THE FEDERAL GOVERNMENT AND MEDICAL TECHNOLOGY:
CROSSING POLICY AND MANAGEMENT THRESHOLDS

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I. INTRODUCTION

Major advances in medicine have for several decades been primarily associated with the fruits of medical science. Illustrations include penicillin and the broad-spectrum antibiotics for use against infectious diseases, anti-viral vaccines for preventing poliomyelitis, chemotherapeutic agents for treating cancers of the circulatory and lymphatic systems, and psychopharmacological agents for treating mental illness.

More recently, the fruits of non-pharmaceutical medical technology have come to prominence in perceptions of innovation in medicine. Nowadays the "machine" in medicine can be too soon and too late with us. Its presence stretches from electronic fetal monitoring before birth to the respirator, intensive care unit, and artificial kidney on the threshold of death. And throughout life's complex passage we encounter the computerized tomography (CT) scanner, the computerized electrocardiogram (EKG), automated clinical laboratory analyzers, and many other manifestations of technology in contemporary medicine.

Medical technology, not medical science, is the subject of this paper. Our concern stems mainly from the recent policy debate about medical technology, which has been preoccupied with questions of cost, efficacy, and safety. Beyond the immediate terms of the debate, however, we are concerned more broadly with the changing role of the federal government relative to medical technology.

In the past few years, the federal government has crossed both policy and management thresholds in its relationships with medical technology. The policy shift has been from conscious prior reliance upon the non-governmental sector for decisionmaking about the development, diffusion, and use of medical technology to increasing involvement of

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the federal government in such decisions. Second, the management transition has been from decentralized to centralized decisionmaking. Centralization, however, has not meant hierarchical but fragmented authority: a complex set of statutes and regulations are being administered by a number of federal agencies, only loosely coordinated with each other, with no one at the top. In short, though it is tempting to describe the shift as one from market to hierarchy, such a characterization oversimplifies the world being left behind and the one into which we are entering.

Medical technology, as defined by the Office of Technology Assessment, refers to "the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the system within which such care is delivered." In this paper, medical technology refers to the means by which health professionals, mainly physicians, deliver care to patients, with emphasis on those means that are embodied in equipment.

In Section II, the case of end-stage renal disease is used to compare federal involvement in medical technology during the 1960s with the current period. Though this case represents very substantial federal involvement for the earlier period, the limited scope of that involvement and the basic optimism toward technology of that era contrast sharply with the present period. Briefly, in Section III, the cases of Karen Ann Quinlan and the CT Scanner are used to illustrate how both the benefits and costs of medical technology have come to be questioned so strongly today. Section IV reviews the increased federal role in medical technology in the present through health planning, medical device regulation, and the analysis of safety, efficacy, and cost-effectiveness. Finally, in Section V, the implications of an increased federal role are examined: efforts to compensate for the medical marketplace require more reliance upon analysis, bureaucracy, legal procedure, and politics in decision-making. The question is whether the outcome will improve patient well-being or merely reveal the limitation of the federal government.

* The non-governmental sector includes both the private sector and non-profit institutions like universities, medical schools, and hospitals.
II. END-STAGE RENAL DISEASE: AN ACTIVE FEDERAL GOVERNMENT IN A PASSIVE ERA

During the 1960s, the federal government played a very limited role in the development of medical technology, and was generally passive toward the non-governmental sector where such technology was developed. There existed few regulatory constraints to introducing new products to the market or to the acquisition of technology by hospitals. Federal reimbursement of medical services through Medicare and (via states) Medicaid, which began only in 1966, paid little attention to the increasing costs of medical care and practically none to the cost impact of technology. The emphasis within medical research and development (R&D), moreover, was heavy on the "R" and light on the "D".

The technology for treating end-stage renal disease was more actively "managed" by the federal government than most technologies. But even that active role stands in such contrast to the 1970s that our basic argument is more strongly supported by the end-stage renal disease case than by a more typical case. Let us briefly consider technical and policy developments and then make some general observations.

End-stage renal disease can be treated by either dialysis or transplantation, though not all who can be treated by the former are suitable candidates for transplantation. There are two kinds of dialysis, hemodialysis, in which an artificial kidney cleanses the blood of toxic substances, and peritoneal dialysis, in which a saline solution is introduced into and removed from the peritoneal cavity of the abdomen and carries off toxic substances that are drawn across the peritoneal membrane. Both types of dialysis can be performed in institutions or at home. Hemodialysis is presently the main form of dialysis treatment. For transplantation, kidneys may be obtained from living relatives or unrelated cadavers. Transplants from living donors are more successful, though cadaver transplants are more frequent. Dialysis and transplantation are often used together: patients awaiting a cadaver transplant are typically treated on hemodialysis; and, if the transplant fails, the surviving patient is placed on hemodialysis. "Technology" in this
context, then, consists of the means of therapeutic intervention—an equipment-based regime of treatment in one case, and surgery plus a regime of post-operative care in the other.

The technical development of hemodialysis can be briefly summarized. The initial experiments dialyzing aspirin from the blood of a dog were performed at Johns Hopkins in 1912. Heparin, developed for other medical purposes in 1918, was eventually used to prevent blood clotting in dialysis. Cellophane, developed for sausage casing in the 1920s, provided the membrane that was the central element in the artificial kidney. The first artificial kidney was developed and used by Willem Kolff in Nazi-occupied Holland in the early 1940s, and almost simultaneously in Sweden and Canada. The initial machine in the United States was built at the Peter Bent Brigham Hospital in Boston in 1947, based on blueprints from Kolff's initial Dutch version. In 1960, continuous hemodialysis became possible with the invention of a vascular access device that permitted the repeated connection of the patient to the machine without recurring surgery. Teflon tubing, which was inert and thus not rejected by the body, was critical to this major technical advance. Later innovations reduced the volume of patients' blood in the "extracorporeal environment," eliminated cooling and rewarming of blood, improved vascular access through the invention of alternative techniques, and increased the available membrane surface area while simultaneously reducing the size of the dialyzer.

The technical development of kidney transplantation can also be summarized briefly. The means of suturing blood vessels dates back to the turn of the century, as do the early animal experiments. Human transplantation began in 1947 at the Peter Bent Brigham Hospital. No attempt was made to control immunological rejection in the few operations performed between 1947 and 1953, and the operations were generally unsuccessful. Growing understanding of immunology led to a series of identical twin transplant operations, beginning in 1954, a far more successful experience. Control of immunological rejection by whole body irradiation was attempted during the 1950s. Then, in 1959 and 1960, published research indicated that rejection could be suppressed through the use of certain drugs, thus ushering in the modern era of
kidney transplantation. Since the early 1960s, substantial improvements have been made in organ acquisition, storage, and transportation. Immunology has proceeded very rapidly at the basic science level, though the translation of that knowledge into improved clinical practice through tissue typing of host and donor has been disappointingly slow.

The main lessons to be learned from the technical or clinical history, in my judgment, are the following. The processes of development of new medical technology are lengthy, typically international, and draw upon technical advance outside of medicine. The stimulus to development is likely to be an unmet clinical need. Both public and private sectors are apt to be involved, and typically more than one governmental agency. The transition from development to use is likely to involve numerous institutional actors, to follow multiple institutional pathways, and to generate disputes about efficacy; data for persuasively resolving such disputes are unlikely to be available.

Treatment of end-stage renal disease, especially by hemodialysis, has always been costly and beyond the means of all but the most wealthy. A General Accounting Office report, based on 1972 data, for instance, found that the average charge for institutional dialysis was $30,100; for home dialysis, $14,900 in the first year and $7,000 in successive years; and for transplantation it was $12,800. Consequently, policy attention has always focused on the federal government as a source of funds for payment of treatment costs. The federal government policy responses reveal an interesting pattern of development. Most significantly, the Veterans Administration began a treatment program for eligible veteran beneficiaries in 1963. In 1964 and 1965, two programs were established within the National Institutes of Health—one in transplant immunology and the other concerned with improving the technical capabilities of the artificial kidney. In 1965, a kidney disease control program was established within the Public Health Service, initially to demonstrate the organizational feasibility of delivering dialysis care, later to expand organizational capacity for such care as well as to build supporting institutions for transplantation. Small efforts at rehabilitation of the renal patient were initiated within the Vocational Rehabilitation Administration. These policy responses were
basically completed when the Social Security Amendments of 1972 included a provision which extended Medicare coverage to those under 65 years of age having chronic renal failure and meeting certain eligibility requirements under the Social Security system.6

The following general observations may be made about the institutional management of medical technology based on the end-stage renal disease case. First, the government's primary involvement in the technology per se was through the research programs of NIH. Second, no regulatory agencies constrained the development and diffusion of either means of treatment. Third, the logic to the PHS policy and program development was in the movement from research to demonstrating the feasibility of delivering care to gradually expanding organizational capacity for treatment. Fourth, the major steps in providing access to care dealt not with technology but with financing: the first was the 1963 Veterans Administration action and the second was the 1972 Medicare amendment. Both the 1963 and 1972 actions made the life-saving benefits of high-cost technology available to victims of kidney failure, the latter removing inequities of access that had arisen in the 1960s.7 Basically, the renal case was of a piece with the optimism of the 1960s in being yet another instance of the fulfillment of technological promise.
III. FORCES FOR POLICY CHANGE: TECHNOLOGY QUESTIONED

Just as there has been rising skepticism about the benefits of technology in recent years, so too has medical technology been subjected to increased criticism. Both the benefits and costs of medical technology have been questioned.

The case of Karen Ann Quinlan brought into sharp relief the questionable value of medical technology. Hospitalized after a near-fatal accident, remaining unconscious in a sustained coma for many months, she was kept alive by means of a respirator performing what medical authorities judged her incapable of doing for herself. The parents of Karen Ann watched her steadily lose weight as she remained comatose with no apparent hope of recovery. After consulting clergy and counsel, they sought permission to have the artificial life support technology withdrawn from her. The ensuing legal controversy was finally resolved in favor of the parents. The respirator was turned off. Much to everyone's surprise, Karen Ann Quinlan survived and does to this day -- still in a coma.

Whatever the merits of the attending physicians' position on maintaining artificial life support, the Quinlan case riveted public attention on the fact that medical technology could sustain life without reference to its quality. This recognition reinforced a general questioning of the benefits of all life-supporting technology, especially when used in instances having a low probability of restoring a patient's life to normal functioning.

The costs of medical technology also became an object of intense concern. The total Medicare expenditures for end-stage renal disease have now reached approximately one billion dollars for about 40,000 patients. In response to program costs, Congress initiated hearings in 1975 which resulted in 1978 legislation which introduced cost control incentives into the program. Automated clinical laboratory analyzers provoked concern for costs. These diagnostic analyzers have demonstrated great efficiency in processing numerous laboratory tests simultaneously, thus driving down the unit costs of such tests. But the lowered unit
costs, coupled with the rapid turnaround times of the analyzers, reinforced by the medical malpractice threat, and facilitated by reimbursement patterns, have led to an increased ordering of laboratory tests by physicians, sharp increases in the volume of tests conducted, and an overall increase in total health expenditures for lab testing.  

The introduction of the computerized tomography (CT) scanner, however, and its extremely rapid diffusion, more than anything else has focused attention on the cost question.  The first scanners were introduced in this country in mid-1973. According to a study of the Office of Technology Assessment, by May 1977, 401 scanners were known to be in use; 921 were reported to be operational by the end of 1977. The price of a CT scanner ranged in early 1977 from $300,000 to $700,000. Annual operating expenses for a scanner were estimated between $259,000 and $379,000. On the basis of 3,000 examinations per year, technical expenses ranged from $59 to $130 per exam and professional expenses from $20 to $43. Fees for head scans, including technical and professional expenses, were estimated to range from $240 to $260 per examination. The estimate of revenues over expenses for operating a CT scanner in 1976 ranged from $51,000 to $291,000, or an annual return on investment of 11 to 65 percent on a $450,000 machine.

The CT scanner also raised questions about efficacy. The head scan rapidly became an accepted diagnostic routine displacing invasive diagnostic techniques and providing greater accuracy, but before any well-designed studies of efficacy occurred. The use of the machine for body scanning is increasing rapidly, though documentation of efficacy is both more difficult and has proceeded less far than for head scanning.

Many observers were appalled at the rapid diffusion of CT scanners with their high unit costs, excellent prospects for "profit" and thus for rapid amortization of machines, and questions about body scan efficacy. What is needed, many asked, for the incentive structure of medicine to function so that benefits and costs are considered together in the acquisition of new medical technology?
IV. NEW FEDERAL GOVERNMENT POLICY AND MANAGEMENT INITIATIVES

The developments described above set the stage for rethinking the laissez faire posture toward medical technology that had characterized the federal government. There has now emerged a complex policy response and a new set of institutions for the federal "management" of medical technology. This response embraces health planning decisions about hospital capital expenditures, regulation of medical devices for safety and efficacy of new medical procedures (including technologies), and decisions on reimbursement that are sensitive to their effects on technology. 15

HEALTH PLANNING

Section 1122 of the Social Security Amendments of 1972 required hospitals seeking to make capital expenditures in excess of $100,000 to secure approval from the state health planning agency. Without such approval, the provision authorized Medicare and Medicaid to withhold reimbursement for services to such institutions. The initial results of this provision have not been encouraging regarding cost containment effects, though some have argued that the prospects were limited in the first place.

In 1974, Congress merged the Hill-Burton Program, the Regional Medical Program, and the Comprehensive Health Planning Program into a single health planning effort. 16 One aspect of that law required states to enact Certificate of Need (CON) legislation by 1980 or lose the federal funds authorized by the Act. (A majority of states have complied with this requirement.) CON laws would require hospitals to seek state approval for major capital expenditures (the threshold of review was raised to $150,000), the addition of beds, or the initiation of any major renovation. The effect of CON statutes on containing the acquisition of costly new medical technology has been disappointing to many, though expectations may have been unreasonable. 17 But Congress reauthorized the legislation in 1977, extending the CON authority to the ambulatory care setting.
In a parallel development, several state governments have enacted state health cost containment commissions. It is reasonable to expect that this development, together with strengthened health planning authority and agencies, will contribute in time to a slower rate of acquisition of new medical technology.

MEDICAL DEVICE REGULATION

The enactment of the Medical Device Amendments of 1976 expanded and extended the regulatory authority of the Food and Drug Administration. The culmination of several years of consideration by both executive and legislative branches, the medical device legislation arose from a concern for accidental death and injury to patients caused by medical technology, and the absence of adequate federal regulatory authority to deal with this concern. 18

It is worthwhile to sketch out the main regulatory provisions of the statute to convey a sense of the scope and complexity of the regulatory pattern being developed. 19 Some general controls from the 1938 Food, Drug and Cosmetic Act are retained—provisions dealing with labeling, adulteration, and misbranding. New regulatory requirements include annual registration of device manufacturers, classification of all medical devices into one of three classes with different controls over each class (see below), notification of FDA by manufacturers at least 90 days before marketing a new device, special treatment of devices found to be hazardous after marketing, conformance to "good manufacturing practices," and controls over device-related research and development.

The product controls over the introduction of devices to the market are exercised according to the classification of devices in the following manner:

- Class I — Devices fall into this class if the above array of regulatory controls is "sufficient to provide reasonable assurance of the safety and effectiveness of the device," or, where information is inadequate for this determination, if the device is not life sustaining or of "substantial importance in preventing impairment of human health, and . . . does not present a potential unreasonable risk of illness or injury."
Class II -- A device not falling in Class I, but for which there is sufficient information to establish a performance standard that assures safety and efficacy, is classified here and is subject both to the above array of controls, and to the requirements that it conform to the performance standard and that the manufacturing firm be inspected at least once every two years. (Where Class II controls seem appropriate but no performance standard exists, then such a standard must be developed.)

Class III -- If there is insufficient information to determine that either Class I or Class II controls apply, and a device is life sustaining or of "substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury," it falls into Class III and is subject to all Class I controls, plus the Class II requirement of regular inspection of manufacturers, plus specific FDA pre-market approval of the device.

The statute provides two routes for obtaining pre-market approval. The first requires the manufacturer to submit to FDA an application for approval which contains information required for a determination of safety and efficacy. The alternate route involves the submission of a "proposed product development protocol" which specifies the tests to be conducted and the anticipated results; if the protocol is approved, completed test results are later submitted along with all other required information showing that the protocol has been properly fulfilled, and FDA approves the device for marketing.

In addition to product controls, the regulatory pattern includes process controls. The "good manufacturing practices" provision of the statute establishes FDA regulatory control over the production process. Since this requirement may threaten the small firm, the law requires FDA to provide "technical and other nonfinancial assistance" to help small manufacturers comply with the regulations.

Regulatory authority is also extended to device-related research and development by the "investigational device exemption" (IDE) regulation.
This regulation comes about because the law establishes pre-market clearance requirements for medical devices about which there is insufficient information to demonstrate safety and efficacy. Devices being investigated in clinical research, practically by definition, are subject to pre-market clearance, since it is the absence of information about safety and efficacy that is the reason for them being investigated. It is necessary, therefore, to exempt investigational devices from pre-market approval application requirements in order to permit the acquisition of data supporting such an application. The IDE regulation reaches not only to the manufacturers of devices but to device-related research and development in non-profit institutions like universities, medical schools, and hospitals. The operational heart of the IDE regulation is protection of the human subjects used in clinical research. The current policy issue turns on whether the authority for insuring such protection should be retained by the Food and Drug Administration or delegated to local Institutional Review Boards.

Policy research on the effects of the medical device regulations is just now beginning. It is expected that the regulations will retard the rate of innovation in medical devices, preventing unsafe or ineffective devices from reaching the market—as intended. But the magnitude of the effects on innovation and the nature of the health effects—-injuries foregone, efficacious devices kept from the market, etc.—remain to be evaluated.

**ANALYSIS OF SAFETY, EFFECTIVENESS, AND COST-EFFECTIVENESS**

In June 1976, the President's Biomedical Research Panel reported to the Senate Health Subcommittee that, among other things, the biomedical research community had no responsibility for transfer of technology from research to clinical practice.22 The Panel's reception by Senator Edward Kennedy and Senator Richard Schweiker was chilly, to say the least. The Senators felt strongly that the medical research community had a large responsibility for the transfer of technology.

Dr. Donald Fredrickson, the Director of the National Institutes of Health, more sensitive to the prevailing political winds, signalled acknowledgment by NIH of a larger role. In early 1977, NIH released
a paper, "The Responsibilities of NIH at the Health Research/Health Care Interface," a document which became the basis of NIH "consensus" efforts.\textsuperscript{23} The consensus effort at NIH involves the identification of medical procedures or technologies emerging from research to clinical application. The intent of the effort is to bring together technical and clinical experts and to determine the areas of agreement and disagreement among them about the efficacy of such procedures. Consensus exercises have been held on hypertension, mammography, dental implants.

One year later, Kennedy, in another Senate hearing, took to task Dr. Julius B. Richmond, the newly appointed Assistant Secretary for Health of the Department of Health, Education, and Welfare.\textsuperscript{24} What was the Department doing to evaluate the development and diffusion of new medical technology, the Senator asked? Richmond was to report back within two months. The response came in late December 1977, with a report entitled "Health Technology Management at the Department of Health, Education, and Welfare,"\textsuperscript{25} which outlined six steps in a technology management system for assessing health technology:

1. Identification and screening of candidate technologies.
2. Centralized priority setting of technologies to be scrutinized.
3. Conduct or monitoring of the technical studies.
4. Translation of technical findings for relevant users.
5. Coordinated decisionmaking to restrain or stimulate the technology.
6. Intervention mechanisms to implement the decisions.

On the basis of this report, and continued interest by the Senate, the Department established an Office of Health Technology. This past year, largely at Senator Kennedy's initiative, legislation was enacted establishing a new National Center for Health Care Technology in DHEW, which absorbed the Office of Health Technology.\textsuperscript{26} The statutory mandate of the NCHCT is to assess "the safety, effectiveness, and cost effectiveness of, and the social, ethical, and economic impact of health care technologies." The operational meaning of this charter will become
clear only with the passage of time. Though initial authorizations for fiscal years 1979, 1980, and 1981 are $15 million, $25 million, and $33 million, the actual appropriations are likely to be at a much more modest level.

The National Center's research agenda is likely to focus on the evaluation of particular medical technologies, their costs, risks, and benefits, and on the development of methodologies for analyzing them. The NIH consensus effort may be absorbed into the activities of the Center and, in any case, will be closely coordinated with Center activities. Where the FDA's concern for efficacy is narrowly construed to mean effective performance of a device under the conditions specified by a manufacturer, the meaning of efficacy used by the National Center is likely to be far broader. Questions of efficacy of one technology relative to competing technologies are likely to be asked, if not answered.

Though the Center has no regulatory function, all DHHS health agencies are explicitly urged to support it and to take account of the findings of its studies and analyses. It can be expected that research, regulatory, and reimbursement agencies will use the work of the Center if it is of high quality.
V. IMPLICATIONS

There are several general implications of the threshold-crossing developments described above, though they bear on how we see the management of medical technology rather than what we do. First, the shift toward a greater federal role in medical technology derives from the general failure of the medical marketplace to consider both costs and benefits of medical services in the decision to produce such services. The factors contributing to this situation include extensive third-party reimbursement of medical services which removes the incentive to patients and physicians to economize in the use of medical services, the influence of physicians in affecting patient demand for medical care as well as in controlling its supply, the limited information possessed by health care consumers and a propensity to rely upon physician judgment, the incentive to practice defensive medicine to avoid the threat of medical malpractice liability, and the tendency of hospitals to engage in non-price competition for physicians through the acquisition of expensive medical technology.

Second, the federal initiatives in medical technology are specifically designed to avoid undesirable outcomes arising from the medical market, namely, unsafe, ineffective, and costly devices, instruments, and equipment. The emergence of federal regulation of medical technology is due to public policy judgments that the private market, left to itself, will not sufficiently avoid these undesirable outcomes.

Third, the shift from non-governmental to governmental decision-making institutions means that great reliance is being placed upon analysis to compensate for market deficiencies. Conceptual clarification of safety and efficacy is difficult enough in general, but combining judgments about risk, benefit, and cost in an analytical calculus for particular medical technologies is likely to prove extremely difficult. Difficult conceptual problems, limited data, and a small analytical community capable of performing high quality analyses are serious constraints to heavy reliance upon analysis. And beyond the intrinsic limits to doing good analysis will be the institutional barriers of the policy process to using analysis.
Fourth, the shift also means placing substantial reliance upon federal bureaucracies. Herein lies a real dilemma: there is good reason to believe that unregulated market institutions will produce socially undesirable outcomes; there is also good reason to believe that government institutions will be only partially effective in compensating for market deficiencies. Limited performance from federal agencies can be expected partly because of the nature of contemporary bureaucracy—limited and fragmented authority, inadequate resources of personnel and money, a mismatch between the tenure of political appointees and the time needed to address the problem, and near impossible requirements of coordination and negotiation among numerous organizational units, to cite but a few problems.

Fifth, the shift to government decisionmaking will also mean increasing utilization of legal and judicial institutions to make important allocative decisions. FDA administration of the medical device amendments is grounded in the requirement of procedural fairness in agency decisions on safety and efficacy. Administrative determinations, moreover, will frequently be subject to judicial review and aggrieved parties can be expected to litigate ambiguous matters of law, regulation, or agency practice. The effects of the legalization of implementation are apt to be diverse. Focusing decisionmaking on choices that are legally defensible may preclude broader analytical approaches, notwithstanding the conceptual limitations noted above. Administrative discretion in the interpretation of Congressional intent is likely to be constrained. Activist judicial "law making" through the inference of legislative intent may be encouraged. One can even imagine Congressional attempts to exercise greater care in drafting legislation. But it is a near certainty that an increasing number and proportion of public decisions will be made in the light or shadow of legal-judicial institutions.

Sixth, where bureaucratic, analytical, and legal means of conflict resolution are found inadequate, parties at interest will attempt to influence both the rules of the game and policy outcomes by political means. The specific means of influence will include formal and informal efforts to influence the language of legislation or regulation, campaign
contributions made to ensure a favorable reception from key legislators, active lobbying for the appointment of executive branch officials favorable to one's views, the selective provision of information to public officials or the refusal to provide any information, etc. The general point is simple, but not to be forgotten—politics will pervade all decisionmaking.

We are left then to speculate about the effects of the changing federal government role toward medical technology. Will the effect of the new policy responses be to alter the incentives of the medical marketplace, and in the right direction? Or will it simply be to accept the existing incentives and seek to alter outcomes by the addition of new controls? Will there be measurable benefits in improved technology or injuries foregone? Will such benefits be produced at increasing or decreasing cost of technology? In short, will the movement away from the imperfections of the non-governmental sector lead to improved health outcomes for patients or will it merely reveal the limitations of government decisionmaking? The answers to these questions will become known only as we move beyond the thresholds we are now crossing.

On the broader question of federal management of technology, what are the implications of the medical technology case? In President Carter's "Science and Technology Message," transmitted to the Congress on March 27, 1979, three areas of federal responsibility for research and development were noted. The first was for R&D that served "the government's direct needs and responsibilities, such as defense, space, and air traffic control." The third was the support of basic research. To these traditional responsibilities was added federal R&D investment "where there is a national need to accelerate the rate of development of new technologies in the private sector," like energy and transportation.

Beyond federal investment in R&D, federal responsibilities for social regulation—worker safety and health, consumer product safety, environmental quality—have expanded in the past decade to constrain or correct the adverse effects of technology. Both R&D to accelerate private sector innovation and social regulation to constrain the adverse effects of technology arise from a perceived failure of market institutions and the acceptance of a compensatory federal role. All such
efforts imply increased reliance upon formal analysis, federal bureaucracy, legal process, and pervasive politics. Consequently, the success of public efforts to compensate for private sector limitations in the management of technology is likely to be limited at best, disappointing to many, and frustrating to all.
NOTES


6. See Rettig, "End-Stage Renal Disease and the 'Cost' of Medical Technology," *op. cit.*


21. 43 Federal Register 20726, May 12, 1976. FDA published the initial IDE regulation as a proposed rule on August 20, 1976, but the public comment was so adverse that the above cited "tentative final rule" was issued. The May 12, 1978 proposal provided for public comment and public hearings; reaction was so extensive and negative that the public comment period was extended. No final rule had been published by the end of May 1979, though it was understood that one was forthcoming.


29. This fact stands out from the research R. A. Rettig has been conducting on the implementation of Medicare's End-Stage Renal Disease Program.