

The Cost and Regulation of Medical Technology: Future Policy Directions

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"I don't really know how much is enough technology; I can tell you this, when we're dealing with patients and when we're dealing with a patient's family, their response to this would be, 'as much as is necessary to get our loved one restored to normal life.' And that's about the only answer I can give."

*Dr. Michael E. DeBakey, heart surgeon,
speaking at the National Leadership Conference
on America's Health Policy, April 29, 1976*

A decade after the federal government plunged into the financing of health care, it has emerged not only as the system's major purchaser, but also as the major influence on health policy directions of the future. The traditional Washington dictum of "he who pays the piper calls the tune," is becoming a reality in health care, albeit not without a struggle. As a result, the new administration of President Carter will have to confront a range of difficult health issues and decide how best to balance the conflicting forces that call for different answers.

The Carter administration, though, will hardly be dealing with a clean slate. Indeed, the health policy stewards of Carter's team will have to recognize that the government already is well on its way to casting an imposing regulatory net over the health care system. The net is incomplete, but the political forces that have nurtured it to this point were put in a more commanding position with the election of Carter. To generalize, these forces lean to the liberal side of the political spectrum and believe that government should be used as

a tool of action, and not as a benign force that has only limited reign, such as President Ford favored.

As the Carter administration moves to address the major health issues before it, no issue will be more complex or far-reaching than how government should seek to influence the cost and diffusion of medical technologies. Modern medicine is pictured in the public's mind, more times than not, as a stunning breakthrough, a result of the miraculous intervention of man and machine. The government has fostered this technological imperative through its attention to and funding of research that leads to the development of life-saving and life-prolonging technologies. And well it should, based on the public's expectations. If the tax-paying public expects anything from the government's investment in medical research, it is eventual relief from diseases that have so far proven incurable, even in the face of a massive federal commitment.

This fascination with technology, though, is giving way to new concerns over its cost and efficacy, in political, social, economic, and ethical terms. Government policy makers are beginning to recognize that the technologies developed by publicly subsidized research are increasing at an uncontrollable rate. And, perhaps more important, these officials are drawing links between this research and what it costs the government as a major purchaser of care. The fear in some quarters is that this trend, if left unchecked, will lead to a public investment in health care that knows no limits.

This article will cover some of the cost implications of medical technology and directions the government is headed in to deal not only with the question of cost, but also of whether existing and emerging technologies are worth the money and the risk to patients and society. Many of the issues are not new, but they are pressing upon the government. The answers will not be for all time either. As in the past, the government will strike temporary balances and eventually move on to cope with problems that emerge from the policy responses.

Technology: Its Cost

The diffusion of technology in the health care system, and particularly in hospitals, is recognized as a primary element fueling the medical cost spiral. That spiral is forcing a commitment of more and more of the nation's resources to finance health care, with a

return that is increasingly being called into question in terms of its effect on the nation's health status. Moreover, the cost explosion has led to a volatile policy-making climate.

The dimensions of the cost spiral were underscored in December 1976 when the Social Security Administration released its estimate of public and private spending for health care in fiscal 1976—\$139.3 billion, or an increase of 14 percent over the previous year. The new total represents 8.64 percent of the Gross National Product, up from 8.3 percent in the previous year. In a study three months earlier, Trapnell (1976) estimated that national health expenditures will total \$180.2 billion by fiscal 1980 under existing policies.

Technological advances are a major factor in the rising cost of health care. McMahon, a hospital industry spokesman, testified to this in public hearings before the House Ways and Means Committee in 1976:

The third factor affecting hospital cost increases is the changing nature of the output of the hospital. As a result of continuing research and new technology, services provided by hospitals are constantly improving in terms of treatment methods and the expansion of capability for dealing with conditions previously untreatable or untreated. Renal dialysis, laser surgery, total blood replacement, cancer therapy, and a host of new diagnostic approaches to diseases are but a few of the many examples of the costly improvements and expansion of hospital services.

Technology, in McMahon and in this article, is defined very broadly. As Russell (1976) suggests, medical technology refers to the ways in which resources are combined in a hospital to produce medical care, and to changes in those combinations, regardless of whether the change is simply a new mix of well-known resources and services or an innovation like the computerized tomography scanner.

Modern technology has made hospitals into capital-intensive institutions. Plant assets in community hospitals totalled some \$20 billion at the end of the 1960s and averaged more than \$20,000 per bed, Foster (1976) said. In 1975, such assets were worth \$31.7 billion (AHA, 1976), or \$33,400 per bed. Technology in the health field has demonstrated a unique characteristic. In virtually all other industries, new technology has the effect of reducing manpower and production costs. But in health care, new technology usually increases both labor and capital costs, a fact which the government is

recognizing increasingly (Hastings, 1976; Council on Wage and Price Stability, 1976).

Butler and Lee (1975) make a similar point in their preface to an updated study by Scitovsky.

In 1967 when Anne Scitovsky published her original work comparing the costs of treatment of selected illnesses in 1951 and 1964, it was recognized as an outstanding piece of technical data collection and analysis. What was not as clear then, but stands out strikingly now, is the great significance of her findings for public policy. This update by her and Nelda McCall of the earlier work confirms where cost increases have occurred. It suggests that the net effect of changes in medical treatment, that is, of changes in technology, tend to be cost-raising rather than cost-saving. The message needs to be heard by everyone interested in health policy.

The shape of this technological change has been altered dramatically in the last decade, as Rice and Wilson (1975) point out. A previous focus was on the use of new antibiotics and drugs that called for no new equipment, but incurred primarily research, development, and marketing costs. Now, the emphasis is on new techniques that are usually resource intense, requiring hospitalization of the patient. Examples of this trend are chemotherapy, open heart surgery, organ transplant, intensive care units for heart attack, burns, and traumatic shock.

It is mostly in the last several years that the impact of this technology and the intensity with which it is applied has begun to win recognition among federal health decision makers. Perhaps the first real attempt by the government to cope with this phenomenon on a national basis came in the Phase IV health cost controls of the economic stabilization program. In this phase, the Cost of Living Council adopted controls that sought to influence the intensity factor by placing limits on expenditures per patient admission. This would have compelled hospital administrators to seek to influence the rate at which technology is applied. The controls never were implemented because the Economic Stabilization Act expired April 30, 1974, and organized labor applied strong pressures on the Congress not to extend it. Nevertheless, disclosure of the controls policy prompted the American Hospital Association¹ to file a lawsuit in an effort to block the plan.

¹The cost explosion after the demise of the economic stabilization program's health cost controls is causing legislators to be very wary of industry's claims that it will

Gaus and Cooper (1976) refer to intensity as the "technology factor." Using the estimates of the American Hospital Association, they say expense per patient per day in community hospitals rose from \$49 to \$147 between 1967 and 1976. More than half of this increase went for increases in wage rates and prices paid by hospitals to maintain the same level of service. The remainder, though, represents the cost of changes in service through new equipment and supplies and more or different levels of employees. This "technology factor," they estimate, represented 47.3 percent of the nine-year increase, or \$46 of today's per diem cost. Placing this estimate in the context of the Medicare program, Gaus and Cooper estimate that this federal program for the elderly spent \$4 billion in fiscal 1976 for technology that has been implemented since 1967.

In an illuminating comment which reflects the lack of information available to federal policy makers on the impact of this technology, Gaus and Cooper asked:

What did we get for our \$4 billion that year and what will we get every year in the future? We are not quite sure. We do know that many new procedures were introduced and many new facilities added. For example, the proportion of community hospitals with electroencephalographs rose from 30 percent in 1969 to 43 percent in 1974; mixed intensive care rose from 42 percent in 1966 to 66 percent in 1974; inhalation therapy from 48 percent to 76 percent; and the list goes on. But has technology improved the health of the aged? And if so, how much? Again, we do not know. Death rates are down, but so are the number of smokers. We have no way of knowing whether improved hospital care is responsible for the improved mortality statistics or whether

hold the line in the future. For example, Sen. Jacob K. Javits, R-N.Y., said in an opening statement April 2, 1976, at a Senate Labor and Public Welfare Subcommittee on Health hearing on medical cost inflation: "Mr. Chairman, it is indeed unfortunate that the promises made to the committee on March 20, 1974, by the American Medical Association and the American Hospital Association with respect to holding the line on increased cost have proven inaccurate. At that time, Mr. McMahon, president of the American Hospital Association, said: 'In sum, we do not think the allegations that Dr. [John] Dunlop [Chairman, Cost of Living Council] has made about the health industry are fair or supportive of the need for continuation of health controls, and that . . . [the absence of control] will not lead, as he is suggesting, to a huge mushrooming of prices and costs in the health industry.' Unfortunately, we all know . . . the litany of the seemingly unending upward spiral. . . . It seems that the sky is the limit. If massive health spending is not regulated we shall have sown the seeds of our own destruction."

improved life style, access to care, etc., has caused the change. We do not even know whether or not many of the specific technologies are efficacious since procedures and equipment often enter the medical marketplace before adequate testing for efficacy.

Gaus, director of the Division of Health Insurance Studies in the Social Security Administration's Office of Research and Statistics, represents a school of thought within HEW that worries more about the economics of emerging technologies than about the potential for improving health status. On the other side, Dr. Theodore Cooper, who, on January 20, 1977, resigned from the post of Assistant Secretary for Health, HEW, leans in favor of considering health questions as more important than costs. These two schools often are in conflict within the department on many policy issues.

Cooper (1976) testified to the cost-benefit of one technology to stress that the added costs apparently are worthwhile:

... the average cost for the treatment of heart attacks in hospitals rose from \$1,450 in 1964 to \$3,280 in 1971, some of which can be accounted for by inflation and some by increasing sophistication of technology and medical knowledge; fortunately, accompanying this increase in the cost of care has come an apparently continuing trend of reduced morbidity and mortality from heart attacks for the last 10 years.

There have been many reasons cited for the rapid diffusion of costly technologies, many of which attack disease after the fact and largely at a symptomatic level. But the reason cited most often (Rice and Wilson, 1975; Russell, 1976) is the nature of the hospital reimbursement system, which provides little incentive for either the hospital administrator or attending physician to favor the purchase of resource-saving technology. On average, more than 90 percent of the cost of hospital care is paid for through this cost-plus, third-party reimbursement method.

The Tale of a Single Technology

No single new technological device has had a more profound effect on Washington's health policy community, nor drawn the link between innovation and cost more distinctly, than the computerized tomography (CT) scanner. Government is concerned about its high cost, but perhaps its chief worry is the rapid diffusion of the scanner,

caution and rational planning seemingly having been thrown to the four winds. The medical professions, and particularly the specialties of radiology and neurology, are far more enthusiastic about its potential as a diagnostic tool than worried about questions of cost and diffusion.

Developed in 1967 by G. Housfield, an engineer working for Emitronics (EMI) Ltd. in Britain, the CT scanner is hailed generally as the greatest advance in radiology since the discovery of the x-ray. Ironically, Banta and Sanes (1976) report that two scientists, Oldendorf and Cormack, working in the United States in the 1960s, constructed tomographic devices that embodied some of the principles later used in the CT scanner, but they were unable to generate any interest for their development in either the medical or industrial sectors.

The scanner is a new diagnostic device that combines sophisticated x-ray equipment with an on-line computer to produce images of sections of the human body. The first machines were head scanners, designed to diagnose abnormalities within the skull, such as brain tumors. More recently, though, scanners have been produced which are capable of detecting lesions throughout the body. By August 1976, Banta and Sanes had identified 321 scanners in use in the United States. Of these machines, nearly two-thirds were head scanners and the remainder were body scanners.

In addition to those scanners already in use, at least 330 scanners have been ordered from manufacturers and/or approved for purchase by planning agencies. Two hundred applications are awaiting planning agency approval for the purchase of scanners. By population, the national average is about one scanner per 664,000 population. When those CT units now approved and/or on order are installed, the national average will be one scanner per 327,000 population. Georgia will then have the largest number of scanners per population—one unit per 130,000 people (Banta and Sanes, 1976).

At this point in the evolution of CT scanning, one's view usually is formed by one's relation to the technology. Radiologists, for instance, have no reservations about the scanner. In their view, it is a breakthrough of sweeping proportions. Dr. Thomas F. Meaney, chairman of the Cleveland Clinic Foundation's Division of Radiology, reflected his enthusiasm in a letter written to Otha W. Linton, Director of Governmental Relations of the American College of Radiology, dated December 1, 1976. Meaney wrote:

I believe it is well acknowledged by all that computerized tomography of the brain has been an unqualified success, both from the medical and financial standpoints with respect to patient care.

In government circles, though, the view of the scanner and its rapid proliferation is more circumspect. The Department of Health, Education, and Welfare recognizes the substantial cost implications of this one procedure for the public treasury. Banta and Sanes (1976), who, incidentally, accumulated far better information on the scanner than was available at HEW, estimated that the 320 scanners now in operation would generate revenue of \$207.4 million a year on the basis of 3,000 scans per unit. The estimated costs would total \$127 million, leaving a surplus of \$80.4 million.

But even more than the immediate cost considerations, what HEW and legislators are fretting about is their inability to influence the placement of scanners through the planning process created by the National Health Planning and Resources Development Act of 1974. Rep. Paul G. Rogers, D-Fla., Chairman of the House Interstate and Foreign Commerce Subcommittee on Health and the Environment, pointed out the problem when speaking before the National Leadership Conference on America's Health Policy. Rogers (1976) said:

. . . Now we're going through this business with the scanner. What's it cost? \$300,000 to \$600,000 to purchase and install. And the Society of Neuroradiologists, a group that probably would not necessarily err on the side of too little, has estimated that there ought to be six or seven scanners in the Washington area. . . . We already have three and a dozen more on order right here in the nation's capital. This cost will run from about \$4-7 million. That's at today's prices. And in England, do you know how many they have? Two, and I think that's where they invented it.

Rogers, who represents an affluent Florida district just north of Miami, has been particularly distressed by the way in which physicians in Dade County have circumvented the planning process there to purchase scanners. The Comprehensive Health Planning Council of South Florida, subsequently renamed the Health Systems Agency of South Florida, concluded in mid-1974 that Dade County's health system could support three brain scanners. Today, Dade County is supporting seven scanners and William C. McCue, the agency's executive director before he resigned at the end of 1976,

said that requests to approve the acquisition of six more scanners "are waiting in the wings" (Iglehart, 1976a).

Two of the seven scanners were placed in an ambulatory care facility and a physician's office. The planning agency has no authority under the 1974 law to veto the placement of scanners in such places. McCue said (Iglehart, 1976a):

If we stop the institutions from purchasing the equipment, the doctors turn around and install it in their own offices.

Although the government has not yet taken direct policy action affecting the scanner and its diffusion, it has displayed its concern in a variety of ways. The Senate Finance Subcommittee on Health, on March 5, 1976, directed the Office of Technology Assessment (OTA), an arm of the Congress, to undertake

a study of the computed tomography scanner, covering such aspects as its usefulness, its costs, its effects on medical care delivery patterns, and ways to improve planning affecting such devices.

The OTA's study by Banta and Sanes (1976) has become a ready reference for information on the uses of scanners, their distribution, utilization, and economics, and on health policy issues raised by the proliferation of this technology.

HEW's health planning program has sought to alert the new national network of health systems agencies to the importance of carefully reviewing all requests for scanners under authority provided by the 1974 law. Harry P. Cain II, the program's director, told the agencies in a memorandum:

Of all the planning and regulatory issues currently before you . . . perhaps none has attracted more public interest than the increase in the number of computerized tomography scanners throughout the nation. . . . Recently we have heard many calls for federal action to limit increases in scanners in order to prompt their appropriate and economical use. We have been asked, for example, to support a national moratorium on the purchasing of scanning units, until more information is available upon which to assess the need for these very expensive machines. Several states, under their planning or regulatory authority, already have declared such moratoriums. While a national moratorium seems to us to be insupportable, we think it is advisable, and important, that we ask you to examine each scanner proposal with considerable care.

A month later, Cooper, HEW's Assistant Secretary for Health, called a meeting of representatives of agencies in the Public Health Service with an interest in scanners to discuss the health policy implications of such technology. Cooper said in a memorandum announcing the meeting:

... this has been an area of intense interest among the Congress, the public, professional groups, manufacturing interests, public interest groups, and the department.

The department's interest in the scanner ranges widely, as does its interest in many other major pieces of new technology. In the Public Health Service alone,² there are six agencies with a legitimate policy interest in brain and body scanners. And this does not include Medicare and Medicaid, the two major health financing programs which pay for scans on individuals eligible for services. Such diversity makes it difficult for HEW to shape a policy that balances the competing interests of the several agencies.

The health planning program has a responsibility under the 1974 planning act to develop a regulatory framework that will provide for the orderly diffusion, but not expensive duplication, of the scanner. The Health Services Administration's Bureau of Quality Assurance serves as the medical advisor to Medicare and Medicaid on whether these programs should reimburse for scans. The brain scanner has been approved for payment, but the body scanner remains, in the bureau's judgment, an experimental device and thus not eligible for reimbursement under the federal programs. The Food and Drug Administration's Bureau of Radiological Health has major regulatory responsibilities for devices such as CT scanners, including standards for personnel who work with such equipment. The FDA's Bureau of Medical Devices and Diagnostic Products and Bureau of Drugs also have a regulatory interest in scanners.

The National Institutes of Health (NIH) has four operational

²The Office of Technology Assessment found, when it surveyed the government to determine interest in the CT scanner, eight agencies outside of the Department of Health, Education, and Welfare with some direct involvement in the device. Those agencies were the Department of Defense, the Department of Commerce, the Energy Research and Development Administration, the Environmental Protection Agency, the National Aeronautics and Space Administration, the National Bureau of Standards, the National Council on Radiation Protection and Measurements, and the Veterans Administration.

scanners it uses with patients clinically. The NIH also is supporting some one hundred research projects which use CT scanning; the largest number of these are funded by the National Cancer Institute. The cancer institute also is funding a major clinical trial to determine the effectiveness of CT scanning. The National Institute of Neurological and Communicative Disorders and Stroke held an International Symposium on Computerized Axial Tomography on October 12–15, 1975.

But the government is not alone in its concern over the scanner. As Phillips and Lille (1976) noted, the innovation has thrown hospitals into “technological shock.” They added:

Surprised by its immediate success and acceptance but stunned by its cost, hospital administrators find themselves in a quandary over the purchase of this expensive equipment—balancing institutional demands versus budgets on one hand, and community needs versus restrictions on the other.

The Blue Cross Association also has taken steps which reflect its concern. The association contracted with the Institute of Medicine in late 1976 to undertake a short-term policy appraisal of the scanner to provide recommendations to Blue Cross on how they may set up payment systems for scanning procedures. Charles A. Sanders, M.D., General Director of Massachusetts General Hospital, Boston, chaired the institute’s scanner study group, which planned to deliver its recommendations in early 1977.

In Maryland, the state medical society is drafting guidelines to regulate the number of private practice head and body scanners and how much doctors can charge patients to cover the cost of the procedure. John Sargeant, Executive Director of the Maryland Medical and Chirurgical Faculty, said in a newspaper interview (Miller, 1977) that, according to the American Medical Association, the Maryland doctors’ group is the only one in the nation that is attempting to regulate the use of the scanner in physicians’ offices.

Policy Directions: More Regulation

The government has abandoned past notions that it should strive to repair the medical marketplace, rather than impose more regulation, as the best way to deal with inequities in the health system. The market advocates made their most forceful effort with the 1971

drive by President Nixon to dot the medical landscape with health maintenance organizations through the provision of public subsidies. Today, HEW's health maintenance organization program is but a tiny outpost in the department's vast bureaucracy, a standing that reflects the lack of enthusiasm in the agency for any renewed efforts to bolster the market.

The trend favoring regulation already has resulted in the enactment of laws that will affect the development and diffusion of technology. At this point, many federal officials view this regulatory network as incomplete. Thus, future policy efforts will concentrate on imposing more regulation by beefing up laws already enacted and fashioning new laws and policies which depend on direct government regulation.

Recent major laws that have an effect on technology are the Social Security Amendments of 1972, the Health Planning and Resources Development Act of 1974 and the Medical Device Amendments of 1976. These laws, enacted after prolonged debate, underscore the government's willingness to opt for regulation to monitor the cost and quality of medical care, allocate the system's resources, and screen the introduction of new technologies.

This sharp turn toward government regulation is a phenomenon which has picked up considerable steam in the 1970s, as these laws illustrate. The government finds direct regulation appealing for two reasons. Most policymakers now agree that there really is no viable medical market. Congressman Rogers (1976) made this point:

The AMA (American Medical Association) maintains that the marketplace is going to take care of all this specialty maldistribution. But I think that the marketplace really is leaning not toward a solution but to a complication of the problem, because people are paying more for the specialist to go to the urban setting. So the Congress is moving in here because the leadership won't be assumed by the profession to do something about it. The problem, I guess, is pretty well set out by now. I think we have problems because the marketplace in health care is unique. It is not competitive. And the incentives are for over-utilization, over-mechanization, over-medication, with a tendency to over-balance.

Secondly, direct government regulation is very appealing to politicians when matters are not going well. As Ball (1974) so perceptively predicted:

Regulation seems to be the approach that addresses itself most directly to the perceived problem. If prices are too high, set rates; if desired services are not available in some area or for some people, fix the responsibility on some institution or organization to see that they are made available; if the quality of service is too low, set standards. Alternatives that involve incentives for performance seem indirect and do not have the appeal of an immediate solution, whereas goals and requirements can be written into law and into regulations giving the appearance, at least, of having solved the problem. We sometimes don't stop to realize that ordering a man to jump ten feet in the air doesn't make it possible for him to do so.

And how right he was. We now have the economic stabilization program, the Health Professions Educational Assistance Act of 1976, and the Professional Standards Review Organizations.

There are two provisions in the Social Security Amendments of 1972 that are having a regulatory effect on medical technology. A third provision, which authorized HEW to finance the treatment of most individuals suffering from end-stage renal disease, will be discussed later. The lesser of the two regulatory provisions, Section 1122, empowered HEW, and through it Medicare and Medicaid, to withhold reimbursement to hospitals for depreciation, interest, and return on equity capital in cases where institutions make capital expenditures in excess of \$100,000 without first winning the approval of the state planning agency.

The capital outlays can be for plant and equipment in excess of \$100,000, for changes in bed capacity of an institution, and for substantial changes in the services provided by an institution. The purchase by a hospital of a large piece of capital equipment such as a CT scanner is, for instance, subject to review and approval by a state planning agency under Section 1122, although this provision has not been aggressively enforced by HEW or the states. Erwin Hytner, a professional staff member of the House Ways and Means Committee and Medicare's former Deputy Director of Program Policy, described Section 1122 in a private interview with the author as:

sloppily drafted and with little teeth. Moreover, it never really has been effectively applied.

Hytner's view squares with a study by Lewin and Associates, Inc. (1975) which found that (1) states approve 90 percent of the dollar expenditures proposed; (2) there is little opposition to expanding

facilities; and (3) proposals to purchase equipment and add new hospital services are almost always approved. Few state agencies were found to have adequate need projections, review criteria, or data resources with which to conduct review functions. The problem, Lewin concluded, is quite often "a lack of management leadership and commitment. . . ."

Even if Section 1122 was effective, however, the capital investment in new equipment only accounts for part of the cost of new technology. Another recent study (Abt Associates, Inc., 1975), showed that equipment purchases alone account for only nine percent of total hospital inflation. The new personnel and supplies required by the equipment add significant costs, yet they are not covered under this provision of the Social Security Act. The study also found that new equipment had a use rate of only 50–60 percent; the equipment had a five to eight year obsolescence rate and little attempt was being made by hospitals to measure the effectiveness of equipment in improving care.

Although state planning agencies are not required under Section 1122 to deal with noncapital costs related to equipment, several state rate-setting agencies are striving to do so. Gaus and Cooper (1976) report that in Washington, Connecticut, and, to some extent New York, regulatory commissions are conducting cost-impact studies in order to determine whether or not they will reimburse for particular equipment. They are looking at all costs connected with equipment in their determination, not just purchase price. This effort is new, but the presumption is, Gaus said in a private interview, that if it proves effective federal policy makers would seriously consider broadening the scope of Section 1122 to include these non-capital costs.

Professional Standards Review Organizations

The Professional Standards Review Organization (PSRO) network has been evolving slowly since enactment of the 1972 amendments. Physicians in many regions have resisted the federally sponsored movement which requires that doctors monitor the cost and quality of federally financed medical care. In part, the concern of physicians stems from a belief that the government would only step up its regulatory demands if medicine rushed to implement the statutory requirements of the new law.

The effect of PSROs on the use of medical technologies would be great, were these physician-dominated organizations to establish norms of diagnosis and treatment of diseases as the law dictates. A PSRO will be compelled to address the issues spawned by the highly technological health care system. It will have to consider the appropriate use of coronary and intensive care units, coronary artery bypass procedures, oral hypoglycemic agents and antibiotics, as well as the efficacy of Papanicolaou smears and alternative treatments of breast cancer. Welch (1973), a respected spokesman for surgeons, said:

The public has long believed that medicine has continued to be a cottage industry. The PSROs for the first time would begin to create a single system that is quite in contrast with present disorganized methods. . . . Physicians will of necessity become cost conscious, a feature that at present is woefully lacking. No longer can they use expensive bed space for ambulatory workups or procrastinate with indicated treatment. Sooner or later they will become involved in risk-sharing with health underwriters.

At this point, Congress is following implementation of the PSRO program rather casually, except for a few professional staff members who were a party to its creation. The father of the program, Sen. Wallace Bennett, R-Utah, retired in 1974 and no legislator has replaced him as a prime overseer. The Senate Finance Committee did hold two days of oversight hearings in May 1974, while Bennett still was active, but the program has sparked no major inquiries since.

The most visible flap involving PSROs in the last two years has been its level of funding. The PSRO program is a creature of the tax committees and mostly the Senate Finance Committee, of which Bennett was the ranking Republican member when he retired. Thus, the appropriations committees feel no keen interest in strongly supporting PSROs with funds that could be used for a range of health-related purposes which enjoy more popular appeal.

Congress has not been quick to judge the performance of the PSRO program, although in some quarters a movement is afoot to create a competing mechanism that is less dominated by private physicians. This movement will be discussed later. Other observers, though, are beginning to question whether PSROs, as self-regulatory organizations of physicians, can be expected to render tough judgments on the use of technology. Havighurst and Blumstein (1975) raised this doubt when they argued that:

although originally conceived by Congress primarily as a cost-control device, physician-dominated PSROs as now structured will systematically exaggerate the value of expensive, high-quality care. As a result, they are likely to perpetuate, if not exacerbate, the allocative biases which already characterize the health care system.

Health Planning

With enactment of the health planning law in 1974, Congress put in place a regional network of health systems agencies that it hopes will improve the process of allocating resources in the health field, including technology. The program's mandate, though, of containing costs while at the same time improving access to care reflects the sharp conflicts confronting Congress as it seeks to fashion the future health system.

HEW designated 196 health systems agencies (HSAs) to serve as the regional planning units in their respective areas. The HSAs, as a part of their vast statutory mandate, must develop short- and long-range health plans based, in large part, on priorities set out in the law. Of more relevance, though, are provisions of the law that will have an effect on technology. These provisions involve the role of states under the act. All states must designate state health planning agencies which will be charged with administering the planning and regulatory responsibilities granted to these jurisdictions.

States also must enact certificate of need (CON) laws by 1980, or suffer the loss of funds authorized under the act. These state CON laws and the federal planning act would serve as the statutory base for a regulatory program intended to influence the diffusion of technology by requiring hospitals to seek state approval before acquiring major pieces of equipment, such as scanners. Hospitals and other institutional providers, including health maintenance organizations, also would be required to seek state approval before adding beds or engaging in a major renovation or modernization program.

Some thirty states already have enacted CON laws. Most were approved before the 1974 federal law became a reality. For the last decade, many state hospital associations have pressed their legislatures to enact CON laws, calculating that such laws would restrict the entry of new health care providers while leaving the public impression that hospitals were striving to contain needless ex-

pansion. The CON laws also force into the public eye requests for new technology and beds. And traditionally, the public has favored such development (Lewin, 1975) because of the absence of a direct and negative economic impact on it.

The impact of these CON laws on the diffusion of technology is a question for the future, but the question of the breadth of scope of these laws ignited an intriguing internal struggle at HEW. The dispute serves well to illustrate a continuing conflict between health professionals, who tend to favor more rather than less technology, and other officials whose biases lean toward limiting resources for economic reasons. The conflict revolves around an issue that very likely will be dealt with early in the Carter administration.

The conflict became apparent during the process which led to the publication on March 19, 1976, of proposed regulations intended to serve as guidelines for the development of state health planning and development agencies. The regulations also outlined minimum requirements for states to follow when enacting their CON statutes.

The CON regulations generated heated debate between the offices of Cooper, Assistant Secretary for Health, and William A. Morrill, Assistant Secretary for Planning and Evaluation. At issue was whether HEW should subject to CON review organized ambulatory care facilities that generated annual revenues of more than \$1 million. The acting director of the health planning program at that time, Eugene J. Rubel, recommended that such facilities be required to seek CON approval if they planned to expand or add a piece of high-cost technology.

Rubel was supported by Stuart H. Altman, who at the time was HEW Deputy Assistant Secretary for Planning and Evaluation, and by Altman's boss, Morrill. Rubel favored a strong degree of regulation in the planning program generally, but Altman and Morrill based their view more squarely on the knowledge that physicians were purchasing CT scanners for placement in ambulatory care facilities without planning approval, at a time when health maintenance organizations were subject to CON review under the law.

Cooper flatly opposed subjecting organized ambulatory care facilities to such review, arguing that it was an inappropriate federal intrusion into the practice of medicine. Cooper was backed strongly by the American Medical Association, which considered the pros-

pect of subjecting ambulatory care facilities to CON review as by far the most objectionable element of the proposed regulations because it would bring "the federal government into the doctor's office," one AMA spokesman said (Iglehart, 1976a).

After a prolonged internal debate, Morrill came around to Cooper's view in opposition to subjecting ambulatory care facilities to CON review. Cooper defended his position in a private interview at the time by saying that the department's thinking was not well enough advanced to set such specific regulation.

I recommended that the preamble [to the regulations] say coverage of ambulatory care facilities needs to be developed, but to just put out regulations based on billings of \$1 million as a criterion, I think is the kind of peremptory judgment that begins to prejudice a constructive and acceptable approach to this issue.

Rubel's successor as health planning director, Harry P. Cain II, rekindled the issue in the fall of 1976 when he recommended that the department seek an amendment to the 1974 law which would explicitly declare that ambulatory care facilities are covered under CON review. Cain's move was based on a concern that the proliferation of scanners in free-standing facilities was seriously eroding support for the new planning effort. "The CT scanner has forced the ambulatory care issue to the fore," Cain said in a private interview. In an internal and confidential program memorandum which sought to justify expanding the scope of the CON provision it was said that:

This modification is necessary so that we can require state programs to provide for review to expensive medical equipment in ambulatory care settings. This equipment often duplicates the services provided by traditional inpatient facilities and can, thus, contribute substantially to increasing health care costs.

Cooper again rejected the planning program's policy overture on ambulatory care facilities. On January 21, 1977, HEW published the final CON regulations, which did not cover ambulatory facilities, much to the displeasure of Congressman Rogers and Senator Kennedy.

In early 1977, Congress will likely move to extend the 1974 health planning law for one year, in accordance with President Carter's decision that short extensions be granted to expiring programs so the administration is afforded some time to cast its

policy recommendations. Congress, though, could very well extend the CON requirement to ambulatory care facilities. And the Carter administration, with its plans to emphasize cost containment, might go along.

The Office of Technology Assessment's report on scanners will provide legislators with a compelling argument that ambulatory care facilities have become, in some instances, centers of high-technology equipment. The report said that about one-sixth of all CT scanners now in use in the United States are in private physicians' offices or ambulatory care clinics. Moreover, the American Hospital Association (1976) and several Blue Cross and Blue Shield plans (1975, 1976) have advanced arguments against the maintenance of CT scanners outside of hospitals.

Although Congress rejected ultimately a highly prescriptive regulatory approach to health planning when it fashioned the 1974 law, the committee staff professionals who pressed for such an approach are still around pushing. In addition, many of the health officials in the Carter administration advocate an active government role, a posture that leads in many instances to direct government regulation. Finally, there are just not enough powerful forces at work to halt the government's relentless drive toward more regulation, a direction that inevitably will make the public sector a more imposing factor in the development and diffusion of technology.

Medical Device Law

The Medical Device Amendments of 1974, signed into law by President Ford on May 28 of that year, represents another significant addition to the government's regulatory phalanx. The amendments create a pervasive, government-dominated regulatory program that will place all medical devices in three classifications, the most stringent requiring pre-market clearance of a product.

Advances in technology in recent years have transformed the manufacture of medical devices into a major industry, with sales the Health Industry Manufacturers Association estimates will total between \$6 and \$8 billion in 1977. The Food and Drug Administration (FDA) defines a medical device as any instrument, apparatus, machine, contrivance, or implant used to diagnose, prevent, treat, or cure a disease. Medical devices range from surgeon's gloves to jelly-filled teething rings, cardiac pacemakers, hypo-

dermic needles, oxygen units, kidney dialysis machines, surgical sponges, prophylactics, air purifiers, crutches, and tongue depressors.

The federal government embarked on its first regulation of medical devices in 1939; in the next three years, the FDA removed from the market a hundred which were deemed dangerous or were obviously defective. The rapid expansion of technology in the years after World War II produced hundreds of new devices and greatly complicated the FDA's regulatory task. During the 1950s and 1960s, for instance, the agency found it far more difficult to recall products because the increasing number of device manufacturers began regularly to challenge FDA actions in courts, thus forcing it to develop extensive evidence to back up its proposed actions.

While continuing to review products already on the market, as a strict interpretation of its statutory mandate allowed, the FDA also began to conduct pre-market clearance reviews, claiming that the devices in question were in fact drugs and thus could be regulated under pre-market clearance provisions of the drug laws. These actions, in turn, were challenged in the courts by manufacturers. Two court decisions in recent years, though, upheld the FDA's authority to determine which products in the legally grey area between drugs and devices could be considered drugs and hence subject to pre-market clearance.

The court decisions prompted the Nixon administration to launch a "Study Group on Medical Devices" at HEW, following the President's declaration (1969) that:

certain minimum standards should be established for [medical] devices; the government should be given additional authority to require pre-market clearance in certain cases. The scope and nature of any legislation in this area must be carefully considered.

In focusing presidential attention on this issue, Richard M. Nixon followed in the footsteps of his two predecessors, Lyndon B. Johnson and John F. Kennedy, both of whom had called for medical device legislation when each occupied the White House.

After years of debate, Congress finally enacted legislation in the spring of 1976. The law includes a broad definition of a device,³

³The new law defines a device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any

thus its impact on manufacturers of medical technology will be quite broad, too.

The medical device law was fashioned in large part by four lawyers who met privately on a number of occasions in 1974. Involved were Peter Barton Hutt, who, at the time, was general counsel of the FDA; Stephan E. Lawton, counsel to the House Interstate and Foreign Commerce Subcommittee on Health and the Environment; David Meade of the Office of Legislative Counsel, and Rodney R. Munsey of the Pharmaceutical Manufacturers Association. A fifth lawyer, Anita Johnson, of Ralph Nader's Health Research Group sat in on some of the later sessions after she protested that the group lacked a consumer representative.

The House Interstate and Foreign Commerce Committee, reflecting the conflicting interests of these lawyers and others who were less intimately involved in the policy process, said in its bill report:

... the committee has developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.

Before enactment of the legislation, the FDA's Bureau of Medical Devices and Diagnostic Products focused its regulatory effort on maintaining vigilance against unsafe devices, as the agency's recently retired commissioner, Schmidt (1976), said:

... in recent years, FDA has had to deal with intrauterine devices that would perforate a uterus, poorly designed and manufactured artificial heart valves, faulty cardiac pacemakers, heart monitors that electrocuted or wouldn't work, improperly designed respirators, electric beds that killed people, a cobalt therapy unit that crushed a woman to

component, part or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

death, others that broke ribs; we've dealt with contaminated catheters, unsterile intraocular lenses resulting in the removal of eyes, unsafe x-ray machines, inaccurate thermometers, unsterile disposable surgical sets, unsafe anesthesia machines, unsafe pump-oxygenators, and the list goes on. Each year, we require hundreds of medical device recalls, and may seek injunctions, product seizures and prosecutions.

The law, as Baram (1976) noted, reinforces the FDA's emphasis on safety, but it also requires the agency to measure devices for their efficacy. The FDA, though, is not required to determine whether one device is more efficacious than another which is manufactured to perform the same task. Baram described the law's major significance to the device industry as "single-mindedness."

Consumer health protection is repeatedly set forth as the primary basis for setting standards and for making other regulatory decisions. Nowhere in the act is mention made of regulating medical technologies on the basis of "economic feasibility" or "technological practicability."

The emphasis on safety and efficacy is consonant with the strong feelings of one of the law's prime sponsors, Rep. Paul G. Rogers, D-Fla., who leaned in this legislation and most other measures⁴ he has championed in favor of consumer protection and safety, rather than questions of cost.

Baram suggested that it is premature to speculate on the implications of the law for the development and diffusion of technology. Other observers, though, have been less reticent to comment on the potential impact of the new law. Nobel (1976), a respected expert in the device field, said:

Over the next decade, health care institutions can look forward to the following undesirable effects: (1) Fewer new devices will be developed and enter the marketplace. (2) Some smaller companies will go out of business, sell out to larger companies, or go into other areas. (3) As the larger companies need to diversify and grow stronger, they will acquire the smaller companies. (4) The diversity of suppliers and competition will be reduced. (5) The price of medical devices and supplies will increase.

⁴The Clean Air Act Amendments of 1976, which failed to become law, was another major instance where Rogers put health considerations before cost questions, to the consternation of the automobile manufacturers.

No interest group involved in the medical device debate disputed that there will be new costs attached to the tighter regulation. The FDA, for instance, told Rogers in a private communication that the estimated costs of scientific review of such devices as prosthetic heart valves, arrhythmia detectors and alarms, and air fluidized beds were, respectively, \$225,000, \$10,000 to \$160,000, and \$4,000 to \$14,500. The agency further estimated that clinical investigations concerning heart pacemakers may be more costly than those for heart valves.

Lawton, the House subcommittee counsel, said in a private interview on January 10, 1977, that Congress took steps in the law to prevent the effects Nobel speculates the Act will have on devices but he conceded:

Regulation is expensive. The important thing is that the committee determined that the need to insure safety and effectiveness of medical devices was paramount to the considerations Dr. Nobel mentioned, including cost. When one speaks in terms of the unnecessary deaths and injuries that have occurred because of less than satisfactory testing of devices, safety and effectiveness considerations just have to take precedence. Beyond this, though, the committee made a conscious effort to avoid the effects that Nobel predicts. The thesis of the legislation is, for example, that the least regulation necessary in order to insure safety and effectiveness is all that is required. Unlike drug law, where all new drugs must face pre-market clearance, fewer than half of all new devices will be subjected to this test, which is expensive. Secondly, the product development protocol procedure is an attempt to speed the approval process as well as an attempt to cut the cost of research by essentially merging FDA's processes for determining safety and effectiveness. Third, the law mandates that FDA extend assistance to small manufacturers of devices in complying with it. It's true, though, that after enactment of the 1962 drug amendments smaller drug companies were gobbled up by the corporate giants. This phenomenon supports Dr. Nobel's thesis of what may happen to some of the smaller device manufacturers, although it is our hope that it won't.

Catastrophic Health Insurance

The legislation which is perhaps most likely to compel Congress to address policy questions surrounding technology, its cost and regulation, on a more comprehensive basis revolves around the

politically appealing notion of protecting all Americans against the economic consequences of catastrophic illness. Such legislation has gained increasing favor with federal policy makers, even though its implications span many social, ethical, and economic fronts.

Sens. Russell B. Long, D-La., Chairman of the Senate Finance Committee, and Abraham Ribicoff, D-Conn., a senior member of that committee, introduced the first major catastrophic health insurance bill in October 1973. This measure attracted 23 other Senate sponsors. Since then, President Ford proposed a catastrophic benefit for Medicare beneficiaries and other key legislators have advanced their own prescriptions, including Rep. Dan Rostenkowski, D-Ill., Chairman of the House Ways and Means Subcommittee on Health. The plans advanced all have been different and no consensus has emerged, but it is clearly an issue that will come before the 95th Congress.

Congress already has enacted one program that extends substantial benefits to individuals afflicted with one catastrophic illness—end-stage renal disease. Although it is difficult to generalize on the basis of HEW's experience with the kidney program, it does provide some insight into how the government has sought, through direct regulation, to implement this effort. Congress initially provided HEW with sweeping powers to finance and regulate the treatment of kidney disease, a reflection of its concern over the potential cost of the program. Looming on the legislative horizon is a new effort to impose tighter regulations in a way that would seek to encourage more renal disease patients to undergo dialysis at home or in less costly institutional settings.

The concern over the cost of financing what Lewis Thomas, M.D., has described as a "half-way technology" was well placed, although it did not stop the Congress from acting. During the 1972 Senate floor debate on the kidney amendment, program cost estimates for fiscal 1976 and 1977 were \$198 million and \$252 million, respectively. Today, revised program cost estimates for the same fiscal years are \$400 and \$500 million, respectively. HEW now projects that after a decade of operation, the kidney disease treatment program will cost \$1 billion, as a result of higher unit costs and a growing number of renal disease patients.

The House Ways and Means Subcommittee on Oversight has been conducting a continuing series of hearings on the kidney program. In a report (1975), the subcommittee expressed its concern over the cost projections:

The subcommittee is deeply concerned with these high costs, which place a heavy burden on the trust funds and general revenues. These costs also limit options to provide protection for the cost of treating equally deserving patients confronted with other forms of catastrophic disease such as hemophilia, stroke, cerebral palsy, cancer, and so forth.

Congress is under heavy pressure from interest groups representing these disease categories to extend its catastrophic coverage to other illnesses. HEW already has funded seventeen comprehensive diagnostic, evaluation, and treatment centers for hemophilia, which are intended to provide information and guidance on the disease to other hospitals. A next step could be financing treatment for hemophilia.

The debate over financing kidney treatment spanned almost a decade, as Rettig (1976) depicts so well in recounting it, although 1972 Senate action stemmed from a hastily drawn, little discussed floor amendment. Congress specified kidney treatment coverage for all renal disease patients covered by social security, about 97 percent of the population afflicted with this disease, and then authorized HEW to say where the treatment could be rendered and how much care these facilities had to deliver to be eligible for reimbursement. Further, Congress directed HEW to create a mechanism to decide who should receive the care.

In the history of federal involvement in medicine, these measures were revolutionary when compared with the degree of intervention that Congress accorded HEW in the administration of Medicare, according to Wolkstein (Iglehart, 1976b). But now the House Ways and Means Subcommittee on Health is preparing legislation that would carry government intervention a good deal farther in an effort to contain costs. Although the measure is still under development, its principal author, Erwin Hytner, of the Ways and Means staff, outlined its major purposes in a private interview on December 6, 1976.

The costs of the kidney treatment program have gotten out of hand. The program has been loosely administered in these first years, in part because Medicare's top priority was putting it in place; financing treatment was the priority. Now we want to seriously consider some rather sweeping changes that we envision could have two major impacts: one, reducing program expenditures by redirecting the place of treatment away from free-standing proprietary kidney facilities, which are making substantial profits, if not abusing the program. And

two, injecting financial incentives that would encourage physicians to urge their patients to use home dialysis or self-treatment in a supervised institutional setting. In other words, the government would be applying in a very direct way its financial leverage to get doctors and hospitals to change a course of behavior they have been following. Also, we will propose shifting Medicare's basis for payment to facilities from charges to costs. And we want to look closely at empowering medical review boards that were created under the original act with making the determination of whether a patient could appropriately use self-care. This decision, then, would not be left solely to a patient and his or her physician. These proposals will stir up a hornet's nest, but we really need to get a very tight handle on costs. The free-standing proprietary facilities are taking over the field of kidney treatment.

Technology and the Biomedical Research Community

Traditionally, there has been little appreciation in the political world for the binding relationship between the development of technology and the government's massive investment in biomedical research. Increasingly, though, as medical costs have increased and public demands have grown for science to account for its government subsidies, legislators and executive branch officials have been raising new questions about the link between technology and research.

No such statement was more compelling, nor drew more attention, than that offered by Gaus in 1975 in testimony before the President's Biomedical Research Panel. Gaus outlined the reasons why Medicare, as a financier of health services, is deeply interested in biomedical research funding and priorities.

Medicare does not finance or engage in biomedical research. It does, however, finance the results of this research. The diffusion and adoption of health care innovations often results in the utilization of far more resources than was initially expended in the research effort and the process plays a major role in the dramatic increases in the open-ended budget levels of the Medicare and Medicaid programs.

In expressing concerns over the impact of new technology on cost, Gaus articulated a view that no other top-level official of Medicare or its parent agency, the Social Security Administration, has stated publicly. Besieged by other concerns deemed as more pressing,

SSA's hierarchy has left to Gaus the issue of Medicare and technology, although Thomas Tierney, director of the Medicare program, said in a private interview that officials must recognize that the idea of controlling technology has enormous implications for public policy.

In a public program, you must have the best as long as the government asserts that the covered population will get the best.

Other voices, though, are starting to be heard. One of the most forceful among them is that of Sen. Edward M. Kennedy, D-Mass., who, as Chairman of the Senate Labor and Public Welfare Subcommittee on Health, is responsible for overseeing the National Institutes of Health, which dispenses \$2.5 billion a year in funds for biomedical research and allied purposes. Another is Dr. Donald S. Fredrickson, Director of the NIH.

Kennedy's keenest interest is in creating a government-sponsored mechanism to assess the value of medical technologies. And he deeply believes that academic medical centers, which received 46 percent of NIH's biomedical research monies in fiscal 1974 (Morgan and Jones, 1976), have a major role to play in such an exercise. In a public hearing on June 17, 1976, Kennedy signalled his strong interest in creating such a mechanism when he asked Cooper, HEW Assistant Secretary for Health:

Is it possible for us to formulate some kind of panel or mechanism or institution which will evaluate what is going on in terms of the medical technique or practice which will include the clinicians and researchers and also a public dimension?

Cooper replied: "I think it is possible to do that."

From the outset of what Kennedy described as a year-long examination of federal biomedical research policies, which he launched with public hearings in June 1976, the senator and his staff assumed that the NIH and its clients would resist addressing questions of assessment, questions which extend far beyond the traditional role of the research community. Kennedy's view was colored in good part by the work of the President's Biomedical Research Panel in 1976, which concluded that the research community had no major responsibility in the interface between research and delivery. The panel also endorsed, without reservation, the job the research community was doing. Officials at the NIH who

followed the panel's work also sensed that the panel's failure to address these broader issues was a significant shortcoming. Seymour Perry, M.D., an aide to Fredrickson, said in a private interview, "I think it really hurt the research community."

Unlike the panel, though, Fredrickson was more sensitive to the strong political currents that surrounded the issues of the biomedical research community's mission, on the one hand, and its strong dependence on public support, on the other. Fredrickson sensed that the winds of change were blowing and, unless NIH began to show some commitment to examining technologies produced by the research community, the federal health policy makers might react in ways that could only be detrimental to research. Fredrickson expressed the essence of his thinking at a hearing before Kennedy in 1976:

I think that there are some new social imperatives for science. They include a full measure of responsibility for what should not be in the doctor's bag, for the rate of transfer of new knowledge into practical use, a sharper concern for matters of ethics and due process in clinical research, technology assessment and public involvement in such decisions.

In an interview subsequent to his congressional testimony, Fredrickson said (Iglehart, 1976c) that he has come to recognize that NIH and the research community it subsidizes have a taller order than simply generating knowledge.

There are new interventions. By this I mean, traditionally we have been laissez-faire. We have created scientific opportunities, but left their execution to a conglomerate of health-care vendors and the voluntary sector. Very often we have done that without making an authoritative assessment of the value of the technology or rendering a judgment on the cost-benefit relationship. We have to get more deeply involved in that process. Some kind of collective authority is needed, because once you have created a piece of new technology, there are forces pushing diffusion that press for its maximum use . . . the profit motive among health vendors and the concept, almost legal, that everybody should have access to what is perceived as the best care available.

Soon after delivering his testimony last June, Fredrickson moved aggressively to create at NIH a policy that underscored what he believed should be the biomedical research community's new commitment to more actively focus its energies on broader health

problems in the future. One political reality pressing upon him was that, as an appointee of a Republican president, Fredrickson had to demonstrate to his new Democratic stewards that there were compelling reasons why he should be retained as NIH director.

Fredrickson surfaced at NIH, two weeks before the November 1976 election, a draft issue paper entitled, "The Responsibilities of NIH at the Health Research/Health Care Interface." In a cover letter to the proposal, Fredrickson said:

The issue addressed is one of exceptional importance to the NIH and the larger biomedical research community: what should the responsibility of NIH be in assuring effective introduction into the health care system of knowledge pertinent to disease prevention, detection, diagnosis, treatment and rehabilitation? How should the NIH organize, what processes must be put into place, to discharge these responsibilities?

In the paper, which NIH distributed among only its institute directors on a "confidential basis," Fredrickson proposed that the agency and the scientific community:

assume a greater responsibility in the selection and use of that knowledge pertinent to disease diagnosis and treatment, which is to become accepted health practice.

Further, Fredrickson proposed that this function be carried out through a mechanism created in each of NIH's research institutes that would:

identify and foster evaluation of appropriate new knowledge on the verge of transfer to the health care community.

These mechanisms would function under the aegis of the NIH, but representatives of nongovernmental professional and lay organizations would be parties to the process.

Fredrickson's proposal generated a good deal of controversy at the NIH. Several of the institute directors argued privately that the new processes could come to dominate the research institutes, sap funds from their on-going research activities and engage the agency in running disputes with organized medicine. On Capitol Hill, though, where word of the proposal soon leaked, the reception was far more positive, particularly from the Kennedy camp. The senator's chief health aide, Jones, said in an interview:

I'm surprised by the paper, surprised that Fredrickson has gone so

far. I think it's fantastic. Fredrickson has taken the lead in asking questions of the research community that we want to press, but within that community his voice has far more real influence than does ours.

The creation of a government-sponsored mechanism to assess technologies and treatment practices would, in some ways, compete with the PSROs. In Kennedy's view, PSROs are too dominated by private physicians, individuals he fears may have a vested interest in a process of treatment assessment and therefore may have a hard time being objective. The assessment process that Kennedy and Fredrickson envision would more nearly be a set of public bodies, set up under the aegis of the government, but also engaging academic researchers, practicing physicians, medical specialists, and other experts.

What Fredrickson is driving at in this early cut at assessment is developing a mechanism through which knowledgeable experts could strive to reach a consensus on what technologies are most effective. For example, the NIH recently completed such a process for the treatment of hypertension. In an interview on December 16, 1976, Robert L. Ringler, M.D., Deputy Director of the National Heart and Lung Institute, said that the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure:

attempted to build a consensus on the treatment of hypertension that would avoid putting everybody with high blood pressure in the hospital for a week. The group set down guidelines for the treatment of this particular disease.

The committee plans to disseminate its findings widely, hoping that physicians who treat individuals with hypertension will embrace the recommendations of the group. The findings will be published in the *Journal of the American Medical Association*.

Fredrickson believes that eventually HEW will link such research findings to stricter guidelines on what services its health financing programs will pay for. He said in an interview on December 16, 1976:

I think it is inevitable that the fiduciary, either government or outside third parties, will begin slowly to make decisions about what it will and will not pay for [on the basis of government-sponsored judgments on what medical practices are the most effective.] They do that now but only in the most general sort of way. I would expect that trend to increase.

The NIH will not be alone in its interest in undertaking medical assessments, if the government decides to plunge into such exercises in a big way. HEW's National Center for Health Services Research and the Center for Disease Control both have strong interests in this area, as do members of the Institute of Medicine of the National Academy of Sciences and its president, David Hamburg, M.D. Indeed, it was the Institute of Medicine that the Blue Cross Association turned to when it sought some quick guidance on the CT scanner. Walter J. McNerney, the president of Blue Cross, said in an interview on December 23, 1976:

How the institute steps up to the plate on this one will have a lot to say about its future usefulness in this area. If the institute performs well, then I will move to an on-going strategy of getting early advice on emerging technologies.

Summary

The federal government's entry into the financing of medical services has spawned a multitude of activities that are affecting every element of the health system. Rising medical costs have become the No. 1 problem for the government because this phenomenon absorbs limited dollars needed to finance many other worthy social goals. In Medicare alone, the costs have jumped from \$5.3 billion in 1968, to \$9.5 billion in 1973, to \$26.1 billion in 1978, to an estimated \$30.4 billion in 1979. As long as medical costs climb at a rate faster than other elements of the Consumer Price Index, the government will be seeking to stem this tide, regardless of the uproar it generates among health care practitioners.

A central facet of this cost spiral, as industry spokesmen acknowledge, is the changing nature of the medical product, particularly within hospitals. The product is becoming more technologically complex and more expensive. Not only are the new machines themselves more expensive, but they require more manpower and additional space. The government has fostered this technological imperative through its massive financial commitment to biomedical research, which generates new knowledge and, thus, new technology. The cost-plus hospital reimbursement system also has served as a powerful force stimulating this imperative.

In the last five years, as Medicare and Medicaid have evolved

into big ticket cost items, federal decision makers have begun to recognize more clearly vital links in the system which drive it; links between the manner of reimbursement and the amount of technology deemed as essential; the development of technology and the degree to which it is regulated; and the effect of this equipment on patients and the quality of care delivered.

The government has begun to intervene in these linkages, principally through new laws that seek to contain costs, insure quality and influence the system's growth. Major new laws that reflect this trend are the Social Security Amendments of 1972, the Health Planning and Resources Development Act of 1974, and the Medical Device Amendments of 1976. All of these laws include new threads of direct government regulation of the health industry, the central federal health policy theme of the 1970s. Looming ahead is more regulation effecting clinical laboratories, kidney treatment, and perhaps costs on a general basis.

Government control of technology is a touchy issue. And the federal policy process sometimes has a hard time dealing decisively with such sensitive matters. Federal decision makers certainly do not want to inhibit the orderly diffusion of life-saving technology. Nor do they favor imposing arbitrary restraints on the use of sophisticated diagnostic equipment, like the brain scanner. But their credulity is taxed when the proliferation of a technological device like the scanner is so rapid and so without rational planning that there seems no limit to the number that ultimately may function in the system.

A new dimension of government activity in the health field is emerging—an interest in the value of medical technologies. This effort, though only in its earliest stages, could stamp even more firmly the government's imprint on the field. The movement stems from a slowly evolving belief at the National Institutes of Health that the biomedical research community must relate more closely to the clinical practice of medicine. The chief political stalwart of this movement is Sen. Edward M. Kennedy, D-Mass.

This effort, plus the many other health regulatory activities that are engaging the government, guarantee that the system will remain unsettled and tension-filled. The government's policy-making mechanisms are imperfect, often slow to react and often lacking in precision. But in most instances, sooner or later—government acts to protect the public's investment. And there is no reason to believe that it won't take the steps it deems necessary to do just that.

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