Federal Policy toward Health Care Technology: The Case of the National Center

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HEALTH CARE SCHOLARS AND POLICY MAKERS HAVE devoted increasing attention in recent years to designing appropriate federal policies toward health care technology (Altman and Blendon 1979; Banta, Behney, and Willems 1981; Office of Technology Assessment 1981). A number of factors appear to have motivated this interest. Health care technologies have been linked to problems with the cost and quality of health care in the United States (Fineberg and Hiatt 1979). There is also a widespread impression that new health care technologies have been entering the marketplace at an increasing rate, and that this trend is likely to accelerate in the future.

Responding to these concerns and developments, the Congress in 1975 directed its Office of Technology Assessment (OTA), a staff agency devoted to research on technology-related issues, to begin a series of studies on health care technology problems. Three years later, stimulated in part by OTA's pioneering work, the Congress passed legislation (Public Law 95-623) creating a National Center for Health Care Technology (NCHCT). Though disbanded in 1981, the National Center remains the only federal program ever enacted whose sole and specific purpose was to affect the way health care technologies are

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used in the United States. Given its tasks and special mandate, understanding the NCHCT's experience may prove highly relevant to future efforts at developing health care technology policy at the federal level.

This paper examines a particular facet of the Center's experience: the political and institutional factors which influenced the implementation of its mandate. That particular focus is chosen for two reasons. Perhaps the most important is that political and institutional factors played a decisive role in the brief history of the National Center, including its early demise. A second, related reason is that political and institutional factors are likely to play a significant part in any future effort to implement technology policy at the federal level. As Bardach (1977) has pointed out, "Implementation games . . . are political games."

This account is not the first to note the importance of political influences in the Center's brief history. In a recent account of the Center and its termination, Perry (1982) discussed in some detail the role of industry and health professional organizations in bringing about the Center's demise. Perry's emphasis is appropriate. There is no question that some outside groups, including the American Medical Association, worked hard and effectively to undermine aspects of the Center's program. Neither the Center's demise, however, nor its performance prior to that event, can be wholly attributed to the influence of its extra-governmental antagonists. A fuller analysis of the Center's experience must take into account a broad array of political and institutional factors which together rendered it highly vulnerable to attack.

For purposes of discussion, those factors can be grouped into two loose categories: organizational influences and environmental influences. Organizational influences consist of political and institutional factors intrinsic to the organization directly responsible for implementing the Congressional directive to establish a National Center for Health Care Technology. This organization is taken to consist of the Department of Health and Human Services (DHHS) and its subunits, of which the new Center was one. Environmental influences consist of political and institutional forces external to the implementing organization.

The designation of these two categories of political and institutional factors—organizational and environmental—is somewhat arbitrary, but has precedent in the literature on innovation in public agencies. Downs

(1976), in particular, has noted the importance of taking into account both bureaucratic/organizational factors and environmental factors in trying to explain or predict the success or failure of efforts at institutional change, of which the Center's creation is arguably a case. While a full exploration of the literature on institutional innovation is beyond the scope of this paper, that literature does identify a number of discrete organizational and environmental influences which, as we shall see, have relevance to the Center's history. Some of those organizational factors include: the availability or lack of availability of resources in innovating organizations (Allison 1971; Downs 1976); the commitment of agency leadership to planned innovations (Bardach 1977; Downs 1976; Yin 1979); the traditional mission and capacity of involved organizations (Allison 1971); the perceived benefits or "payoff" of the innovation for involved organizations (Yin 1979); and decisions concerning the bureaucratic placement of the innovative function or task in involved organizations (Gawthrop 1979). Some environmental influences relevant to the Center's experience include: the presence and nature of constituency support or opposition to a proposed innovation (Yin 1979); the visibility of the innovation among constituencies (Downs 1976); trends in fiscal policy; and trends in political ideology within government and the nation as a whole (Downs 1976).

In exploring the effect of such environmental and organizational influences on the Center's functioning and demise, we will emphasize the ways in which these factors affected the Center's ability to implement particular strategies for affecting the use of health care technologies. By strategies, we mean the general methods or policy approaches through which the Center was directed or sought to achieve its objectives in the area of technology policy. By focusing on the success or failure of its policy initiatives, rather than on the Center as an institutional entity, we can examine directly the institutional or political viability of certain generic governmental approaches to influencing the use of health care technologies. Even when employed by the same institution, different approaches with the same policy objectives may encounter very different political and institutional obstacles, and enjoy different probabilities of success (Downs 1976).

The paper itself proceeds in three parts. The first section provides background on the policy problem the NCHCT was created to address, and discusses the strategies Congress chose to pursue through its mandate to the Center. The second section provides a brief overview

of the Center's history, examines the Center's attempts to implement its mandate, and discusses policy implications of the Center's experience. A third section presents concluding remarks.

I. Health Care Technology: Problem and Solutions

A brief description of the technology policy problem is essential to understanding the Center's experience. Such a discussion must begin with a definition of the term "health care technology."

Popular notions of what constitutes a health care technology typically emphasize large, expensive, readily identifiable pieces of equipment such as CAT-scanners, electronic fetal monitors, nuclear imaging equipment or ultrasound imagers. In fact, the definition of technology used in most policy discussions is usually much more inclusive and less precise. The definition contained in the Center's enabling statute, P.L. 95-623, is typical:

> For the purposes of this section, the term "health care technology" means any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services.

As this construction of the term makes clear, "health care technology" refers in most policy discussions to the entire gamut of practices, procedures, and devices employed by health care practitioners and institutions in delivering health care services.

Current concerns about health care technologies have developed out of evidence that they are not always optimally used by health care providers and patients. New health care technologies, it is argued, are often widely applied before their safety and efficacy have been fully assessed (Gaus and Cooper 1979; Fineberg and Hiatt 1979; Office of Technology Assessment 1981). Similarly, some existing technologies are thought to be applied excessively or inappropriately. The inappropriate use of new and existing technologies is encouraged, the argument continues, by prevailing incentives (financial, professional, institutional, and cultural) in the health care system, as well as by the extraordinary productivity of medical science in generating new technologies.

The misuse of technology, it is felt, contributes to problems in both the cost and quality of health care. For example, one-third of the increase in the annual cost of hospital services can be attributed to growth in the "intensity" of services used during an average stay (Joskow 1981). Increased use of new and existing health care practices, procedures, and devices has undoubtedly contributed to the growth in intensity of care. Questions are raised about whether the marginal benefits of these applications of technology justify their costs (Fineberg and Hiatt 1979).

Comparable questions are raised about the effect of technologies on the quality of care. The excessive or inappropriate use of health care practices, procedures, and devices may result in reduced patient comfort, unnecessary complications, and even increased illness and death. Gastric freezing, which resulted in several patient deaths but had no known efficacy, is cited as an example of the way misuse of technology may impair health care outcomes (Office of Technology Assessment 1981).

Whether the focus is on quality, cost, or some other valued objective of health care delivery, one feature of the health care technology problem seems to merit special emphasis. In an important sense, technologies themselves are not the culprit. As the final report of a 1977 conference on medical technologies concluded:

> New technology as such does not significantly boost costs: it is the *behavior* of individual persons and human institutions—the way in which they use the new technology—that leads to the cost rise (Altman and Blendon 1979).

Health care technologies do not apply themselves. Their use results from human decisions: chiefly, the decisions of health care practitioners. If technology is a problem, that problem has its origins in patterns of medical decision-making which are in some way suboptimal: either misinformed or inappropriate in light of society's resource constraints. "Solving" the technology problem, therefore, requires nothing less than optimizing medical decision-making: making certain that health care institutions and practitioners utilize new and existing medical practices, procedures, and devices in a fashion that produces maximal patient benefit for a given investment of medical resources.

Achieving this goal may be practically or theoretically impossible (Schwartz and Joskow 1978). Certainly its attainment is beyond the capacity or competence of the public sector acting alone. Nevertheless,

the federal government could promote incremental improvements in health care decision-making through a number of possible strategies or policy approaches (Banta and Behney 1980). In devising the legislative mandate of the National Center for Health Care Technology, the Congress directed it to pursue three such strategies: knowledge development, knowledge processing, and, indirectly, the regulation of health care technologies.

1. Knowledge development. It is now widely recognized that we know little about the safety, efficacy, cost, and cost-effectiveness of many new and existing medical practices, procedures, and devices. Without such knowledge, physicians and other health professionals can hardly be expected to use their medical armamentarium efficiently.

"Technology assessment" is a term which has come to describe a form of knowledge development considered particularly relevant to technology policy (Banta and Behney 1981). In most policy discussions, the term is used to include a variety of knowledge development activities which range from clinical trials testing the safety and efficacy of medical practices, procedures, and devices, to cost-effectiveness and cost-benefit analyses, to ethical and legal assessments of the societal implications of particular technologies.

The support of knowledge development through funding technology assessment is clearly one way in which the federal government might contribute to optimizing medical decision-making (Office of Technology Assessment 1978), and the Congress placed heavy reliance on this policy approach in designing the new National Center. Public Law 95-623 directed the Secretary of the Department of Health and Human Services, acting through the Center, to:

- undertake and support (by grant or contract) assessments of health care technology;
- encourage and support (by grant or contract) research, evaluations and demonstrations respecting the safety and efficacy of particular health care technologies.

The Center was also empowered to set priorities for research activities concerning health care technologies throughout the Department of Health and Human Services. Recognizing that research and demonstrations, and especially clinical trials, can be quite expensive, the Congress provided the Center a relatively generous authorization of $73 million over three years.

2. Knowledge processing. While necessary, knowledge development alone will not solve the technology problem. The history of medical science is replete with examples of new findings which languish unappreciated in medical journals (Comroe and Dripps 1977), and of instances in which new technologies were rapidly adopted based on information later found to be inaccurate, incomplete, or unreproducible (Fineberg and Hiatt 1979).

These phenomena suggest that medical practice might be improved through the development of systems for, in effect, processing information concerning health care technologies: gathering new and existing information, validating it, interpreting it, packaging it, and disseminating it to appropriate public and private audiences. One typical knowledge processing activity is the consensus development conferences which have been recently sponsored by the National Institutes of Health (Perry and Kalberer 1980).

Knowledge processing activities figured prominently in the mandate of the National Center for Health Care Technology. Public Law 95-623 created an advisory body to the NCHCT called the National Council on Health Care Technology. Consisting of 18 experts on health care technology and a number of ex officio government officials, the Council was instructed among other things to undertake the following tasks:

- after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the use of particular health care technologies;
- promptly publish, disseminate, and otherwise make available through the National Library of Medicine, standards, norms, and criteria.

The Center was instructed, as well, to collect a list of "emerging technologies": medical practices, procedures, and devices which were in an advanced state of development, or in very early stages of use. This list was intended to serve as a guide for setting priorities in knowledge processing and knowledge development efforts.

3. Regulating health care technologies. A third possible federal strategy for influencing the use of health care technologies is the direct regulation of their development, dissemination, and use. Politically sensitive,

the regulation of medical technologies is also technically difficult, for it assumes the regulator knows how technologies should be used in a vast array of complicated medical situations (Blumenthal, Feldman, and Zeckhauser 1981).

As its administrators would later emphasize, the Center was assigned no statutory authority to regulate health care technologies. While this view is technically correct, the National Center was assigned responsibilities which supported regulatory or quasi-regulatory functions of the Department of Health and Human Services. Specifically, the Center was authorized to "make recommendations to the Secretary respecting health care technology issues in the administration of the laws under the Secretary's jurisdiction, including recommendations with respect to *reimbursement policy*" (italics added).

The authority to make recommendations concerning reimbursement policy was intended to strengthen the administration of a departmental function which, though not strictly regulatory, was widely regarded as coercive by important health care groups. Section 1862(a) of the Social Security Act requires that Medicare reimburse providers for all "reasonable and necessary" services delivered to Medicare patients (Greenberg and Derzon 1981). Implicit in this provision is the authority to decide that certain technologies are not "reasonable and necessary" in particular uses or under any circumstances.

Prior to the Center's creation, administration of the "reasonable and necessary" provisions of Medicare was widely regarded as inadequate. When the issue of whether to pay for a particular test or treatment arose, officials of the Health Care Financing Administration (HCFA) generally made the decision based on ad hoc inquiries among physicians in the Public Health Service, scientists at the National Institutes of Health (NIH), or experts in the medical community at large. The resulting advice was often slow to arrive, or was uneven in quality. As one former HCFA official commented, the process was "ripe for suit or scandal" (Smits 1981). The Center's authority to advise the secretary on reimbursement policy was specifically inserted by authors of the House version of P.L. 95-623 in the hope that the Center's involvement would improve the speed and quality of Medicare coverage decision-making.

As one DHHS official would later emphasize: "We say again and again, our opinion is advisory and HCFA does not have to accept it" (Hanft 1981). However, advisory or not, the Center's involvement in

coverage decision-making linked it in substance and appearance to a function which directly influenced the potential marketability of new products and the range of choices available to health professionals in treating an important patient group. The Center's advisory role to HCFA, therefore, was generally regarded as regulatory or quasi-regulatory by important interests outside government.

In choosing these three approaches to the technology problem and in creating the National Center to implement them, the Congress had no guarantees of success. Like so many initiatives by our national legislature, this was an experiment in governance. The following section explores the results of that experiment, seeking its political and institutional lessons for policy toward health care technology.

II. Implementing Strategies: The Center's Record

The Center after Enactment

In the annals of federal health policy initiatives, the National Center for Health Care Technology may rank as one of the briefest and smallest on record. Though authorized to spend $73 million over three years, the Center was appropriated only $7.8 million during that time. Its official staff allocation, also set by the appropriations process, was never more than 20, but creative management by the Center's director, Dr. Seymour Perry, enabled the NCHCT to obtain the services of 39 individuals.

The Center's authorization expired at the end of fiscal year 1981, and by that time the Carter administration, which was, by and large, sympathetic to the Center, had been replaced by a Reagan administration determined to reduce federal spending and ideologically opposed to regulation in health or other spheres. The Reagan administration opposed the Center's reauthorization. The Republican Senate complied with the administration, but the House reauthorized the Center, largely because of the vigorous support of Congressman Henry Waxman (D.-Cal.), chairman of the Health and Environment Subcommittee of the House Committee on Energy and Commerce. The Center also benefited from the fact that, during floor consideration in the House,

its legislation was attached to a Medicaid proposal which had strong support from state governors. During House-Senate conference, the House prevailed.

In reauthorizing the Center, however, the Congress curtailed its activities through legislative changes which had the effect of reducing its capacity to undertake knowledge development and processing activities, while leaving its quasi-regulatory authorities intact. The Center's authorization was drastically reduced to a total of $12 million over three years. Since research activities consumed most of the Center's budget and are inherently more expensive, this change in budgetary authority undercut the Center's knowledge development capacity. The revised legislation also eliminated its authority to devise and distribute exemplary norms, standards, and criteria for the use of health care technologies.

While the congressional decision to reauthorize the Center briefly heartened the Center's supporters, their hopes were soon dashed. In the appropriations process, the administration emerged triumphant. Provided no funds for fiscal year 1982, the Center ceased to exist in October 1981.

Knowledge Development

While the Center's staff was proud of the quality of the research it undertook and supported, the NCHCT was never able to fully implement its knowledge development strategy. By the fall of 1981, the Center was supporting only a minuscule research program of about 20 projects costing about $2 million annually. The NCHCT's failure to accomplish its knowledge development objectives reflected the influence of political and institutional factors, both environmental and organizational in nature.

Perhaps the most important environmental factor was the increasing pressure to slash federal spending and reduce budget deficits. While the effort to cut federal spending reached unprecedented proportions in the Reagan administration, budgetary pressures had an important effect on the Center even during the Carter administration. Carter's Office of Management and Budget repeatedly cut the Department of Health and Human Services requests for Center funding. Senate and House appropriations committees generally cut the formal administration

request still further. As one former appropriations staffer put it, "There has to be a pretty damn interesting reason for a Senator to put money in a new program these days" (Lierman 1981).

Other environmental factors help to explain why the Center's research activities never stimulated sufficient congressional or administration "interest" to compete for funds in a time of scarcity. First, the Center lacked significant constituency support for its knowledge development activities. The Center's research strategy did not have clear, well-understood benefits for groups not directly supported by Center funds. Unlike biomedical research, which has an apparent link to human health and disease, technology assessment and related activities are much more difficult for laymen and even uninvolved researchers to comprehend. As Dr. Julius Richmond (1981), Assistant Secretary for Health when the Center was created, would later comment:

> It was difficult to generate much support because you didn't have an [action] arm. You could define studies, but what would you do with them? . . I didn't see any great pressure from constituent groups or more liberal health constituencies to do something about this issue.

This absence of constituency support created a fundamental political weakness which made the Center's knowledge development strategy vulnerable not only to cost-cutting pressures in the Congress, but also, as we shall see, to bureaucratic competitors as well.

A number of organizational factors combined with environmental factors to frustrate implementation of the Center's knowledge development strategy. To begin with, the Center research mission lacked vigorous backing from key leaders within its parent organization, the Department of Health and Human Services. As Richmond's comments indicate, senior administrators in DHHS had as much trouble as outside constituents perceiving the short-term benefits of knowledge development activities. The small size of the Center also created a vicious cycle. Pressed for time, busy senior officials tended to assign the Center's activities lower priority than larger programs, with the result that the Center lacked the patronage needed to make it grow. Not surprisingly, middle level officials working to make the Center function felt abandoned. "We didn't get the support we needed at the administration end," commented Ruth Hanft (1981).

Still another organizational factor undermining the Center's knowledge

development strategy was competition over funds and authority between the Center and powerful, preexisting research agencies within the Department of Health and Human Services. To understand the nature and sources of that competition, it is necessary to briefly discuss the organizational setting in which the National Center found itself.

At the time the Center was created, three agencies in the Department already had legislative authority to do the research the Center was mandated to perform. The National Institutes of Health, the single largest supporter of health research in the world, was authorized to undertake virtually any research related to human health and disease. In 1979, the year the Center became operational, the NIH actually spent over $136 million on clinical trials testing the safety and efficacy of health care technologies (Office of Technology Assessment 1981). Similarly, the National Center for Health Services Research (NCHSR), a small research agency in the immediate office of the Assistant Secretary for Health, had authority to conduct evaluations of health care technologies. Finally, the Health Care Financing Administration (HCFA), through its Office of Research and Demonstrations, had authority to conduct research and demonstrations related to its reimbursement functions.

For varying reasons related to their missions and capacities, none of these agencies was considered appropriate by congressional proponents of the Center for undertaking the research it was assigned. The National Institutes had the resources (its budget in 1979 totalled $3.2 billion), but not the interest or ability to undertake technology assessments as these were envisioned by congressional policy makers. The agency defined its mission to exclude the assessment of social and economic impacts of health care technologies and, among a staff of thousands of professionals, did not have a single economist when the Center was created.

While the strength of the NIH's traditional mission made it a problematic home of the Center's knowledge development activities, the National Center for Health Services Research was regarded as unsuitable because it appeared to be an agency in decline. Its budget had suffered staggering cuts, plunging from over $80 million in 1968 to less than $30 million in 1978.

Finally, the Health Care Financing Administration presented a different set of problems. Though it had a research arm, it had little research experience compared with the NIH or the NCHSR. It had no formal

peer review system for judging the scientific merit of research grants. Long on economists, it was short on physicians and health scientists. As Dr. John Ball (1981), a physician in the Office of Science and Technology Policy, observed, "I don't think HCFA will ever have the medical expertise or the mindset or the philosophy to do what the Center does."

All three of these agencies felt at various times and in various ways that the Center was encroaching on their institutional territory. From the Center's viewpoint, frictions with the NIH were by far the most important. Two organizational factors aggravated this competition. The first was the lack of resources available to the Department of Health and Human Services as a whole. A direct consequence of an environmental problem—prevailing budgetary stringency throughout the federal government with shortages of money and staff—cast the Center as a new claimant on a fixed pool of research resources within the Department. The resulting competition for funds and personnel became explicit from the moment the Center's legislation was enacted. To fund its fiscal 1979 activities, the Department of Health and Human Services asked the congressional appropriations committees to divert funds from the National Institutes of Health to the Center. Later, in the final throes of the 1982 appropriations battle to save the Center, Congressman Waxman introduced an amendment on the House floor which would have funded the Center out of the 1981 NIH appropriation. Both efforts failed. Few agencies have been more successful in defending their budgets over time than the National Institutes of Health, which has powerful constituencies in the Congress and research communities, and which has learned over thirty years how to mobilize those constituencies in its support (Strickland 1971).

A second source of friction between the Center and the NIH was the fact that the Center's mandate threatened NIH's institutional autonomy. The Center, it will be recalled, had authority to set priorities for research on health care technologies anywhere in the Department of Health and Human Services. "If you really carry technology assessment to its endpoint," commented Hanft (1981), "it will question where you put your development money."

The prospect of an outside agency trying to influence NIH research or development activities was profoundly troubling to some NIH officials and to some outside constituents of the NIH. As one such group, the Association of American Medical Colleges, commented:

> It should be noted that there is a continuing danger for NIH . . . that research on basic processes of health and disease supported by a federal agency may suffer from the political pressures for short-term gains with an emphasis on application and large-scale service programs. Therefore, care must be taken not to permit or force the NIH to broaden its mission (Sherman 1980).

Given the Center's lack of funds, the redirection of existing departmental resources represented virtually the only way to accomplish its research objectives. However, the Center never sought to influence NIH resource allocations, directly or indirectly. The decision not to implement its authority to coordinate research on technology in the Department reflected, in all likelihood, a recognition that the NIH would have strongly contested any such initiative. Speaking of the Center's potential role in coordinating departmental activities on technology, Dr. David Calkins (1981), former special assistant to Secretary Patricia Harris, commented, "The only way that could happen would be for the Secretary to provide pressure and leadership." Research concerning health care technology was simply not important enough at senior levels of the Department to justify that kind of investment of concern and energy. The payoff was too remote, the subject too abstract, and the Center too small and politically isolated.

Policy Implications. This series of environmental and organizational obstacles constituted serious political and institutional impediments to the knowledge development strategy which the National Center was mandated by Congress to pursue. As a means for affecting the use of health care technology, the Center's research initiative suffered environmentally from a general scarcity of governmental resources and lack of constituency support. Organizationally, the Center's knowledge development mission faced manifest and latent opposition from powerful competing agencies in the Department, but lacked strong commitment from the Department leaders.

Since the collapse of the Center's research strategy, advocates have proposed alternative approaches to generating new knowledge concerning health care technologies. Bunker and his colleagues have suggested the creation of a nongovernmental Institute for Health Care Evaluation to support research on medical practices, procedures, and devices (Bunker, Fowles, and Schaffarzick 1981). Funding would be provided primarily by private-sector groups, though government might assist through grants or contracts. While attractive in certain ways, the

proposed Institute fails to address a fundamental political problem which undermined the Center's research strategy. That strategy failed in large part because private groups, including the insurance companies, were unwilling to lobby on behalf of the Center's research budget. Given 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.

While the discussion of private approaches continues, the federal government has embarked on another experiment in developing new knowledge concerning health care technologies. During consideration of recent amendments to the Social Security Act, the Congress quietly adopted a provision creating a 15-member Prospective Payment Assessment Commission, which will advise the Secretary of Health and Human Services concerning the implementation of Medicare's new prospective payment system. At the initiative of a small group of congressional staff, the new Commission was granted authority and funds to support "original research and experimentation, including clinical research," on a range of matters, including the safety, efficacy, and cost-effectiveness of medical technologies. Two features of the Commission's mandate are especially novel. First, its members would be appointed by the Director of the Office of Technology Assessment, giving the new body an appearance of independence and objectivity. Second, its support would come from the Medicare trust fund, which advocates of technology assessment have long sought to tap (Bunker, Fowles, and Schaffarzick 1981).

Since the president's signature on these new provisions is barely dry, their full effect may not be known for some time. Still, a cautionary note is in order. Unlike usual trust fund expenditures, monies for the new Commission will apparently be allocated through the normal appropriations process, a requirement which could make the Commission's knowledge development function vulnerable to environmental problems which undermined the Center's research efforts. Lacking any significant constituency, technology-related research has not competed well in the appropriations process with traditional research activities.

The Commission's independence may also prove a mixed blessing. The Congress has never before initiated major research programs outside the executive branch of the federal government, and may be reluctant to provide substantial funds to a commission whose accountability is

obscure, and whose research mandate overlaps so greatly with that of the ever-popular NIH. In addition, since the executive branch tends to react with suspicion to organizations which assume its functions but are beyond its direct control, the president is likely to oppose funding the Commission's research programs. Finally, the NIH and its constituents could, over time, seek to curtail the Commission's clinical research activities if those are perceived to be drawing money away from the NIH.

As the potential difficulties of these alternatives make clear, the problems which frustrated the Center's knowledge development strategy will not yield to quick or simple solution. The Center's research mission embroiled it in the politics of health care research, an arena in which the warfare is no less intense for the fact that gladiators sometimes don white coats. The Center came to this competition, however, as a weak new recruit with few environmental or organizational resources at its disposal. This weakness reflected characteristics inherent to the knowledge development strategy and cannot be attributed to peculiar features of the Center or the individuals involved. As long as the government faces resource scarcity, as long as the payoff of technology assessment seems diffuse and distant, as long as that activity's constituency remains weak, as long as the department's leadership is busy and politically attuned, and as long as other research agencies remain protective of their prerogatives, knowledge development concerning health care technologies will be difficult to institutionalize in the federal government.

Knowledge Processing

The National Center for Health Care Technology undertook a number of activities involving the collection, synthesis, validation, packaging, or dissemination of existing knowledge concerning health care technologies. In accordance with its authorizing legislation, the Center compiled the first known list of health care technologies on the verge of widespread application in clinical medicine. The Center also co-sponsored with the NIH several "concensus conferences" which brought together from around the country selected experts for the purpose of evaluating the safety, efficacy, costs, and cost-effectiveness of particular technologies. Finally, the Center undertook specific efforts at collecting, synthesizing, and assessing existing knowledge for the

purpose of assisting regulatory authorities within the federal government. These latter efforts are discussed in the next section.

Viewed through the prism of the Center's experience, knowledge processing activities have some characteristics which facilitate their implementation. Collecting and synthesizing existing knowledge is generally cheaper than initiating new research, an advantage in a time of fiscal scarcity. Knowledge processing also has immediate, visible products in the form of reports and other documents, which make knowledge processing activities easier to defend before skeptical administration and congressional observers looking for quick results. Such products may also have short-term utility to potentially influential constituency groups, including physicians, hospital administrators, insurance companies, and state and local regulators.

These relative advantages aided the Center's attempts to implement its knowledge processing strategy. Several constituency groups, including Blue Cross and Mutual of Omaha Insurance Company, made brief, hesitant efforts to organize in support of the Center during consideration of its appropriation in the fall of 1981. Though the effort failed, it indicated a measure of political support never achieved by the Center's research program.

Despite this tentative indication of progress, however, the Center's knowledge processing strategy encountered environmental and organizational obstacles which ultimately frustrated this mission. A key environmental factor was vocal opposition from two powerful interest groups: the American Medical Association (AMA) and the Health Industry Manufacturers Association (HIMA) (1980), an increasingly powerful spokesman for 450 companies manufacturing medical devices.

As we shall see, HIMA and the AMA opposed the Center's knowledge processing activities in part because these supported regulatory activities which the groups considered contrary to their clients' interests. But the AMA and HIMA opposed the Center's knowledge processing functions on more general grounds as well. They concluded correctly that by gathering, synthesizing, validating, and disseminating information concerning health care technologies the Center could influence decisions by private actors, such as hospitals and insurance companies, and by other governmental actors, such as the courts and nonfederal regulators. The AMA challenged the competence of the Center, its council, or any governmental actor to evaluate health care technologies.

As one AMA official said, "Nothing in history suggests that any group other than the profession can come to grips with efficacy decisions or technological advances" (Sammons 1981). HIMA was particularly concerned that misguided evaluations could stifle innovation or damage small, new companies dependent on the success of particular devices.

Both the AMA and HIMA formally opposed the reauthorization of the Center. The AMA singled out for condemnation a particular knowledge processing function of the council, its authority (never actually employed) to establish "exemplary norms, standards, and criteria" for the use of health care technologies. For its part, HIMA sought the elimination of the Center's authority to compile a list of emerging technologies. During the conference between the Senate and the House, the phrase "norms, standards, and criteria" was dropped at the insistence of Senator Orrin Hatch (R.-Utah), new Republican chairman of the Senate committee with jurisdiction over the legislation. Hatch's staff had been working closely with HIMA and the AMA.

Organizational obstacles also affected the implementation of the Center's knowledge processing strategy. Like the Center's knowledge development strategy, its authority to process knowledge concerning health care technologies threatened the interests of preexisting agencies in the Department of Health and Human Services. Once again, the Center found itself in competition with the National Institutes of Health.

Prior to the Center's creation, the NIH had been under pressure from certain congressional quarters to review results of its extensive research program and interpret them for the practicing physician (U.S. Senate 1976). For years the NIH had stoutly resisted this pressure, but in May 1977 Dr. Donald Frederickson created a new Office for the Medical Applications of Research (OMAR) at the NIH. Located within the Office of the Director, OMAR was "the focal point for a program aimed at improving the translation of the results of biomedical research pertinent to health care into knowledge that can effectively be employed in the practice of medicine and health" (Department of Health and Human Services 1980).

Though NIH staff viewed OMAR as a major initiative linking NIH with the health care delivery system, its implementation was characteristically cautious. OMAR was a tiny office with a staff of 6 and a budget of $2 million. It relied exclusively on calling "concensus

development conferences" of the kind discussed above. Fearful of the bruising politics of the delivery system, it tried consciously to distance itself from regulatory decision-making.

Within OMAR, the attitude toward the Center was openly hostile. OMAR officials viewed the processing of scientific information related to health care technologies as OMAR's mission. Reflecting NIH's general skepticism toward social and economic analysis, OMAR staff felt that the National Center added little to what OMAR itself could do, and described the Center as merely a "post office" for transmission of NIH data to appropriate bureaucratic audiences (Lowe 1981). In departmental deliberations and in private communications to Capitol Hill staff, OMAR officials volunteered the opinion that the National Center was an unnecessary bureaucratic appendage which could be severed in the name of governmental efficiency. Hatch personally quoted these statements, erroneously attributed to Frederickson, in public justifications of his decision to oppose the reauthorization of the Center.

Interestingly, OMAR itself never came under attack and survived the first Reagan budget cycle unscathed. Outside interest groups did not consider OMAR a threat, in part because they did not expect it to be effective in influencing the behavior of regulators or private decision makers. "NIH is so amorphous I guess I don't have a real expectation of where things could get focused out there," commented one industry representative (Molliter 1981). Constituency groups were aware of NIH's research orientation and its desire to avoid regulatory entanglements. Also, OMAR benefited from the popularity of the NIH's biomedical research mission. Alone among the major discretionary health programs, the NIH escaped absolute budget cuts during the first two Reagan budget cycles, a factor which facilitated OMAR's survival.

Policy Implications. The NCHT's difficulties in implementing its knowledge processing strategy, and the contrasting advantages of OMAR, prompt a number of generalizations concerning federal efforts to collect, synthesize, validate, and disseminate information concerning new and existing health care technologies. Though knowledge processing is relatively inexpensive compared with knowledge development, and has a greater apparent, short-term payoff, these advantages have not been sufficient to overcome environmental and organizational obstacles to this strategy. Constituencies likely to benefit from knowledge pro-

cessing activities have not been strongly committed to those efforts. In contrast, groups which feel threatened by the products of knowledge processing have demonstrated a strong commitment to terminating or modifying governmental activities in this area. In the eyes of these groups, knowledge processing is legitimate up to a point, but no further. OMAR's concensus development conferences, largely non-directive, are acceptable. The National Council's authority to recommend standards of practice is not. Whether the federal government *should be* involved in recommending standards of practice is debatable. Its political and institutional capacity to do so seems severely constrained for now by this environmental obstacle.

The knowledge processing strategy pursued by the Center also faces important organizational obstacles within the federal government. NIH has laid claim to knowledge processing activities related to the technical and scientific aspects of health care technologies. Backed by its immense scientific credibility, NIH's claim has proved persuasive. Faced with apparent duplication and rivalry between OMAR and the Center, the administration and Congress chose to scrap the Center.

However, because of its traditional mission and capacity, NIH is an imperfect home for knowledge processing activities. As previously noted, NIH lacks the ability to undertake social and economic analysis related to the uses of health care technologies. The agency is also hesitant to make strong interpretations concerning the implications of existing information. As one NIH official commented, "The notion that they would have to . . make choices between this chap's data out of MIT and this chap's out of Stanford was an alien thing" (Carson 1981). Finally, some observers question whether the agency responsible for funding the development of so many new technologies can objectively evaluate the utility of those new practices, procedures, and devices.

Given the Center's failure, and the drawbacks of NIH as a home of knowledge processing activities, the Health Care Financing Administration has been suggested as a possible alternative. However, HCFA is as weak in scientific and technical analysis as NIH is in the economic and social area. What is more, HCFA's overriding interest in cost control creates an apparent conflict of interest.

Whatever the merits, NIH currently dominates formal knowledge processing activities in the department. A natural consequence of organizational and environmental forces, this outcome ensures for now that the federal government will take a cautious and restricted approach

to the collection, synthesis, validation, packaging, and dissemination of information related to health care technologies.

Regulating Health Care Technologies: Coverage Decision-Making

Given the political and technical difficulties in regulating health care technologies, it may seem surprising that the Center was most successful in implementing those functions most directly related to regulating medical practices, procedures, and devices. Yet, this was clearly the case.

The Center, as we have seen, was charged with advising Medicare authorities concerning which health care technologies merited reimbursement under Title XVIII. In so doing, the Center increased the speed with which that advice was provided and the quality of the advisory opinions. During its brief existence, the Center responded to more than 70 requests for information or opinions from Medicare authorities (Perry 1981). It eliminated a backlog of several dozen queries which had been awaiting Public Health Service action at the time the Center was created. About 40 percent of the Center's opinions advised against covering particular health care technologies, and in virtually all cases, HCFA followed the Center's lead. Some of these decisions were credited with saving the Medicare program between $100 million and several billion dollars (University of California at Los Angeles School of Public Health 1981; Center for the Analysis of Health Practices 1981). When the Center was reauthorized, its mandate to advise HCFA was explicitly preserved.

The Center's relative success in implementing its quasi-regulatory functions reflected the happy confluence of environmental and organizational factors. Among environmental factors, perhaps the most important was, paradoxically, the pressure to reduce federal expenditures. Though the Center's coverage process consumed 30 to 40 percent of its annual budget, this was a trivial sum compared to the savings which the Center was credited with achieving through its coverage decisions. The Center's cost-saving appeal was particularly effective in softening the opposition of Hatch and his staff and strengthening the advocacy of House Democrats during the House-Senate conference considering the reauthorization of the Center (Kessler 1981).

The Center's coverage role also attracted qualified support from

HIMA officials, though for very different reasons. These officials conceded privately that some sort of coverage determination process under Medicare was inevitable, and felt the Center deserved support for the quality and openness it had brought to the existing process. As one HIMA staff member put it, "Since HCFA's going to regulate anyway, the idea is let's get the best information" (Lowe 1981). In their background discussions with House and Senate staff, HIMA officials did not oppose preserving the Center's coverage functions.

The Center's efforts to implement its coverage process were also assisted by certain organizational factors. The Center's involvement in the coverage process had a number of direct benefits for the Department of Health and Human Services. For officials desperate to conserve program resources, the possibility that Center advice might reduce Medicare expenditures did not go unnoticed. The Center's involvement in coverage decisions also had a special benefit for HCFA. The Center not only improved the quality of coverage decisions, but shared and diffused the associated political heat.

Because of these perceived payoffs, the Center's coverage role generated greater leadership commitment in DHHS than its other functions. Senior Department officials were willing to devote some energy and political capital to nurturing a working relationship between HCFA and the Center, and to containing any incipient rivalries. One tangible result was a memorandum of understanding, signed by the Assistant Secretary of Health and the administrator of HCFA, which specified in detail how the Center and the Health Care Financing Administration would share responsibilities for coverage decisions.

The value of the Center's reimbursement advisory function was so clear, however, that such overt interventions from senior Department leaders were less essential to the Center's quasi-regulatory functions than to its other tasks. Most interagency problems concerning reimbursement decision-making were handled by a Departmental Technology Coordinating Committee which had been established to execute the Center's mandate to coordinate technology policy in DHHS. Chaired by the director of the National Center, this committee was considered highly successful in the area of reimbursement policy, but had virtually no impact on the allocation of research dollars (Perry 1981).

Despite these organizational and environmental advantages, the Center's efforts to implement its quasi-regulatory coverage function were ultimately terminated. This occurred because the Center was

unable to overcome major environmental obstacles: the prevailing antiregulatory ideology in Washington and opposition from affected constituencies.

Antiregulatory sentiments had their most forceful embodiment in the election of Ronald Reagan as president in November 1980. Senior officials in the Reagan administration were nearly unified in their opposition to the Center, and much of that opposition resulted from their concern with its support of regulatory and quasi-regulatory activities of the Department of Health and Human Services. As Lynn Etheredge (1981), Chief of the Health Branch of the Office of Management and Budget, would later comment: "For a two million dollar agency, it gained unusual prominence and symbolic importance. It became a symbol of government and the future of health care regulation."

Several factors accounted for the Center's elevation to this exalted, if unlucky, status in the Reagan administration. First, the creation of the Center increased the visibility of the coverage process, and focused attention on all the organizations involved with this quasi-regulatory function. Second, the Center's opponents sought to make it a symbol of the danger inherent in government regulation. The AMA, in particular, sought to portray the Center as a first step down a slippery slope toward government control over the daily practice of medicine (Rubin 1981).

Third, two key Reagan appointees had an unusual familiarity with the Center because of their involvement in its creation. As a member of the House Committee on Interstate and Foreign Commerce, Representative David Stockman had personally opposed the Center during committee consideration of its enabling legislation. After his appointment as Director of the Office of Management and Budget (OMB), Stockman was heard to refer to the Center and its supporters as "latter-day Luddites." Colleagues at OMB claim that he had decided to disband the Center even before he assumed his new post.

Richard Schweiker, Reagan's appointee as Secretary of Health and Human Services, also knew the Center well. As ranking minority member of the Senate Subcommittee on Health and Scientific Research, he had originally cosponsored the legislation creating the Center. But during subcommittee deliberations, he strenuously opposed conferring on the Center any direct or indirect regulatory authority, including any role in the coverage decision-making process.

Given the views of these pivotal officials, the administration's

formal opposition to continuing the Center and its quasi-regulatory functions should come as no surprise. OMB refused to approve any monies for the Center in the Reagan administration's 1982 budget. Schweiker never appealed that decision. The administration's budget recommendations were subsequently adopted by the appropriations committees, which were anxious to avoid administration vetoes.

Policy Implications. Attempts to implement the Center's quasi-regulatory strategy suggest a number of lessons for technology policy. To begin with, regulatory strategies for affecting the use of health care technologies face major environmental obstacles. From an environmental viewpoint, the Center fought the fight for increased regulation of health care technologies on relatively favorable terrain. In a time of intense concern over the cost of health care for government and society alike, the Center produced an eminently saleable product: concrete decisions which were alleged to save more federal dollars than they cost. Equally important, during a time of growing opposition to federal regulatory activities, the Center never actually regulated anything. It only advised another agency about decisions which, in themselves, were not strictly regulatory. With these advantages, the Center's coverage function attracted support from certain health legislators and their staffs and even from natural opponents such as HIMA.

However, that support could not overcome the opposition of administration conservatives and other outside interest groups. A natural question is why opponents of the Center's quasi-regulatory role proved so effective. The answer has two parts.

First, the constituency for the Center's coverage role had inherent weaknesses. The strategy's appeal depended importantly on its potential to restrain health care costs. Historically, the constituency for cost-control has never proved a match for interest groups opposing the regulation of the health care system. The benefits of cost-control measures are spread among millions of consumers, who tend to lack the organization and motivation to be effective in promoting cost-control (Wilson 1975).

Second, constituencies opposing the Center's regulatory strategy have inherent strengths. Regulatory approaches to affecting the use of health care technologies constitute frontal assaults on the autonomy of health professionals. In nontotalitarian societies, governments have rarely won such battles, for the professions control major weapons. They monopolize the knowledge necessary to make wise policy, and

their voluntary compliance is essential to the effective implementation of regulatory decisions.

The termination of the Center's coverage function, therefore, cannot be ascribed entirely to chance events such as the appointment of hostile officials to key health posts. Rather, that result stemmed in part from fundamental political obstacles to governmental regulation of the health professions and other major health care interest groups. Recent attacks on other health care regulatory ventures, including the national health planning program and the professional standard review organizations, demonstrate the same political forces at work in other program areas.

These major environmental obstacles to the regulation of health care technologies should not, however, obscure the long-term political and institutional strengths of the Center's quasi-regulatory mission. From an organizational standpoint, the Center's coverage function was cheap, useful, and, as a consequence, supported by departmental leaders. A function which serves basic organizational needs at little cost may acquire a bureaucratic life of its own and, indeed, this seems the case with the Center's advisory role in coverage decision-making. After the Center's demise, its advisory function was quickly revived and transferred to a smaller, less visible unit now located in the National Center for Health Services Research. There, this quasi-regulatory activity continues to operate with a much smaller budget and a relatively inexperienced, but slightly larger staff.

The coverage advisory function also retains environmental advantages in the form of a loyal band of congressional allies. These supporters seem heavily influenced by the coverage function's compelling logic as part of the federal government's effort to responsibly administer the Medicare program and control its costs. In a new effort to increase the size, visibility, and credibility of the coverage decision-making process, Congress recently assigned that task, in slightly modified form, to the newly created Prospective Payment Assessment Commission. In so doing, the Congress seems to be expressing the view that the coverage function will continue to have a role under the revised payment methods—based on diagnosis related groups (DRGs)—contained in the new Medicare amendments. This conclusion seems reasonable. Medicare administrators must still decide whether the development of new technologies justifies adding new DRGs or increasing compensation under old ones. The administration may not agree, and the future of this new attempt to bolster the coverage function remains

uncertain. Nevertheless, the organizational and environmental advantages of the coverage advisory function seem likely to ensure its survival in some form over the long term. Its size, scope, visibility, and effectiveness will depend in part on the relative balance between the environmental forces opposing the regulation of health care technologies and the forces favoring this particular quasi-regulatory function. The balance between these forces will, in turn, be heavily influenced by a range of factors, one of which is whether the growing cost of medical care erodes the strength and legitimacy of interest groups such as the AMA, and softens the ideological opposition of administration conservatives.

III. Conclusion

The history of the National Center for Health Care Technology suggests that all the major strategies it pursued—knowledge development, knowledge processing, and the regulation (through coverage decision making) of health care technologies—face important political and institutional obstacles to their effective implementation at the federal level. Those obstacles are both environmental and organizational in nature, vary somewhat from strategy to strategy, and affect prospects for the long-term success of alternative federal approaches to solving the technology problem.

Prospects seem most problematic for knowledge development as an approach to affecting the use of health care technologies. Vulnerable to budgetary pressures, poorly understood, and bereft of strong environmental allies, knowledge development concerning health care technologies cannot flourish until budget deficits ease and a constituency matures. Even then, competition from the National Institutes of Health will pose a formidable obstacle requiring determined, creative leadership to overcome.

Prospects seem somewhat brighter for knowledge processing activities at the federal level. Less expensive than research, more easily understood, and more directly useful to outside groups, knowledge processing has attracted greater constituency support and seems less vulnerable to fiscal crisis. These relative advantages, however, have been blunted by environmental and organizational disadvantages, including opposition from industry and professional groups, and competition from the NIH.

The political and institutional outcome has been a compromise, in which knowledge processing activities continue, but only in the cautious format of OMAR's consensus development exercises. Pressures to improve the quality, or control the costs of health care may further knowledge-processing activities by motivating supporters and undermining opponents. Still, methods must be found to include the NIH in those activities without allowing it to dominate.

Finally, one of the unexpected lessons of the Center's experience is that its quasi-regulatory strategy seems to have the most favorable long-term prospects. Possessing the strongest organizational and environmental advantages, the Center's coverage-related functions were its most successful activities. They have also been partly resuscitated since the NCHCT's demise. Indeed, through new Medicare amendments, attempts are underway to reform and strengthen the coverage advisory process. The success of these new initiatives is by no means assured; but perhaps the relative durability of the coverage function constitutes another small piece of evidence that, as Starr (1982) suggests, we are witnessing an important change in the balance of power between the medical profession and other societal groups. While the coverage function threatens professional autonomy most directly, it also offers apparent benefits to Medicare administrators and to public and private advocates of health care cost control. If Starr is accurate in predicting further decline in the cohesiveness and political strength of the medical profession, then the aggressiveness and visibility of the coverage function may increase. Indeed, the political and institutional momentum of the coverage process could bolster other approaches to affecting the use of health care technologies. Arguing the need to support Medicare program decisions, advocates of knowledge processing and knowledge development concerning health care technologies may be able to capture funds and personnel for these less visible functions. This seems precisely the logic which underlay the congressional decision to include research support within the authority of the newly created Prospective Payment Assessment Commission.

Predicting societal trends is difficult enough. Predicting their consequences for a particular set of governmental functions is more hazardous still. For now, it seems wise to conclude simply that, judging from the National Center's experience, a coordinated, multifaceted, and carefully crafted approach to the technology problem may be difficult to devise in the near future. More likely is a continuing series of ad

hoc experiments, building on political and institutional opportunity. It remains to be seen whether future experiments can make more fundamental inroads on the problems the Center was created to address.

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