THE DEVELOPMENT OF MEDICAL TECHNOLOGY:
A POLICY PERSPECTIVE

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by

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I. INTRODUCTION

Within the past decade, the view of medical technology has changed substantially. In the late 1960s, for instance, the National Academy of Sciences' Committee on Engineering in Biology and Medicine complained that few market incentives existed for private firms to develop new medical devices. "Industry is ready and willing to supply the biomedical engineering field when a viable market can be established. But the economic problems associated with this market appear to be the major deterrent to its development."¹

Sentiments like the above are seldom voiced today. Instead, medical technology is prominent among the long list of national

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health problems. The "machine" in medicine can be too soon and too late with us. Its presence stretches from electronic fetal monitoring before birth to the respirator, intensive care unit, and artificial kidney on the threshold of death. And during life's complex passage we encounter the computerized tomography (CT) scanner, the computerized electrocardiogram (EKG), automated clinical laboratory analyzers, and all the many other manifestations of technology in medicine.

Technology deserves definition. In this paper, medical technology refers to those means of diagnostic, therapeutic, and rehabilitative medical intervention that are physically embodied in equipment and related supplies. We exclude from consideration both surgical procedures and pharmaceutical means of intervention.²

Although substantial attention is now being paid to medical technology, very little has yet been directed to analysis of the development process leading to new medical technology. The purposes of this paper, therefore, are threefold. First, we characterize the supply side of the medical technology market, with attention to the nature of technical change in medicine, the nature of the innovative process, and the incentives of service providers that affect the development of medical technology. Second, we identify three areas of public policy—research and development, reimbursement, and regulation—affected by and in turn affecting the development of medical technology. Finally, we hope that the paper points to some useful areas of further research.
II. THE SUPPLY SIDE OF MEDICAL TECHNOLOGY

TECHNICAL CHANGE IN MEDICINE

In research and in policy deliberations, technical change is often dealt with in narrow conceptual or empirical terms, partly because today's problems present themselves narrowly and partly because the full complexities of technical change can be analyzed only with great difficulty. This understandable narrowing behavior is normally essential for analytical purposes, but it can cause important determinants of technical change to be overlooked.

Rapid technical change is occurring in medicine, witness the recent concern for medical technology. Less well appreciated are the diversity, breadth, and depth of sources feeding this rapid change. Analysts and commentators, especially those within the health care system, tend to conceive of the sources of new medical technology as residing primarily within medicine. A corollary view is that the National Institutes of Health, through which the public invests over $2 billion annually in medical research, is the driving force behind new medical technology and thus the immediate objective of policy attention. Such views of medical technology have limited analytical and policy utility.

In general, technical change in any area will always be a product of forces specific to the area, both market and technical, and of the general set of technical opportunities in society at any given time. In their discussion of the "natural trajectories" of technical change, Nelson and Winter, identify several "that are common to a wide range
of technologies." These natural trajectories include two well treated in the literature—the progressive exploitation of latent scale economies, and the increasing mechanization of human labor—and two that are more characteristic of the 20th century—"the exploitation of understanding of electricity and the resulting creation and improvement of electrical and later electronic components, and similar developments regarding chemical technologies." The testimony of the scientific community suggests the practical exploitation of recombinant DNA technology may become such a trajectory in the years ahead.5

The applicability of this general point to medicine should be clear upon a moment's reflection. The development of medical technology will proceed, in some measure, from sources internal to medicine—from the worlds of both clinical research and clinical practice. But it will also proceed from sources external to medicine, from major streams of technical change in our society that increasingly penetrate and find application in medicine. Advances in electronics, materials, optical and imaging capabilities, measurement and instrumentation, and computation are resulting in important medical applications in diagnosis, therapy, rehabilitation, and organization of services.6 Medical technology (as embodied in physical equipment) is frequently the result of the convergence of modern medicine with modern engineering. Convergence of different and historically separate streams of technical change complicates analytical efforts and potentially frustrates the formulation of public policy.
Expertise, data, and analytical models for understanding the development of medical technology are all in scarce supply. In a slightly different context, some of us at Rand attempted to characterize the interactions among science, technology, and medical practice several years ago. Each of the three "streams of activity" in Fig. 1 has its own internal dynamics as well as its patterns of interaction with the other two streams. Science feeds critical new information to technology. In turn, technology supplies science with new capabilities (e.g., instrumentation) and new problems. Both science and technology generate new clinical applications, sometimes independently and sometimes jointly. Clinical medicine, however, is often the basic source for the problems that scientific and technological activity addresses. At the societal level, therefore, we can use this characterization as a first approximation to the broad processes of technical change in medicine.

THE INNOVATION PROCESS

At the level of specific medical technologies, there is a clear need for a model of the process by which new products are developed and introduced into use. The elements of such a model, suggested by the literature, include the following: Technology usually evolves over a lengthy development period; an unmet clinical need often provides the demand stimulus to invention; there is a high frequency of international development activities and often simultaneity of invention; an innovation is often a complex bundle of component technologies; complexity may not yield significantly greater efficacy; new applications of medical technology emerge from broader
Fig. 1 - Sources of technical change in medicine
technological trends; diffusion of medical technology is sometimes very rapid,\textsuperscript{12} both public and private sectors are probably involved; and there are many institutional pathways from development to use.\textsuperscript{13}

An adequate model of the innovation process should provide information or insight about the activities of the developers of medical technology—especially those of private-sector firms. To evaluate policy options, it is important to have an understanding of the behavior of developers, including motivations and incentives as well as performance.\textsuperscript{14} Lacking studies of the developers of medical technologies, we must rely on general findings from non-health areas of research. We know a fair amount about development patterns and activities in commercial and military aircraft, for example, because of sustained policy-oriented research on the subject spanning nearly three decades.\textsuperscript{15}

The research strategy used in Rand studies of the aircraft industry deserves brief comment because it is probably applicable to an understanding of private-sector activities in medical technology. For the first five years of research, Rand developed and interpreted case study material. Only after this step was it possible to postulate statistical models to conduct more rigorous empirical tests. From time to time throughout the decades of research, researchers posed policy issues and tendered answers based on the best available research at that time. In the area of medical technology, we believe that the state of factual knowledge about publicly and privately supported R&D is similar to that at the early period of case studies in the aircraft industry (with obvious major differences between
industries such as the differences in "markets" for the end products).

We have attempted to characterize the "supply" side of medical technology at the institutional level in a way that focuses on the private firm engaged in developing new products for the medical care market (see Fig. 2). This model assumes that private firm decisions about research and development investments and the introduction of new products depend on signals from the marketplace and from the ever-accumulating body of scientific and technological knowledge flowing from research and development. Because the social R&D investment is assumed to consist of both publicly and privately funded research programs, the relationship between private firm R&D and publicly supported R&D is one of the key interactions deserving analytical attention. How, for example, does the private firm draw upon the scientific and technical body of knowledge that has been created in large part from publicly financed research?

Some answers to this question are suggested by the literature and by anecdotal information. The medical technology industry appears to be less concentrated and to consist of smaller firms than the pharmaceutical industry. In some cases, they are simply small companies; in others, they are small divisions in large organizations having other product lines and markets of much greater size. There is also some evidence that the R&D investment (as a percent of sales) in medical technology by private firms is lower than in pharmaceutical firms, though it also appears to be growing in certain product lines and markets. We also believe that the medical technology
Fig. 2—Medical technology "supply system"

*"Total" refers to "National Support for Health R&D", for 1976. This is defined as: medical and health-related projects, resources, and general support, but no training or construction. The NIH component contains certain items not customarily classified as R&D such as foreign currency programs and portions of cancer control, National Library of Medicine, and program management.

firm differs from the pharmaceutical firm in another way: The latter is apt to rely primarily upon an internal R&D capability, and the medical technology firm is likely to have a capability consisting of internal scientists and engineers plus "external consultants" in clinical medicine.

Given these characteristics, it is important to understand how such firms keep abreast of technical opportunities, especially those requiring some biological or biochemical knowledge about clinical medicine. One tentative hypothesis we have developed is that the private firms are working at the frontier of the engineering world—electronics, materials, etc—and that they secure the necessary biological and biochemical knowledge from physicians who practice in major medical centers. Such centers are usually major teaching hospitals affiliated with a university medical school or the university hospital itself. Physicians in such centers have a stream of patients who present the clinical problems that define the need for new technical advance, and they are engaged in clinical research, or closely associated with those who are. Clinical researchers in major medical centers, moreover, are frequently underwritten by the federal government through the National Institutes of Health, and probably aware of important advances occurring in the basic medical sciences.

One of the basic mechanisms by which innovation in medical technology occurs, we hypothesize, is through the complex interactions between engineers in small, private firms and physicians in institutional settings that provide the twin resources of patients and knowledge about major basic and clinical advances in the biological and life sciences.
INCENTIVES FROM SERVICE PROVIDERS

Of at least equal importance to scientific and technological advances that fuel innovation in medical technology is that suppliers also respond to the requirements and preferences of physicians and hospitals, the providers of medical services. Incentives operating on these providers influence the development and marketing of new medical technologies. We briefly describe some of the important hypothesized incentives acting on physicians and hospitals that affect the purchase and use of new medical technologies.

Search for Better Means of Medical Intervention

Many of the conditions and diseases afflicting humanity currently have no known cures and very imperfect interventions. It is part of the medical profession's responsibility to try to do better. In addition, a larger potential demand for the services of new medical technologies results from the increasingly severe case mix in acute-care hospitals for three reasons: (1) There are fewer less difficult medical problems treated in the hospital setting. For example, the declining birthrate results in a decreasing proportion of hospital discharges secondary to normal delivery, there are fewer admissions for mental illness (a disease category using little of hospitals' acute care resources), and utilization review pressures decrease length of stay and possibly prevent questionable admissions. (2) Some diseases have recently received more aggressive treatment (e.g., chemotherapy for cancer, transplants and chronic hemodialysis programs subsequent to the coverage for chronic renal failure under the Social Security Amendments of 1972). (3) Recently introduced
medical technology provides more aggressive treatment (e.g., trauma and burn centers).

If physicians believe that specific medical technology will significantly improve their patients' care, they have a professional responsibility to consider adopting it. In pursuit of this responsibility, of course, many other factors also come into play.

**Characteristics of the Medical Services Marketplace**

**Direct Provision of Non-Hospital Medical Services.** The issues here are of "consumer" ignorance, of provider-controlled demand, of third-party reimbursement, and--partly as a consequence of these--of inability to weigh costs and benefits of new technologies.

Both the consumer and provider of medical services usually view the consumer as largely uninformed and untrained to raise options and make choices concerning the provision of medical services. Moreover, the physician's often specialized training has concentrated on handling just such decisions. So choice of services is delegated largely to the physician. As a consequence of the commitment to better medical intervention as well as of the nature of medical school training, the physician is inclined to want to use the "latest advances." This is likely to limit the degree of price competition and increase the influence of other, possibly perverse, incentives. Moreover, many physicians' incomes are determined in part by the number of services performed.¹⁹

Because many of the services provided in the medical marketplace involve third-party reimbursement, even if the person receiving the service took a primary role in the choice of services, he would pay
only a small fraction of the price of the service. Thus, there is little incentive to use "discretion" in services requested or to be "cost conscious" in selection of providers of services. Moreover, the reimbursement source has had little economic or institutional incentive to challenge costs; these are usually approved and ultimately passed on to the insurance buyer (or the taxpayer). 20

Largely as a consequence of the above, there is no framework in the provision of medical services for deciding when the application of a new medical technology to a particular problem area makes such a marginal improvement in the outcome that it is not worth the cost. The dilemma is that choice of medical services is currently delegated to the physician, who has little incentive to do the cost-benefit assessment unless there are some professional risks involved. In fact, other pressures operate on the physician to choose any action that yields an improvement, almost regardless of the size of the improvement or its cost. The cases of some uses of the CT Scanner or of Total Parenteral Nutrition are good examples. 21 If the choice were put more squarely on the shoulder of the receiver of medical service, it is still not clear that such a cost-benefit evaluation would be made; at the time of the decision, either the patient cannot make a decision (e.g., is in a coma) or may ask for "anything that will help," especially when the costs are, for the most part, not internalized. 22

Defensive Medicine. Physicians have only slight risks when applying a technology where it is marginal, but where its consequences are indistinguishable from no treatment at all. Severe risks arise
from applying technology where its consequences are pernicious, or from not applying a technology where it could have made a contribution. Increases in the rates for malpractice insurance provide ample evidence of the risks but yield little information about how they affect the market prospects for the suppliers of new medical technologies.

**Non-Price Competition Through Medical Technologies in the Hospital Sector.** New technologies may be introduced by hospitals to attract physicians or keep them to entice them to hospitalize their patients in that facility or refer them to it on an outpatient basis.²³ Similarly, the provisioning of a very sophisticated emergency room may be undertaken to increase the prospects of keeping beds filled, because emergency admissions can frequently be the beginning of longer hospitalizations. Here again, price competition really does not enter. This characteristic of hospital practice may lead to very rapid diffusion of technology.

**Growing Regulatory Constraints.** The signals received by the suppliers of medical technology are being altered by the development and growth of federal regulatory efforts. Capital expenditure limitations, state certificate of need laws, health planning regulations, medical device regulations, and a growing concern for the cost effects of technology are changing the incentives for suppliers of medical technology. This dynamic, and its relation to public and private R&D efforts, however, is very recent and as yet poorly understood.
Criteria for Reimbursement. The criteria by which private or governmental reimbursement sources have determined that a new procedure should be covered are often determined by medical association peer review bodies and medical consultants for insurance companies. The eventual price determined for such newly covered procedures is generally associated with establishment of "relative values." Private firms may direct considerable attention to the early and "properly priced" authorization for reimbursement of the services of their new products. Even if the criteria have remained unchanged in the past, the increasing extent of federal reimbursement, coupled with a growing concern for cost containment, may encourage a more cautious approach to coverage of new technologies. Technical assistance on reimbursement decisions could ultimately require considerable government "technical consultant" participation.
III. SOME POLICY ISSUES FOR MEDICAL TECHNOLOGY

Three areas of federal health policy are related to the development of medical technology:

- Research and development
- Reimbursement
- Regulation

The development of medical technology affects and has implications for each of these areas, and each in turn has reciprocal effects upon development. The limited understanding of the development process, however, means that substantial research is needed before definitive policy guidelines can be devised. Here we attempt to indicate some of the major policy issues that will be illuminated by greater understanding of the development of medical technology.

RESEARCH AND DEVELOPMENT

The welfare economics literature has articulated a rationale for public investment in research and development that is now widely accepted. The basic argument is that the private sector will systematically underinvest in the production of new knowledge relative to the socially optimal level of investment because of the externalities, uncertainties, and indivisibilities associated with such knowledge. This underinvestment is especially acute at the basic research end of the R&D spectrum. Consequently, a prima facie case may be made for public investment in R&D, especially in basic research.
There is also an implied division of labor between public and private sectors in the support of R&D. The key policy issue is to determine the practical criteria for assessing the appropriate extent of public support of R&D.

Where the productive process is creating private goods for consumption or investment by individuals or firms in the private sector, the public sector should only invest in basic research. R&D that is related to product development is considered the province of the private sector and not an area where public investment is generally desired or effective. Where the purpose of the activity is the production of public goods, as in national defense and exploration of outer space, public R&D investments should encompass the full range of the spectrum.

In health, as in other areas of public policy, the public and private sectors have a complex relationship in the joint production of goods and services. The determination of the appropriate public R&D investment in medical technology is a matter on which general normative guidance can be given, but interventions in specific situations must be guided by empirical knowledge. The case for federal investment in basic research in the biomedical and life sciences we regard as compelling, although the optimal level of such investment is clearly a matter of judgment. As noted above, a continuing stream of scientific development in the basic and clinical life sciences is funded primarily by the National Institutes of Health. There is also a continuing stream of technical advance in such critical science-based technologies as electronics and materials, funded by
an array of agencies, including at least the Department of Defense, the National Aeronautics and Space Administration, the Department of Energy, and the National Science Foundation.

The appropriateness of public R&D investments directed toward the development of new medical technologies is not clear. Where a strong private sector is able to exploit new technical knowledge for application in the health care market, there is little rationale for public R&D. Public R&D programs concentrated on medical technology are distributed across several federal agencies, including the NIH, the Veterans Administration, NASA, and DOE. However, the nature, scope, and level of public investment in R&D related to medical technology has yet to be thoroughly analyzed.

Very little is yet known about the structure of the medical device industry in the private sector, let alone about patterns of R&D investment and new product development. The Food and Drug Administration is conducting some work that will seek to improve upon the existing SIC classification of the industry, as well as work to estimate the economic effects of the medical device regulations. But the private sector situation can be described as an information void. Empirical research (along the lines suggested by our model) revealing the amounts of public and private R&D in a given area and the interactions between these sectoral investments is necessary to the formulation of normative guidelines.

REIMBURSEMENT

The effect of federal reimbursement for the provision of health services upon the rate and direction of technical change in medicine
is largely unexplored territory. Indeed, policy officials have seldom recognized that such effects are important. In our judgment, they deserve thorough analytical attention. There are serious analytical problems in addressing this question because the government is only one major reimbursing party in the national health care market. The government's share, however, has increased steadily in the past decade and is now substantial. Furthermore, several proposals for national health insurance would place the government in a monopsony position in the "buying" of health services. Outside the area of medical technology, recent research indicates that the procurement of electronics by the Department of Defense has had as much or more to do with innovation in that industry as did the electronics-related R&D supported by DOD.29 In one area of reimbursement policy where the government now has a monopsony position—the payment for end-stage renal disease services—there is reason to believe that a screen (or cap) on reimbursement to facilities has induced cost-reducing technical change among suppliers.30 This entire area deserves significant and sustained research attention.

REGULATION

Public policy toward medical technology has been largely regulatory. Two different regulatory "gates" have to be passed through as technology leaves the development stage, and the constraints applied at these gates affect the nature of the development process itself. The first is the regulation of medical devices by the Food and Drug Administration under the authority of Medical Device Amendments of 1976. All device manufacturers must register with FDA, all devices
are classified by the agency, some devices can be introduced to the market on the basis of general controls, some because they meet performance standards, and others require pre-market approval because data are not available to establish performance standards or the devices are used for life-sustaining and life-supporting purposes. In addition, process controls are applied to production ("good manufacturing practice") and to clinical investigation of new devices.

FDA regulation is directed to the safety and efficacy of medical devices, narrowly focused on performance of devices under carefully prescribed conditions. The effects of device regulation upon the development of medical technology are not yet well understood, given the newness of the regulatory pattern, the limited knowledge of the industry, the absence of data, and some difficult conceptual problems in measuring effects. Research in other technology areas has revealed that the testing stage of product development is critical. The vital role of testing is a well understood feature of private sector practices and is a continually relearned lesson by the Defense Department.31

The process of developing new medical technology involves several types of testing—animal studies, clinical trials, and experimental clinical use (usually in tertiary medical centers). But the issue here is the thorough and timely testing of new equipment to confirm its efficacy and establish its safety. Some have argued that the diffusion and use of the CT scanner was sooner and at a faster pace than valid evidence of its efficacy would justify.32 But some technologists and other innovators have expressed concern that if the
FDA imposes too severe restraints on experimental use by human subjects, for example, progress in medical technology may be stifled.\textsuperscript{33} FDA testing requirements will undoubtedly alter test activities and documentation, with possible implications for the substantive information revealed by testing and the timely use of test results.

It is probable that innovation will be slowed, as intended, to the extent that regulation functions to keep unsafe or inefficacious devices from the market. Device regulation should not inhibit competition among firms nor the development of competing technical approaches to particular medical problems. The effects of device regulation on the development of medical technology is an area of policy concern that will require clarification by further research.

The second regulatory "gate" through which medical technology must pass is the Certificate of Need (CON) requirement applied by the area-wide Health Service Agencies (HSAs). Here, as with device regulation, the regulatory pattern is too recent for us to know how it is functioning, let alone what its effects are upon the development of medical technology. One of the policy issues of importance is whether the development of criteria for judging cost-effectiveness of medical technologies should be decentralized to the two hundred HSAs or developed centrally through the concentration of the relevant expertise.

We strongly favor central development of criteria for HSA use, with full critique of such criteria by all affected parties. In the process of establishing these criteria, it is important to avoid premature choice of technical solutions to a medical problem through
limitations in the selection of equipment. Technical competition can be fostered in medical technology in several ways. In decisions to develop medical equipment supported with public funds, developers exploring different technical solutions to the same problem can be financed. In the selection of equipment to be procured by the government (e.g., VA hospitals), standardization can be avoided until clear test or clinical information establishes a preferred option. And more generally, analysis of medical technology can concentrate on "medical conditions/disease states" for which there are competing technical solutions. For example, for patients with a neurologic symptom (e.g., severe headache) and whose major concern is brain tumor, comparison can be made by controlled clinical trials. Evidence of use of diagnostic procedures can also provide insights; in this example, pneumoencephalograms are reported to have dropped by 20 to 80 percent and cerebral angiograms by 15 to 65 percent after the introduction of CT scanning.\textsuperscript{34}

Another issue has to do with HSA responses to technologies that go from a cost above the review threshold of $150,000 to a cost below it in successive generations. Where suppliers are "unpackaging" complex technologies into component technologies and thus avoiding the review threshold, such behavior should be scrutinized to determine if the components can operate independently or with other manufacturers' equipment, so that service costs could be reduced or competition increased, or if the "unpackaging" is merely intended to circumvent the regulatory threshold. Where suppliers reduce capital costs of technologies by shifting the ratio of capital to operating
costs, this also should be scrutinized. But planners should regard positively a decline in costs of technology as a result of technical learning and declining unit prices of production. Innovation in medical technology that is genuinely cost-reducing should not be penalized. This area also requires analysis before sound policy formulation is possible.

FUTURE POLICY RESEARCH

From what we have already discussed about the process that leads to new medical technologies, some elements of the research agenda should be clear.

- Descriptive "micro" studies of on-going R&D in the public and private sectors.

- Investigation of the influences of service providers on the
  - product development decisions of firms
  - incentives (or lack thereof) for developing and introducing cost-reducing technology

- Development of methodologies for validation of medical technologies with respect to efficacy and safety.

- Analysis of governmental effects, especially
  - policies specific to medical technology (e.g., FDA device regulation, CON requirements, reimbursement)
  - policies that operate differentially on firms by size and degree of involvement in medical technology (e.g., device regulation possibly causing small or marginal firms to exit the industry)
  - more general policies that encourage technological innovation across several sectors of industry (e.g., favorable tax treatment of R&D)
  - policies that may have inadvertent pernicious influences (e.g., device regulation inhibiting nonmedically oriented electronics firms from entering the industry, or causing an increase in the cost of successful innovation).
The policy questions for medical technology have to do with public policies to establish incentives that affect development, introduction, and use of medical technology in ways that balance the need for innovation, concerns of safety and efficacy, and cost of control. These questions can be approached intelligently, however, only after substantially more research has been done to illuminate the nature of the underlying processes of technical change in medicine.

2. This definition is narrower than that of the Office of Technology Assessment, U.S. Congress, Development of Medical Technology: Opportunities for Assessment, Washington, D.C., 1976. We do not recommend our definition for widespread use; it is merely convenient for this paper.

3. This is implied in Martin S. Feldstein, The Rising Cost of Hospital Care, Washington, D.C., Information Resources Press, 1971, esp. pp. 46-51; and in Karen Davis, "The Role of Technology, Demand and Labor Markets in the Determination of Hospital Costs," in MarkPerlman (ed.), The Economics of Health and Medical Care, Wiley and Sons, New York, 1974, esp. p. 300. The argument is explicit in Clifton R. Gaus, Testimony before the President's Biomedical Research Panel, Transcript of the Meeting Proceedings (7th), held in Bethesda, Maryland, September 29-30, 1975, pp. I-75 through I-78.


5. See the testimony of Joseph Stetler, President, Pharmaceutical Manufacturers Association; Dr. Joseph Grady, Research Head, Department of Infectious Disease Research, Upjohn Co.; and Dr. Ronald E. Cape, President, Cetus Corp., pp. 329-350 in U.S. Senate, Committee on Commerce, Science, and Transportation, Regulation of Recombinant DNA Research, Hearings, 95th Cong., 1st Sess., November 2, 8, and 10, 1977.


10. That not all new medical products have come from the direct application of science and technology to medical problems, as suggested by the case of the computed tomography (CT) scanner. The CT scanner is, in large part, an ingenious engineering solution to the task of coordinating x-ray equipment and computers without advancing the capabilities of either basic component. See R. Gordon, G. J. Herman and S. A. Johnson, "Image Reconstructions from Projections," *Scientific American*, Vol. 233, No. 4, October 1975, pp. 56-68.


14. A related study is R. D. Peterson and C. R. MacPhee, Economic Organization in Medical Equipment and Supply, Lexington Books, Lexington, Mass., 1973. The study is based largely on published U.S. government data including Bureau of the Census data on three 4-digit SIC categories: Surgical and Medical Instruments (SIC 3841, which includes a range of products from "suture needles" and "diagnostic apparatus" to "hospital furniture"), Surgical Appliances and Supplies (SIC 3842, including "sterilizers," and "adhesives, gauze, cotton"), and X-ray Apparatus and Tubes (SIC 3693, including x-ray, EKG and EEG equipment and related items). The authors also used some company annual report data and information obtained by a questionnaire that is not published (nor is their sampling scheme or sample coverage described). They devote a six-page section of the book to "Innovativeness," which includes observations organized under technical inadequacy, superficial innovation, ignorance of medical needs, and patient monitors.


16. Based upon personal communication from Food and Drug Administration staff.


18. The following set of reasons for this trend draws heavily upon the work of A. Schroeder and J. A. Showstack, "The Dynamics of Medical Technology Use: Analysis and Policy Options," paper prepared for the Sun Valley Forum on National Health, Inc., August 1977, p. 27.
19. Ibid.


23. For a model of the hospital as "club" established to maximize the incomes of the attending physician staff, see Mark V. Pauly and Michael Redisch, "The Not-For-Profit Hospital as a Physicians' Cooperative," _American Economic Review_, Vol. 63, March 1973, pp. 87-99.

24. The Blue Cross Association recently turned to the Institute of Medicine for advice on reimbursement for CT scanning; see Institute of Medicine, _A Policy Statement: Computed Tomographic Scanning_, National Academy of Sciences, Washington, D.C., 1977.


28. As a practical matter, Eads has argued that market failure is conceptually attractive as a rationale for public investment but has substantial problems of a practical nature associated with actually measuring the degrees of market failure and applying appropriate decision criteria in the instance. Market failure, he notes, is often in the eye of the beholder and thus tends to become a political argument for public intervention. See George Eads, "U.S. Government Support for Civilian Technology: Economic Theory versus Political Practice," _Research Policy_, Vol. 3, 1974, pp. 2-16.

30. This tentative conclusion has emerged from a study of the Medicare End-Stage Renal Disease Program by R. A. Rettig, sponsored by the Health Care Financing Administration.


The findings regarding testing for military development programs are generally consistent with practices by private-sector firms when they are engaged in production and sales in competitive, nongovernment controlled, and unregulated markets. See, for example, discussion of the computer industry in A. J. Harman and A. J. Alexander with M. R. Davis and A. D. Lee, *Technological Innovation by Firms: Enhancement of Product Quality*, The Rand Corporation, R-2237-NSF, November 1977, Sec. III.


33. Some have argued this in the case of equipment for renal dialysis. For a description of the development history of this medical technology, see R. A. Rettig, "End-Stage Renal Disease and the 'Cost' of Medical Technology," prepared for the Sun Valley Forum on National Health, Inc., August 1977. Also available as Rand P-6029.


35. In fact, recent regulatory actions have penalized such actions; see Los Angeles Times, "Medical Firm Lowers Prices, Raises Roof; Ommimedical Expects Praise for Cheap Brain Scanner But It Draws Criticism," August 6, 1978, Part VI, pp. 1, 9.