on new technologies required by the FDA is valuable to practitioners. The only new interest group directly and adversely affected was the device industry, which was segmented across other "industries" like electronics and drugs and was not very cohesive at the time. Indeed, its trade association, the Health Industry Manufacturers Association (HIMA), was only founded in 1974 in anticipation of increased federal regulation (Kosterlitz 1986). During the last decade, the FDA has struggled to implement the detailed provisions of the law. There has been some controversy over the agency's commitment to regulation (U.S. House of Representatives. Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce 1983). Changing views about federal intervention in the 1980s have led to reduced expenditures for drug and device regulations. Even in a climate hostile to regulation, however, there has been general support for the role of the FDA in knowledge development and regulation.

Using Breyer's model, it can be concluded that the FDA provided a reasonably good institutional match for its goals. From a political perspective, the agency was relatively invulnerable, and it was experienced in technical evaluations of safety and efficacy. There was, and continues to be, strong public support for a federal role in product safety. Powerful, organized provider interests were not directly threatened by the FDA's activities, and industry has generally accepted the presence of regulation (Louis Harris and Associates 1982). Indeed, the chairman of a major drug and device firm recently wrote:

We should never stop arguing against unnecessary regulation and heavy-handed administration. But we must also remember: Safety and effectiveness were the intent of Congress in 1976 when it passed the Medical Device Amendments. We did not argue with those objectives then, and we do not argue with them today (Bays 1986).

New Assessment Institutions: Legislative Branch/Office of Technology Assessment

As part of the concern for the impact of technology on society, Congress established the Office of Technology Assessment (OTA), which began operations in 1974 (Institute of Medicine 1985). The

OTA is part of the legislative branch, and it serves as an advisor to Congress. The office is governed by a twelve-member, bi-partisan board composed of six senators and six representatives. In 1975, the Health Program of the OTA was established to advise Congress on health care technology and to undertake assessments at the request of chairmen of congressional committees, the congressional advisory board, or the OTA director, subject to congressional approval. The assessment goals are quite broadly defined, including all aspects of technology from safety to ethical and social impacts. The program has both a small staff (13) and a small budget (\$1.6 million in 1985) (Institute of Medicine 1985).

The OTA produces reports, technical memoranda, and case studies. OTA reports make no formal recommendations on legislative policy, but are intended to provide Congress with information on alternatives and options for policy making. In drafting these reports, the OTA staff convenes an advisory panel of experts drawn from the private sector. The case studies provide information for use in the reports and information on specific technologies (U.S. Congress. Office of Technology Assessment 1982b).

The Health Program serves a useful, but limited, technology assessment function. Using Blumenthal's categories, the program can engage in knowledge development and some level of knowledge processing but has no regulatory power. The OTA accumulates and evaluates important health information, but does not threaten any particular interests because of its limited advisory role as a research arm of Congress rather than an independent policy-making institution. The OTA Health Program understood its own limits when it recommended that Congress consolidate technology assessment within the executive branch of government (U.S. Congress. Office of Technology Assessment 1976). That recommendation was later implemented and will be discussed in the second part of this article. It is first necessary, however, to review the other new institutional arrangements that preceded it.

Institutional Politics in the Executive Branch: Department of Health and Human Services

The executive branch of government had ongoing medical assessment functions and encountered serious organizational problems during this period. Those activities were housed within the Public Health Service

(PHS) of the Department of Health and Human Services (DHHS). There were a series of institutional shifts in the 1970s that impeded the progress of technology assessment in that branch of government.

PHS had two primary loci of activities related to technology assessment. In 1960 the National Center for Health Statistics (NCHS) was created from two units of the PHS, with authority to gather data on virtually every aspect of health. Its power was successively broadened throughout the decade (Bunker 1980). The NCHS, however, was beset by bureaucratic agency rivalries (U.S. Senate. Committee on Human Resources 1978). Although appropriations rose modestly from 1974 to 1978, it was plagued with problems of inadequate financing. Indeed, as early as 1973, it was noted:

What an incongruity: we bear health-care costs that in their size and growth stagger everyone, but yet Washington is hesitant to allocate 1/4000 of the \$80 billion to obtain facts that would help decide whether this huge sum is being spent appropriately (Ingelfinger 1973).

By the end of the decade, the problems of inadequate funding were no better. Although the NCHS budget had doubled, it did not keep pace with annual expenditures for health care. And, while Congress expanded NCHS's authority to move from data gathering to broad-based knowledge processing, budget limitations precluded it (Bunker 1980).

The National Center for Health Services Research (NCHSR), another PHS unit, had been formed in 1968 to study a particular segment of health care—the organization, financing, and outcomes of health services. It remained an administrative unit until Congress institutionalized it by statute in 1975 (Public Law 93-353). Its primary charge was funding assessment research. Despite the stated need for better understanding of the behavior and performance of the health industry, NCHSR also suffered serious financial constraints during the early seventies. Its own funding declined from \$80 million in 1968, to \$58 million in 1973, to \$26 million in 1978 (Blumenthal 1983; Bunker 1980), an inflation-adjusted 80 percent reduction in research support during this period (U.S. Senate. Committee on Human Resources 1978). In sum, the growing awareness of the importance

of assessment activities was not accompanied by a strong commitment of resources.

The National Institutes of Health (NIH), another entity in the PHS, plays a major role in technology development through the funding of clinical research and trials. In 1978, the new director of NIH established the Office of Medical Applications of Research (OMAR) to evaluate existing and new technologies (Perry and Kalberer 1980). OMAR's primary goal was knowledge-processing through the use of consensus-development conferences, emphasizing technical issues of safety and efficacy rather than broader questions of cost or social impacts of technology. Again, the federal commitment was small. OMAR began with a staff of six and a budget of 2 million dollars (Blumenthal 1983). The 1985 budget for technology assessment was only 1.8 million dollars. At most, OMAR conducts no more than seven conferences per year.

OMAR, while a small unit, fared better than other assessment entities within PHS. OMAR has remained unthreatening to private interests because consensus development doesn't have a definitive influence on the behavior of the private sector, is largely nondirective, has no priority-setting mechanism and avoids regulatory outcomes (Blumenthal 1983). Again, Breyer's model is instructive. The institutions within the executive branch, particularly NCHS and NCHSR, lacked strong extrinsic political support and were vulnerable to intrinsic infighting within PHS. While they struggled for survival, the politically more powerful NIH managed better than others to escape absolute budget cuts and, thus, OMAR survived (Blumenthal 1983).

By 1978, despite the recognized need for some form of technology assessment, there was still no clear notion of how to achieve it. It is true that the FDA continued its comprehensive regulatory program with modest success and the OTA Health Program undertook broad-based knowledge development and knowledge processing on a small range of issues. Programs at PHS, however, were less stable. Commitments to the NCHS and NCHSR declined, while the OMAR program at NIH was small and limited in scope. The knowledge-development and knowledge-processing activities in both the legislative and executive branches were spotty. Budgetary problems and institutional politics plagued many of the assessment institutions. The controversial National Center for Health Care Technology (NCHCT) was born in this unstable environment.

Time Out: Rise and Fall of the National Center for Health Care Technology

The short life of the National Center for Health Care Technology (NCHCT) dramatically illustrates the consequences of regulatory mismatch. NCHCT was a classic 1970s solution that enhanced and concentrated government power over technology assessment. The American Medical Association (AMA) opposed the creation of NCHCT as interfering with medical practice and HIMA thought it was a threat to innovation. NCHCT was supported by other specialty groups. When it began its activities in 1978, NCHCT faced powerful external opponents and it was vulnerable to internal struggles among branches of DHHS, particularly from NIH. At the time of reauthorization in 1981, the opponents in the private sector allied with antigovernment ideologues of the new administration to close down the agency. Thus, while the goals of NCHCT—to coordinate government technology assessment—appeared well-matched to the structure of the agency, dynamic political factors coalesced to defeat it.

Partially in response to the OTA's 1976 *Report on the Development of Medical Technology*, Congress created NCHCT to coordinate technology assessment within the administrative structure (Public Law 95-623). Its mandate, broader than any prior agency, was to examine new and existing technologies in order to assemble data on effectiveness, cost, and social and ethical issues. Aided by an eighteen-member advisory council representing many interest groups, it could engage in knowledge-processing activities, including the identification of emerging technologies and dissemination of its findings.

NCHCT was beleaguered for several reasons. The first was financial. Despite the broad-based mandate, NCHCT received only \$7.8 million of its expected \$73 million budget from 1978 to 1981. Limited resources greatly diminished its capacity to engage in knowledge development. Thus, NCHCT was most active in knowledge processing, primarily because data synthesis is cheaper than initiating studies and produces tangible results (Blumenthal 1983). Through creative leadership, the staff did complete evaluations of seventy-five technologies, concluding that 40 percent of these were either unproven or ineffective, and were not recommended for coverage and reimbursement (Perry 1982).

The second reason was internal and external strife. Competition for

funds and personnel created conflict among all elements in the DHHS. In particular, it has been argued that the authority of NCHCT to set the federal research agenda threatened NIH (Blumenthal 1983). Powerful external groups, concerned about rising medical costs and unnecessary uses of new technology (Fineberg and Hiatt 1979), were threatened by the actions of NCHCT. Although NCHCT had no real regulatory power, the newly created Health Care Financing Administration (HCFA) could request information from NCHCT to make coverage decisions under Medicare. Thus, NCHCT recommendations could potentially affect the marketability of products or access to medical procedures, threatening producers because it might limit sales and physicians who might believe in or profit by the technology. It was often difficult for affected interest groups to distinguish knowledge processing from regulation, at least in outcome.

By 1981, when it was necessary to reauthorize NCHCT, its early opponents resurfaced. Testimony by the AMA and HIMA was highly critical, although other organizations spoke in its defense, including representatives of the American College of Physicians (U.S. House of Representatives. Subcommittee on Health and the Environment of the Committee on Energy and Commerce 1981). No one within NCHCT or DHHS had the clout or perhaps the inclination to save it. The political environment had changed; cries for deregulation, budget cuts, and private-sector solutions to social problems all worked against NCHCT (Blumenthal 1983). Although Congress reapproved NCHCT in 1981, the administration failed to authorize funding. The agency closed its doors in 1982.

The private interests that helped to defeat NCHCT probably believed that by eliminating its efforts to control information they had prevented the government from becoming the gatekeeper of technology. However, NCHCT had also provided an open forum for debate of technology issues. The changes that occurred in the next two years made it clear that federal involvement in medical technology assessment was inevitable.

Round Two: Technology Assessment in the 1980s

A significant change in the political environment precipitated major realignments in attitudes toward medical technology assessment in the early 1980s. The passage of the Social Security Amendments of

1983 (Public Law 98-21), establishing the prospective payment system (PPS) for Medicare, institutionalized medical cost containment as a dominant federal policy. In this context, interested parties understood that information on benefits and costs was now essential in order to persuade government, the direct and indirect purchaser of over 40 percent of medical technology, as well as cost-conscious private payers, to cover them. Federal technology assessment was, in some form, inevitable.

This environment generated serious tension. On the one hand, the private sector had prevailed in the defeat of NCHCT and now saw its own role in technology assessment as primary. It was supported by the strong ideological preferences of the Reagan administration for reducing the size of government. To implement PPS, however, HCFA needed technology assessment information. The new problem was how to bake and serve a technology assessment pie that would satisfy both private and public sector expectations. Medical technology assessment is an expensive proposition if done thoroughly and comprehensively. At the same time that it was clear that technology assessments were critical and inevitable, cost constraints had become a priority. With pressures to keep costs down, there was little incentive for anyone to produce the needed information. How well the environment has responded, and will respond, to this tension will ultimately determine the success or failure of present strategies.

Changing Federal Role in Technology Assessment: The Legislative Branch

Several entities emerged in response to the changes in Medicare. At the same time as it established PPS, Congress created the Prospective Payment Assessment Commission (ProPAC) (Public Law 98-21) to analyze the impact of PPS on health care. It is a fifteen-member, permanent, independent commission in the legislative branch; OTA's director appoints commissioners who must represent a range of health care perspectives. The commission is charged with making recommendations to DHHS (April report) on appropriate payment rates and reports directly to Congress with comments on the actions of DHHS (November report). Thus, this independent commission can influence decisions on PPS in the executive branch and serve as a watchdog through its legislative role as well.

ProPAC's activities include two of Blumenthal's three layers of technology assessment. While only a portion of its responsibilities involve assessment, ProPAC can evaluate technologies that may have a critical effect on hospital inpatient reimbursement and has authority to collect original data using laboratory and clinical trials (but has not done so thus far). Therefore, it can undertake knowledge-development functions. ProPAC can also engage in knowledge-processing activities, collecting and assessing information in order to identify appropriate patterns of health resource use. ProPAC does not, however, make final coverage decisions and so has no formal regulatory function (U.S. Prospective Payment Assessment Commission 1985, 1986).

ProPAC presents some institutional solutions that reflect changing attitudes toward federal technology assessment. NCHCT had concentrated power in DHHS. ProPAC is structurally situated in the legislative branch, is appointed by OTA, which is bi-partisan in its own right, reports to DHHS and directly to Congress. Thus, ProPAC communicates with, but is independent from, DHHS. This is an important compromise because it allows participants from the private sector, as members of ProPAC, to attempt to influence the direction of PPS from several perspectives. And, because cost containment was inevitable, interested parties in all fields of health care realized that cooperation with ProPAC was necessary to affect policy. Although HCFA has not always supported ProPAC's recommendations, without some counterweight to HCFA, cost considerations under Medicare might predominate (Iglehart 1983). Thus, ProPAC is a politically acceptable institution for all parties involved.

Changing Federal Role in Technology Assessment: The Executive Branch

During this period, the executive branch has continued to struggle with structuring technology assessment functions. After the demise of NCHCT, some assessment activity has continued in the Office of Health Technology Assessment (OHTA), a small entity within NCHSR. OHTA has significantly less independence and more limited authority than NCHCT. HCFA forwards to OHTA requests for evaluations and the two staffs work closely together in developing the scope of the analysis (Institute of Medicine 1985). These evaluations are limited to safety and efficacy issues and are tied to HCFA's coverage decisions.

OHTA's minuscule budget for 1985 of \$700,000 virtually precludes any knowledge-development activities.

Another round of reshuffling within DHHS occurred with the passage of the Health Promotion and Disease Prevention Amendments of 1984 (Public Law 98-551). This new law attempted to reemphasize the importance of technology assessment within PHS, absent many of the controversial functions of the deceased NCHCT. For example, NCHSR was renamed the National Center for Health Services Research/Health Care Technology Assessment (NCHSR/HCTA), but the functions of technology assessment remain in OHTA, unlike the independent NCHCT. Nor does NCHSR/HCTA have the authority to establish priorities of technologies, another controversial NCHCT function, and remains limited to advising HCFA on coverage issues. The proposed budget of \$3.5 million for technology assessment in 1986 is insufficient for substantial knowledge development. However, the NCHSR/HCTA can utilize OHTA to engage in knowledge processing, such as the development of criteria and methods to make coverage decisions. There is an opportunity for private-sector participation in the assessment activities through the National Advisory Council on Health Care Technology Assessment, a new group composed of representatives from a variety of disciplines and interest groups. This advisory council met for the first time in early 1986; it is too early to evaluate its activities.

Public-Private Partnerships

Recommendations of a larger role for the private sector in medical technology assessment surfaced in the literature soon after the demise of NCHCT. Many proposals were based on the premise that the public and private sectors should cooperate in technology assessment, and that the partnership should be part of the private sector rather than a public agency (Bunker, Fowles, and Schaffarzick 1982; Perry 1982; Relman 1982; Brandt 1984). There are several explanations for the popularity of these proposals. A cynic might suggest that the private sector had destroyed any viable role for government by defeating NCHCT, and now sought to control the direction of assessment itself. An optimist would argue that medical technology assessment is a public good that requires the joint efforts of all interested parties to accomplish the goals, and the private sector now wanted to contribute

its fair share (Bunker, Fowles, and Schaffarzick 1982). Whatever the motives, however, it was clear that the need for information, and the ideological preference for private-sector participation, gave life to this concept. Bringing the idea to fruition, however, presented the chronic and difficult structural questions: who would control the "partnership," what would the scope of its activities be, and who would pay for its work?

The Institute of Medicine (IOM), chartered by the National Academy of Sciences in 1970 to examine health policy and advise government, promoted the partnership concept. The IOM formed the Committee to Plan a Private/Public Sector Entity to Assess Technology in Medical Care in 1983 (Institute of Medicine 1983). Its final recommendations appeared in the Barondess report (Dr. Jeremiah Barondess of Cornell Medical Center was the chairman). The report called for the creation of a partnership composed of fifteen members from the public and private sectors with "ideal" financial support coming equally from both. Its responsibilities would include knowledge development and knowledge processing.

Congress based the public/private partnership provisions in Public Law 98-551 on the Barondess report. The law authorized a grant to establish a Council on Health Care Technology, composed of ten members from the private sector appointed by the IOM, three members of the public sector appointed by DHHS, and the Director of OTA as an ex officio participant. The new entity was to be funded by a \$500,000 federal grant on the condition that twice that amount be raised in the private sector. The activities of the council were to include knowledge development through the stimulation, coordination, and commission of assessments, and knowledge processing through the promotion of assessment, review of existing technologies, and development of criteria and methodologies for assessment and establishment of a clearinghouse for information on available data.

President Reagan dealt a minor blow to the partnership concept when he signed the law in October of 1984. He objected to the structure of the council because the appointments clause of the Constitution prevents Congress or any entity that is not an agency of the United States from appointing persons to carry out official tasks (U.S. Constitution, Art.2,sec.2,cl.2). Citing *Buckley vs. Valeo*, (424 U.S. 100), the 1975 Supreme Court case construing the structure of the Federal Elections Commission, the President recommended that the

council be reconstituted either as a governmental agency in accordance with the Constitution or as a private nongovernmental organization whose members do not have significant duties pursuant to a public law (*Weekly Compilation of Presidential Documents* 1984). In response to these concerns, Congress passed technical amendments in 1985 (Public Law 99-117) that removed the original provisions that DHHS appoint three members of the council and the director of OTA be an ex officio member. Council membership was now to be entirely drawn from the private sector. The public side of the partnership was limited to providing the matching grant and requiring the council to submit an annual report to DHHS for transmittal to both houses of Congress.

The IOM Council held its first meeting in early 1986; it is too early to evaluate its work. It has succeeded, however, in raising funds from a variety of private sources, including professional organizations, producers, and insurers (Institute of Medicine 1986). Judging from the initial response, it would seem that Blumenthal's predictions (1983) were off the mark: "[G]iven their previous disinterest in research on health care technologies, these private interests seem unlikely to commit substantial funds of their own to knowledge development efforts." Industry support validates the conclusion that changing political realities make private-sector participation in medical technology assessment essential.

Evaluation

Have we produced a coherent set of institutional arrangements to undertake medical technology assessment? As the previous discussion makes clear, we do not have one superagency directing assessment activities, nor do we have a simple set of structures. Instead, there is a complex web of interlocking institutions situated in both the legislative and executive branches of government, as well as in the private sector. Nor is there a clear division among their functions. There are mechanisms for public/private interactions as well as overlapping responsibilities. While this environment might appear "incoherent" at first glance, the present structure comes close to satisfying Breyer's model. The following discussion highlights the strengths and deficiencies of the present plan.

A successful structure must adequately address the tension identified

earlier—that is, creation of an acceptable balance between the public and private sectors with secure and sufficient resources. The current institutional arrangements may well succeed on the first issue and, while there remains a chronic undervaluation of medical technology, there are some new sources of funding on the horizon. One of the achievements of the last few years has been a fundamental acceptance of the necessity for both the public and private sectors to participate in the process. In the late 1970s, industry perceived that the federal regulators would control technology assessment and bias outcomes in favor of cost containment or other public goals. Even if that fear was unfounded, it provided a strong rationale for industry to resist federal technology assessment efforts. In the wake of changing economic conditions, private interests have accepted the necessity for government intervention in this regard because it was clear that cost containment would proceed with or without technology assessment.

For its part, however, government has not barred meaningful participation by the private sector, recognizing its particular contribution and expertise. The institutionalization of an advisory role for the private sector in ProPAC, with direct lines to DHHS and to Congress, an advisory role at NCHSR/HCTA, and a controlling role in the Council on Technology Assessment all give the private sector a greater stake in technology assessment. It is important, however, to recognize that each sector has particular strengths and weaknesses at various levels of assessment and the success of the balance between public and private roles depends on an understanding of these divisions.

Knowledge Development. The present institutional arrangement permits knowledge development from a wide variety of institutions, both public and private. A diversity of perspectives is beneficial and reflects the pluralism of the society in which technology is consumed. Both the public and private sectors have much to contribute to the base of information upon which policy is made. Thus, the proliferation of institutions charged with responsibility in this area may ultimately contribute to the “coherence” of technology assessment.

There are, however, two important conditions that must be satisfied. The first is resources. Developing information about medical technologies is the costliest of all assessment activities. There has been a chronic shortage of resources for knowledge-development activities. In the past, with the exception of scattered assessments by professional research organizations and professional groups, and private corporate research

and development activities, the federal government has borne the costs of technology assessment. And that federal contribution has been niggardly at best. Additional resources must be committed. There are several possible sources to supplement direct federal grants. The IOM Council has successfully raised funds from private companies, insurers, and professional organizations. Of course, dependence on voluntary private funds is a mixed blessing. Particular contributors may try to control outcomes which will bias council conclusions and raise questions of legitimacy. In addition, the funding is inherently unstable as economic downturns or disapproval of council decisions could threaten the income stream. Some of these problems can be overcome with a broad diversity of contributors and controls on the size of the contributions. Other options include laying claim to a portion of Medicare trust funds. Senators Proxmire and Durenberger have both introduced bills that would sponsor studies on medical outcomes from this source (U.S. Senate 1986: S. 2114, S. 2554). Use of Medicare funds, however, may be inappropriate if medical services are reduced as a consequence. (Of course, in the long run, technology assessment may itself reduce costs by identifying inappropriate use of technology.) Other untapped sources include a mandatory tax on insurers, providers, or consumers. Compulsory taxation provides a reliable and steady source of money and eliminates expectations of direct influence on assessment conclusions. Perhaps the voluntary strategy will be a necessary bridge to recognition of the need for assessment and for additional mandatory sources of funds. At the very least, the private sector has now "bought" into the concept and may be willing to accept public participation down the road.

Second, although diversity is beneficial, multiple activities may leave information gaps. Thus, coordination is essential and can be considered an important link between knowledge development and knowledge processing.

Knowledge Processing. This includes designing systems for gathering, validating, interpreting, and disseminating information. Diversity of perspectives is important here as well, particularly when interpretations of data go beyond technical questions of cost or safety, and involve ethical value or resource distribution tradeoffs between cost and benefits. On the other hand, there are risks of duplication and waste, particularly when developing a clearinghouse for data. In addition, it is difficult to draw a distinct line between organization and interpretation of data

and regulatory or quasi-regulatory effects. In some ways, he who interprets the data may control the outcome. Neither the public nor the private sector must acquire a monopoly on conclusions about medical technology, or dominate the setting of criteria and standards. Clear pathways are now lacking by which the many institutions authorized to engage in knowledge processing will communicate among themselves and identify the perspectives that they bring to bear on the issue. Perhaps informal channels, such as the participation of federal officials in IOM council meetings as observers, will suffice. There is a risk, of course, that identification of lines of communication will suggest hierarchies that threaten the balance between public and private institutions. As a matter of policy, it is better to clarify the lines of communication and resolve the tensions than try to avoid them. As presently structured, however, blurred links may create weakness in the present institutional environment.

Regulation. This is one area that belongs to the public sector alone. Given the self-interest of the private sector, the Constitution forbids excessive delegation of lawmaking authority to private interests. In the case of medical technology assessment, ultimate decisions about distribution and access are public policy issues. Although the IOM council, for example, includes individuals from many health care fields, it is not representative in the political sense—the members are not chosen by the public to “represent” them. Nor is the group accountable to the public, thereby lacking legitimacy as a policy maker. Thus, the federal government’s role is essential.

At this time, the FDA does an adequate job of regulating the safety and efficacy of drugs and devices, and HCFA has undertaken the task of making Medicare coverage decisions. There are serious, though understandable, shortcomings in federal policy making toward some of the difficult social issues such as distributional equity of lifesaving technologies. The recent publicity surrounding organ transplantation illustrates the dilemmas that government has not yet solved. These critical social issues must be aired in a public forum and Congress should make comprehensive policy decisions. It has been observed that: “implicit rationing will not suffice. Increasingly we are going to have to say no, and we must be prepared with reasons” (Lowrance 1986). In sum, Congress and federal regulators will not be able to avoid the hardest distributional and equity questions indefinitely.

Conclusion

Our present institutional structure can accomplish technology assessment if we carefully attend to the need for an appropriate balance between public and private roles and for adequate financial support. There has been much institutional experimentation in the last two decades, and despite many false starts, progress has been made. The private sector has moved from hostility and suspicion to acquiescence, if not acceptance, of the need for federal technology assessment. The opportunities for cooperation among branches of government and the private sector may also presage greater institutional coherence in the future. Applying Breyer's model, there appears to be a rational match between the institutional forms and the goals to be achieved, although some deficiencies remain. Recalling the analogy composed by Edna St. Vincent Millay: there has been progress in construction of the loom. Although the fabric has some imperfections, the weaving has surely begun.

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