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OBSTACLES TO DEVELOPING AND USING TECHNOLOGY

The Case of the Artificial Heart

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For some observers, the artificial heart represents the latest, and perhaps the most flagrant example of the health system's tendency to favor the rapid introduction of expensive but ineffective technologies over efforts to prevent disease and to improve access to care (5;6;19;44;45). Even if it can be perfected, they argue, its opportunity cost in terms of other foregone health benefits would be exorbitant. The ultimate failing of the health care system, it would seem, is its failure to establish mechanisms to select among alternative uses of resources. If such mechanisms had existed, some critics believe that the quest for an artificial heart never would have begun and certainly its premature clinical uses could have been prevented (6;45).

In this paper we examine the history of the artificial heart to determine whether the health system is as favorable to the development and use of expensive health care technologies as is generally believed. Contrary to the conventional wisdom, we discover that there has been continuous opposition to the development of the heart, although for varying reasons and with varying effect. In particular, the agency most responsible for the artificial heart, the National Institutes of Health (NIH), has been extremely cautious in supporting the early development and application of the heart, but has not always had its way. Regulatory reviews also have slowed experimentation with the device. Because of the changing fi-

nancing arrangements for hospitals, there are now substantial constraints on the diffusion of new medical technologies, including the artificial heart. At the same time, of course, other powerful influences have hastened the heart's development. Not the least of these has been the advocacy of a committed group of researchers and the ever present urge to extend life when hope is offered.

We believe that a review of experience with the artificial heart is useful in understanding the forces affecting the rate and direction of change in health care technology generally, and life-saving devices in particular. The effort to develop the heart has been shaped importantly by professional values, research group rivalry, congressional involvement, bureaucratic competition, commercial interest, intense media attention, technological uncertainty, and the desperate needs of identifiable patients. All of these factors interact to determine the rate at which new technologies are developed and introduced into the health care system. A critical question is whether changing reimbursement rules and increased competition among health providers will influence the balance among the forces promoting and constraining health technologies like the artificial heart.

RESEARCH AND DEVELOPMENT

In 1964, the National Institutes of Health initiated a program to develop an artificial heart that could be used in patients by the end of the decade (52;56). The program was expected to create a family of cardiac assist and replacement technologies, including a totally implantable device, that would extend the lives of the thousands of patients who suffer from terminal heart disease. Almost from the start, there were claims that the program was unrealistically optimistic and inadequately managed. The leadership of the NIH generally shared these doubts and fought to slow the artificial heart's development. In so doing, senior NIH officials were part of a familiar conflict in the research community between those favoring investigator-initiated basic research and those favoring centrally directed applied research (49;58).

Like many other NIH research programs, the initial impetus for the artificial heart program came from a few well-known medical investigators working outside of government (34;41;57). During the late 1950s, a small group of physicians, including Willem Kolff, Frank Hastings, Adrian Kantrowitz, and Michael DeBakey, had, on their own, without the help of engineers, constructed mechanical devices for assisting or replacing the natural heart. Because artificial heart research was not a separately identified program within the National Heart Institute, these researchers were forced to compete for resources with all others seeking support for heart-related projects (52). Not satisfied with the level of support that was made available under this arrangement, they tried to convince the director of the NIH and various Institute advisory committees of the need for an independent development program for the artificial heart. They also sought support among members of Congress and the biomedical research lobby that had championed so successfully other NIH causes (41;56;57).

The researchers' efforts to create an autonomous program came to fruition in July 1964 when the first congressionally approved funds became available and the Heart Institute formally established a program office to manage development work. The Heart Institute recruited Dr. John R. Beem, a senior research official

at Warner Lambert, to direct the program. Because the NIH was legally prohibited from providing grants to private firms, the program office was forced to acquire for the first time a contract management capability (56). Nine contracts were subsequently awarded to firms for the design of prototype blood pumps, control components, driving mechanisms, and materials. The technologies developed were to be made available to institute grantees upon request (51).

The results of initial investigations convinced the project staff that a larger and more tightly planned program was required. Beem believed that the aerospace industry possessed the skills necessary for developing an artificial heart (4). These skills, he felt, could be enlisted by relying on the systems management techniques developed in successful defense projects. In this approach, a central group would coordinate the integration of system components, evaluate and select competing technologies, and manage the development process (32).

Although a few influential members of the medical research lobby endorsed the artificial heart program, the biomedical research community generally did not embrace the goals of the project (29;56;59). Many researchers expressed dismay at the artificial heart program's technological orientation. In their view, the key to heart disease lay in discovering its underlying causes, and not in the development of expensive technologies to be applied after the disease has run its destructive course (56). They feared that an emphasis on artificial heart research potentially would threaten other more valuable research endeavors. B. L. Horecker's criticisms of the early stages of the artificial heart program were typical of many in the biomedical research community:

> I have examined these projects and am convinced that they are for the most part ill conceived and highly unlikely to accomplish the stated objectives. Most of them have been awarded to industry. They represent superficial research. (26)

Members of the biomedical research community, wary of the program's goals, found its management techniques equally objectionable (32;56). The artificial heart program departed dramatically from the NIH's standard practice of awarding investigator initiated grants to university researchers. The scientific community expected that the program's reliance on contracts with firms might set a precedent for other targeted research programs in the field of artificial organs. The research strategy adopted by the program threatened to upset the scientific community's dominance over the direction of NIH programs. Above all, members of the basic research community feared that the expansion of the contract programs would lead to a reduction of support for basic research, and possibly to the political restructuring of the biomedical research system (52).

Proponents of the artificial heart were able to overcome opposition to the program because of the relatively small size of its initial budget, less than one million dollars during a period of budgetary expansion at the NIH. The decentralized decision-making process at the NIH further enabled proponents to lobby Congress directly without proceeding through the administrative hierarchy. Based on a highly optimistic technical and economic evaluation, the program office in the spring of 1965 drew up an ambitious five-year master plan for the artificial heart, with a proposed budget exceeding $100 million (25). Congress approved the plan in late 1965 with little debate (56). Subsequently a Heart Institute advisory

panel added its endorsement to the plan, suggesting that the program be accelerated.

Dr. James Shannon, the Director of the NIH, chose instead to curtail the program (54;56). In September 1966, upon the recommendations of Heart Institute Director Robert Grant, Shannon reallocated $5 million dollars from the artificial heart program's fiscal year 1967 budget of $13 million, to the more medically oriented Myocardial Infarction Program, designed to further understanding of the causes and the clinical management of heart attacks (40). This effort, relying entirely on disciplinary-based grants to support biomedical investigators, would explore three broad program areas: quantitative methods for diagnosis, risk factors causing myocardial infarction, and pharmacologic and other modes of treatment. Like their medical school clients, Shannon and Grant undoubtedly hoped that medical research would eventually prevent or cure myocardial infarction, eliminating the need for the artificial heart altogether (21;56).

Shannon's redirection of the program initiated a decline in its budgetary priority. The artificial heart program shrank from over 5% of the Heart Institute budget in 1967 to 2.5% a decade later (38). As Claude Lenfant, the current director of the National Heart Lung Blood Institute, recently stated, "It is clear that the artificial heart program never absorbed a major portion of NHLBI resources and . . . tended to receive an ever decreasing share of those resources"(33).

Despite funding cutbacks, the program office retained its technological optimism about the feasibility of a totally implantable artificial heart (52;53). Although several options for energy sources, including battery and biological fuel cells were considered, the nuclear system appeared to be the most desirable (27). Both the Heart Institute and the Atomic Energy Commission sponsored development of plutonium fueled thermal engines throughout the latter half of the decade (18). (The Atomic Energy Commission was required by law to be involved because it held development responsibility for any nuclear materials used and was eager to promote the artificial heart which it saw as a means of demonstrating the peaceful aspects of nuclear energy.) However, the two agencies could not agree on system responsibility for the nuclear powered device. As a result, two parallel and competing programs existed for a time, both dedicated to developing nuclear-powered artificial heart technology. By the early 1970s, devices had been constructed that performed adequately in bench and animal tests. Concerned about the environmental hazards of nuclear technology, Congress in 1975 eliminated the Atomic Energy Commission's budget for the artificial heart (18).

Scientists had also begun to question the acceptability of nuclear energy as a power source for the artificial heart. The Heart Institute in 1972 had established a special advisory panel to evaluate the economic and ethical implications of the nuclear powered heart (2). The advisory panel recognized the cost implications of the artificial heart, but took no position on how its widespread use might be financed. The health risks of the nuclear powered heart generated greater concerns, with the panel ultimately recommending that devices not be used until the hazards to nonrecipients could be identified better and protected against (2;22). Following the advisory panel's report, the Heart Institute began to phase out its support for nuclear powered devices, so that by 1980 all federal funding for nuclear systems had been discontinued.

When the Institute began to deemphasize the nuclear device, the artificial heart program was moved into the Division of Heart and Vascular Diseases and

required to pursue the more modest goal of developing ventricular assist devices (37). Throughout its first decade, the program was never able to gain the budgetary and organizational priority that advocates had desired. Had the program not benefited from the support of a few prominent investigators, the opposition might have prevented the project's continuation. It was not until the highly publicized Barney Clark case in 1982 that attempts were made to reestablish the artificial heart as a major research goal of the National Heart Lung Blood Institute (NHLBI).

CLINICAL TRIALS AND EXPERIMENTATION

The clinical program at present seems chaotic and nearly hopeless. Of the first five recipients of permanent artificial hearts, all suffered from serious clinical complications, including strokes, before they died. Some commentators have proposed a moratorium on further implants, suggesting that the entire clinical effort was ill conceived (44;45). Yet, the record of the artificial heart reveals a carefully scrutinized and regulated process for moving from animal to human trials.

The era of the permanent mechanical heart began in earnest in 1982 when Dr. Barney Clark, a dentist, received an implant at the University of Utah, of a heart model developed by Dr. Robert Jarvik. The surgeon was William DeVries. At the time, NIH officials did not consider the pneumatic artificial heart, which required patients to be tethered to a bulky power driver, ready for human trials. They believed that recipients would face a severely impaired quality of life of indeterminate duration, requiring constant medical surveillance (20). Dr. William Pierce, who leads a research team at Pennsylvania State University, agreed with the NIH view, stating that the Utah group's decision to begin human trials depended on the personal desires of the developers and the patient (31;43). The Utah-Humana team did forge ahead with trials of the pneumatically driven device by raising private funds to pay for the implants.

What is often overlooked is that only one of the roughly 12 research teams developing the heart technology has circumvented NIH controls and actually begun human experiments with permanent devices. All of the other U.S. research teams have complied with NIH's restrictive policies toward the clinical application of mechanical support or replacement technologies. As a device sponsored by NIH contracts becomes ready for clinical application, it must undergo an exacting review to guarantee the device's safety and reliability for human implants (37;39;60). Devices must not only comply with general criteria established for the clinical investigative use of therapeutic devices, but also must meet specific criteria established by the NHLBI. (These criteria are especially important for devices, such as the artificial heart or ventricular assist devices, because neither good animal models nor standardized protocols exist to guide the transition from animal to human implants.) For a device to proceed into clinical application, investigators must demonstrate through experimental evidence from animals that on balance, the patient has more to gain than lose from the use of the device (39). They must also show that the device offers benefits equal to or greater than any accepted therapy or experimental technique. Finally, the investigators need to establish clearly the expected reliability of the device for its intended life. The

NIH relies on experts to evaluate data, recommend further studies, and ultimately to determine a device's readiness for human use.

The Utah group may have successfully evaded the NIH's controls on human experimentation by seeking private support, but the procedures for gaining regulatory approval from its Institutional Review Board (IRB) and the Food and Drug Administration (FDA) did cause important delays. Before approving the research protocol submitted by Dr. DeVries, the Utah IRB thoroughly reviewed the risks and benefits of the implant and the procedures for obtaining informed consent (61). The board initially allowed implants in a very limited patient pool—those patients undergoing open heart surgery who could not be weaned from the heart–lung machine (61). With IRB approval and after a short delay, the FDA accepted the Utah team's application for an investigational device exemption under the Medical Device Amendments of 1976.

In spite of opposition from the NIH, the FDA believed its legislative mandate under the medical device amendments was to rely whenever possible on qualified institutional review committees rather than government officials to supervise the clinical testing of devices (12). Moreover, the FDA regulations are not as protective of patients as are the NIH's guidelines for the experimental use of medical devices. The FDA does not require that a device demonstrate a benefit to the patient, but only that "the risks to the subject are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, and whether the study is scientifically sound." Regulatory officials accepted the experimental protocol because of its promise to generate new knowledge that could not be gained through animal experiments (46).

The regulatory process produced further delays in the first two implants. After eighteen months in which no patients fit the restrictive patient selection criteria, Dr. DeVries applied for a relaxation, which enabled him to perform an implant on Barney Clark, who was suffering from congestive heart failure due to cardiomyopathy. Following the Clark implant, the surgical team had to wait an additional eighteen months for IRB approval for its second implant (35). Dr. DeVries has stated that the process of obtaining regulatory approval from the Utah IRB and the FDA was one of his principal reasons for moving the human trials to the Humana Heart Institute, where he hoped for far less delay (1).

The regulatory hurdles are by no means over; the failure of the first four U.S. implants makes the prospect of completing the full series problematic. In December 1985, an advisory panel to the FDA tightened regulatory controls on the permanent artificial heart by requiring a case-by-case review for each implant. Even if the research team completes the planned seven experiments, it will have to reapply for permission to perform any additional implants. Furthermore, there is no guarantee that pre-market approval will come quickly once the device becomes ready for manufacture.

Although the process of clinical experimentation is clearly more constrained than commonly believed, the use of the artificial heart as a bridge to cardiac transplantation is reducing the existing barriers to its clinical application. At least a half dozen groups have conducted or plan to initiate trials with temporary artificial hearts or assist devices for patients awaiting transplants. The surge of interest in these devices results from the desire of cardiac surgeons to provide a means of sustaining those patients who would probably die while awaiting a donor

heart (13;14). With the development of cyclosporine, patients can better tolerate the two staged procedure, in which the use of an artificial heart or assist device is followed by a transplant. The staged procedure tends to diminish the opposition of transplant surgeons, who have been some of the harshest critics of the artificial heart (10;35). By applying it as a temporary measure, surgeons can also elude the FDA's stricter requirements for permanent artificial hearts and place devices in younger and presumably healthier transplant candidates. Artificial hearts used as a bridge-to-transplantation thus confront less strict regulatory guidelines despite the fact that temporary implants may of necessity become permanent, if physicians fail to locate suitable donor hearts (30). Nevertheless, it seems likely that the FDA would intervene if surgeons began implanting devices in large numbers of patients with no reasonable prospect of receiving transplants in the short term. And if the use of the artificial heart is confined to legitimate transplant candidates, then the number of hearts implanted will be constrained, like transplants themselves, by the number of available donor organs.

COMMERCIALIZATION

One of the original goals of the artificial heart program was to develop an industrial capacity in biomedical engineering (4). This was considered especially important in the early 1960s when bioengineering was not well developed as a discipline. Ironically, many in the biomedical research community now consider an industrial capacity in artificial organ research more of a societal liability than a successfully realized goal of the program (6;44;45;47). Investigators in this community believe that the possible profit to Robert Jarvik, Humana, and the surgical team is likely to lead to choices that may not be in the best interests of patients. Others argue that artificial heart research in the for-profit sector should be regulated, even though not currently dependent on NIH funding, because of the years of development work supported by the federal government.

Contrary to the belief that commercial motives are unusual in the development of medical devices and procedures, the pattern of government support of basic and applied research and industrial funding of the development of medical devices is common. Involvement of private industry in development and marketing of life-sustaining devices, such as dialysis machines, intra-aortic balloon pumps, and heart–lung machines, is quite familiar in America. Indeed, reliance on private industry is the principal method for transferring new knowledge into practical application in medicine. There is no practical alternative in our economy to the dependence on private industry for the manufacturing and marketing of medical devices. It must be recognized that commercial motives of firms such as Symbion, Thermedics, and 3M do promote the development and use of devices; the artificial heart, however, is not unique in this regard.

Much of the debate over the commercialization of the artificial heart has focused not on the companies developing the technology, but on the involvement of Humana, the nation's third largest proprietary hospital chain, in the sponsorship of clinical trials. Thus the clinical application of the heart has been caught up in larger debates about the role of profit making organizations in the provision of health services. Humana's sponsorship has undoubtedly accelerated the pace of clinical trials by reducing financial barriers and enabling researchers to circumvent

some regulatory controls (50). Furthermore, it has freed investigators from the traditional constraints of academic medicine.

Humana's strategy of seeking out a leading clinical research group to gain prestige is perhaps the most controversial aspect of the artificial heart's commercialization (3). Despite the continuing debate, it is premature to judge whether Humana's marketing strategy has influenced the scientific evaluation of the human trials. Moreover, it should be noted that Humana's decision to use the artificial heart as a marketing device was not all that deliberate, but only evolved slowly as a result of a financial investment in Symbion, the Salt Lake City corporation that fabricates the Jarvik artificial hearts (9;36). Only after it invested in Symbion on the advice of a financial management company did Humana consider sponsoring the clinical application of the artificial heart (36). As yet, Humana's funding of the artificial heart implants does not seem to have initiated a rush among for-profit hospital chains to sponsor clinical research in the area of artificial organs. Of all the research groups developing artificial heart technology, only Symbion is affiliated with a for-profit hospital chain.

Nevertheless, the advertising needs of powerful for-profit health care enterprises are potentially important new elements spurring the development of health care technologies in the United States. Should large numbers of enterprises attempt to develop highly visible new devices, the rate of experimentation with celebrity technologies could increase significantly. Experimentation, however, is not equivalent to dissemination and application. The ultimate attractiveness of medical technologies to health care organizations will depend importantly on whether third parties will pay when they are used.

THE HEART IN A CHANGING REIMBURSEMENT ENVIRONMENT

Many physicians describe their colleagues as being indiscriminate in their purchases of technology. If a technology exists, physicians will apply it, without certainty of its effectiveness or without clear indications of which patients can be expected to benefit (55). Similarly, third party payers supposedly can not resist pressures to pay for costly therapies that prolong life (6;19;36). The critics of the artificial heart and its staunchest advocates share this view, assuming that once a workable artificial heart is developed, payment will automatically follow. Because of an important shift in the politics of health care, however, there is certain to be great resistance to providing reimbursment for the artificial heart as well as other medical technologies.

The investment of over $200 million in research and development notwithstanding, the federal government seems unlikely to initiate a program to finance treatment for terminal heart disease as it did for end-stage renal disease. On the contrary, the federal government's current policy is to transfer health care costs away from the public sector (23). Although the end-stage renal disease program was once considered a possible precedent for some form of catastrophic health insurance, expanding program enrollments and their consequences for the Medicare budget have become a deterrent to further initiatives aimed at covering the costs of particular life-saving technologies (49).

The private sector is also likely to resist coverage for the artificial heart. Although third party payers readily provide coverage for technologies with high per-patient costs in situations involving small patient populations and highly identifiable victims, they are much more reluctant to cover technologies that result in large total costs (7). Renal dialysis is the classic illustration of a technology for which insurers delayed coverage over a decade, while thousands died, until Congress finally adopted a special financing program (49). The incentives for deferring coverage decisions will only intensify as the health care system embraces prospective payment and tighter controls on health care costs.

Both the public and the private sectors are moving toward a predetermined budget for health care, which will increase the scrutiny applied to costly emerging technologies. With such a constraint, new technologies are likely to be introduced only if they promise to replace established technologies and free up equivalent resources (55). The artificial heart, for example, might be compared not only with a variety of procedures for heart disease, but also with treatments for non-heart related conditions. A recent Massachusetts Task Force on Organ Transplantation translated this principle into practice, recommending that heart and liver transplants should be performed only when they could be done within an existing cap on hospital expenditures (48). The federal payment system based on diagnosis related groups may be less onerous to new technology than the recommendations of the Massachusetts Task force, but surely will be more constraining than the previous cost based reimbursement system (42).

The prospective payment system for in-patient care adds uncertainty to the payment process by introducing another regulatory step (15;42). Once an emerging technology receives coverage from the Health Care Financing Administration (HCFA), it is reimbursed at rates equal to existing treatments even if it is more costly. The Prospective Payment Assessment Commission, a new quasi-regulatory enterprise, and HCFA share responsibility for periodically updating prices for costly but quality-enhancing new technologies. Confronted with ever changing medical practices, these agencies first must establish priorities for possible readjustments, and then collect and analyze large amounts of data before setting rates. Rate setting procedures necessarily lead to delays in providing full reimbursement, making the introduction of technology less attractive financially (15).

In contrast, the marketing of technology may counteract some of the constraints reimbursement places on technology. Structural changes in the health care system and declining patient volume are forcing hospitals to compete aggressively for patronage. Advertising of the availability of celebrity technologies has become one of the many new marketing strategies designed to attract patients. Humana's experience with the artificial heart demonstrates how organizations can use technology to gain national recognition and perhaps a competitive advantage.

The marketing of technologies to lure patients is not unique to hospitals. By highlighting their coverage for complex technical procedures, health maintenance organizations (HMOs) hope to capture a greater share of the health care market. Harvard Community Health Plan, for example, has an advertising campaign that includes two patients—one a middle-aged recipient of a heart transplant and the other a mother whose newborn infant has survived because of neonatal intensive care (24). Competition among health maintenance organizations may spur the

spread of life-saving technologies rather than reduce the reliance on complex procedures. However, a successful marketing strategy requires a technology's adoption in only a few highly publicized cases, and not its widespread use.

CONCLUSIONS

Some observers believe that the health care system, including its research component, is inherently biased toward the pursuit of expensive therapies. The history of the artificial heart demonstrates, however, that obstacles to the development and dissemination of costly technologies may have been underestimated in the past. The NIH leadership tempered the rate and direction of the heart's development almost from the start of the program, and deterred all but one of the twelve groups working on the permanent device from implanting it in humans. The NIH's caution resulted as much from the internal politics of the agency as from concerns about the rational management of technology. Nevertheless, NIH opposition had an effect.

Regulatory policy, particularly the Medical Device Amendments of 1976, constituted an additional impediment to the development and use of the artificial heart. Though the procedures governing medical experimentation have not completely prevented human trials, the FDA's requirements certainly have limited the number and types of patients receiving artificial hearts. Restrictions imposed by the University of Utah's institutional review board proved onerous enough to cause DeVries to move to a for-profit health care corporation that promised him a freer hand.

Development work on the artificial heart was begun in a period in which the hospital financing system was generous to technology. But even under the retrospective cost-based payment system, private and federal payers had strong incentives to postpone coverage decisions for technologies with enormous total costs. Moreover, after the experience with end-stage renal disease, it is far from certain that the federal government will ever embark on a similar program for the artificial heart, or that the Medicare program will cover it under normal procedures. Prospective payment appears to be strengthening the incentives to delay coverage, thus adding obstacles to the development and use of costly emerging technologies like the artificial heart.

This is not to minimize the powerful influences that continue to foster technological change. Research groups still press for their favored projects. Congress often interferes to increase appropriations or to redirect research efforts. Rival bureaucracies may provide varying interpretations of regulatory standards, creating loopholes for certain technologies. Health care organizations now have incentives to adopt and market technologies for the purpose of attracting patients. Perhaps most importantly, the limited use of the artificial heart as a bridge-to-transplantation illustrates the remarkable resiliency of technology in eluding both technical and regulatory obstacles.

The powerful appeal of health care technologies in our society should not lead us to believe that the development of new technologies is unconstrained or inappropriately rapid in all cases. As the history of the artificial heart demonstrates, factors promoting and retarding the progress of this highly visible technology have been more balanced than the conventional wisdom holds. Even if

the scales ultimately tip toward widespread use of the artificial heart, similar technologies may not follow suit. The reason is that some of the factors that inhibited the artificial heart's development may grow even stronger in the future.

One such barrier is opposition from segments of the biomedical research community to using federal funds for highly applied research and development projects. The ability of small and influential groups of scientists and laypersons to win congressional approval for targeted research efforts, often over administration opposition, has long irritated advocates of basic biomedical research. They view projects, such as the artificial heart or the cancer institute's extensive program to develop new chemotherapies, as drawing funds from basic research. This struggle between basic and applied researchers over the allocation of resources within the NIH occurred even in the mid-1960s when funds for research were plentiful (56;58). In the current more financially constrained environment, the contest between advocates of fundamental and applied research is likely to intensify, further limiting federal commitments to expensive clinical projects like the artificial heart.

The decentralized and somewhat chaotic nature of federal regulatory and reimbursement policy creates additional impediments to commercialization of new technologies. The responsibility for regulatory and reimbursement policy is shared among an increasing number of agencies, including the NIH, FDA, HCFA, the Congressional Office of Technology Assessment, the Prospective Payment Assessment Commission, the Office of Management and Budget, and the National Center for Health Services Research and Health Care Technology (28). In addition, the private sector has recently become involved. The Institute of Medicine of the National Academy of Sciences, with federal support, will soon begin activities in assessing health care technologies. The American Medical Association and a number of subspecialty societies have begun their own technology assessment activities (28).

Not all of these agencies and groups have regulatory authority. But a number do, and a strong negative opinion from any of them on the safety, efficacy, or cost-effectiveness of a technology could hurt efforts to bring it to market. The sheer magnitude of groups that could pass judgments on new technologies will keep companies and their lobbyists busy for years as they line up support among all these agencies.

The resulting process for controlling health technologies is far from systematic, but those who favor greater restraints on the development and use of new health care technologies may find that the current system serves their purposes better than they anticipated. A seemingly "irrational" regulatory and reimbursement policy may have the effect of reducing society's allocation of resources to high technology medicine. Ironically, this disorderly process may restrain technical change in health care as much as the establishment of formal mechanisms to select among alternative uses of resources.

Clearly, the barriers to the development of costly devices have been underestimated in the past; changes in regulatory and reimbursement policy have strengthened the obstacles to technological change. Some will no doubt find the slower technological progress that results reassuring, others disappointing. Yet delays in the introduction of new technologies like the artificial heart are the inevitable consequence of a decentralized and increasingly cost-conscious health care system.

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