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Factors Affecting the Development, Diffusion, and Use of Medical Technologies

Technology is not an historical institution like science and capitalism, but is rather the essence of man in **an active and uncritical state.**

—H. T. Wilson

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INTRODUCTION

Information on medical technologies is needed by various private and public parties at every stage in the development and diffusion of medical technologies. All markets need good information to function effectively. However, the market for medical technologies has some unique characteristics that affect the type of information needed and the timing of that information.

Because of the many social values related to medical care, there is a degree of public responsibility for ensuring that medical technologies are safe, efficacious, and, in some cases, cost effective. Various Federal agencies provide research funds, regulate market entry, and decide which medical technologies will be reimbursable for Federal beneficiaries. Technology assessment information is often needed in order to make responsible decisions that protect the public safety and the public purse, yet do not unduly impede the innovation process.

This chapter is intended to set the stage for a critique of the current "system" for assessing medical technologies. The first section summarizes selected aspects of the innovation and diffusion process for drugs, devices, and surgical and medical procedures. The second section explores research, regulatory, and reimbursement policies that affect the development, diffusion, and use of medical technologies.

Additional material concerning the drug and device industries and the Federal policies that affect the innovation process is presented in appendix D. Appendix E contains five case studies of medical technologies which are intended to illustrate some of the points made in this chapter, especially regarding the way in which technologies are developed and adopted and the effects which Federal policies have on the process.

INNOVATION PROCESS FOR MEDICAL TECHNOLOGIES

In some respects, the innovation process for medical technologies parallels that for other technologies. Although there are many variations, a basic model of the process can be outlined. An innovation is conceptualized by recognizing both technical feasibility and potential demand. If a decision is made to pursue the innovative idea, problem-solving activity follows, drawing from available information and from further research and development (R&D) activities. If a solution to the problem is found, it may be the one originally sought, or a solution to a modification of the original problem.

Sources of Medical Technologies

Drugs

The U.S. pharmaceutical industry is composed of about 600 firms. These include a small number of large firms which produce most of the innovative drugs and a much larger number of relatively small firms which produce and market mainly generic and some patented drugs. The industry is characterized by high and rising development costs for new products, and there has been a strong shift toward greater concentration of new products in the largest firms.

Since the late 1950's, the number of new chemical entities and number of firms producing a new chemical entity has declined (174). Innovative outputs have been concentrated in the ***20*** largest of the 600 drug firms, and most of this concentration is among the top four to eight innovators. From 1957-61 to 1967-71, the four largest firms in the industry nearly doubled their share of innovative output. During the same period, however, their share of total prescription drug sales remained fairly constant.

These observations suggest that most of the large drug firms are dependent on a few drugs for much of their income. Apparently, after the patents for new products expire, generics erode some of the market captured by the innovating drug firm, and the large innovative firms regain their share of total sales through the introduction of new drugs.

The Food and Drug Administration's (FDA's) regulatory responsibilities regarding new drugs are discussed in the next major section of this chapter.

Medical Devices

The U.S. medical devices industry has experienced substantial growth since World War II. Industry sales in 1977 were $8.1 billion—five times the amount in 1958 (corrected for inflation). Growth has been predominantly in the number of firms rather in their size. The U.S. medical devices industry is composed of several thousand firms—many specialized small firms which together have a small share of the market and a few large firms with a high market share. There are high entry and exit rates in the industry, mostly among small firms (8).

Dominance by large companies suggests the presence of economies of scale, while the persistence of many small companies suggests that economies of scale do not apply to specialized areas. Possibly, however, the large firms really represent the industry; i.e., rather than representing the differentiation of the industry into small and large functions, the large number of small firms may represent a high-birth, high-mortality, and high-turnover sector of the industry (122). Arthur Young & Co.'s (8) survey of the industry, for example, did not differentiate between bankruptcy and acquisition in its observation of high-turnover rates for small firms. However d'Arbeloff (79) comments that high-turnover rates may reflect a high-risk, high-profit atmosphere for small firms.

In general, small firms fill a special niche in the market, and their growth into larger firms is hindered by conditions such as advertising requirements, links with distribution channels, and the need for new capital expenditures (355). Thus, the industrial pattern is that of limited internal growth, with acquisition or establishment of additional companies being the primary method of expansion. Small plants are opened to manufacture new products following invention and development, while large plants are opened by large companies to take advantage of lower operating costs. These large companies tend to be extremely diversified as a whole, yet there is little product diversification within their medical devices plants (8).

Recently, the distribution of medical devices has shifted from small regional and local suppliers to major national dealers. National dealers are often subsidiaries of large manufacturers or are acquirers of small manufacturing firms. The advantage of larger firms is that they are better positioned to provide special buyer education through their larger, better trained staff (355). The inability of potential manufacturers to gain access to these networks is an additional barrier to growth of the small firms entering the medical devices field and probably accentuates their acquisition by larger manufacturers.

The U.S. medical devices industry is somewhat insulated from price competition by the high level of third-party reimbursement, and price competition is not as significant a force in mitigating price increases as it is in other industries. Nevertheless, there is a high degree of product differentiation, and the industry appears to be competitive at various levels even though the market for the most part is price insensitive (8).

FDA's regulatory responsibilities regarding medical devices are discussed in the next major section of this chapter.

Medical and Surgical Procedures

The invention, development, and diffusion of medical and surgical procedures can to some degree be described by the model of the innovation process developed for products and their manufacturing processes. For the most part, however, medical and surgical procedures are developed within the practice of medicine. Furthermore, the initial diffusion of medical and surgical procedures is relatively uninhibited by Federal regulation.

New procedures usually involve some drug and/or device. However, a focus on procedures separate from the technologies which are used in them is necessary, because physicians, as users, are both generators (technology-push) and purchasers (demand-pull) of these innovations. Thus, it is important to understand how physicians perform these dual roles. But there are no standard determinants of when or how procedures become medically acceptable (197) and few criteria for when they become obsolete.

Influences on the Diffusion of Innovations

The medical literature on communication about and adoption of innovations is weighted toward studies of single diagnostic or therapeutic medical technologies. There is a large literature on how physicians learn about and adopt new drugs and a growing literature on specific devices or techniques, but very little literature on the communication about or the adoption of complex medical procedures that may not involve drugs or hardware (e. g., psychotherapy). In practice, however, the crucial distinction is between communication which informs the physician about novel technologies and that which influences physicians to act (405). Even though the most important source of new knowledge about improvements in medical technologies is the professional literature, physicians cite professional colleagues more often as sources they turn to when deciding to *use* a new procedure for the first time (145,233, 234).

The importance of informal communication both in the process of scientific discovery and in the diffusion of technological innovation seems to be a feature in all fields of technological discovery and diffusion (213). Moreover, it may be that there is a prestige hierarchy, where those at the top are "trend setters" (49). If this is so, widespread adoption of an innovation could be enhanced by convincing influential organizations to adopt it first, then letting prestige-seeking organizations imitate them.

Physicians of greater prestige do tend to hear about innovations sooner than others (62), and they are also mentioned by their fellow professionals as influential sources of information on the medical practice of others. However, the adoption process when the adopting unit is an organization (e.g., hospital) is substantially different from the process when the adopting unit is an individual (e.g., physician in solo practice) (178,405), and these processes differ by the level of complexity of the organization. Outside forces such *as* third-party reimbursement or regulatory practices may also affect how quickly the individuals in the medical community learn about or adopt a technology.

These theoretical and empirical findings point to a kind of general scenario. Medical and surgical procedures usually begin as user- (e.g., physician) generated innovations. In medicine, an innovative procedure may be in the form of the adoption of an existing drug for a new purpose or changing the mixture of drugs and their dosages to adapt them to a different medical problem. In surgery, it may be in the form of a modification of an existing technique (usually accompanied by modifications of the devices being used) for application to a new use. In treatment areas that do not depend on drugs or devices (e.g., psychotherapy) or in which drugs and devices are used but are not crucial to the innovation (e. g., primary care), it may be an innovative interpretation of the existing knowledge (e.g., the multiple schools of psychotherapy which have sprung up or the new specialty of "family practice").

Increasingly, innovations in procedures arise in academic or academic-associated centers, where physical and professional ***resources are readily*** available; a research, innovation-seeking atmosphere is encouraged; and contacts with others in the field extend not only nationally, but also globally. Innovators in such settings know how

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to present the innovations in a manner that will be technically acceptable, and they also have the prestige that gives them access to professional meetings and journals to publicize their results. Their presentations and publications not only diffuse the innovation to a wider audience, but, more importantly, begin to legitimize it. Depending on the claimed innovation's nature, usually defined in terms of how it might revolutionize or at least substantially affect the related area of medical or surgical practice, other academic centers will begin to pursue the innovation as well.

At this point, several Federal agencies may enter the picture. The National Institutes of Health (NIH) may provide support for the innovator and researchers in other health centers in the form of randomized clinical trials (RCTs), most likely conducted in some of the clinical research centers funded by NIH. A new use for a drug, invention of a new device, or modification of an existing device requires FDA approval. Investigational new drug or device uses approved by FDA for limited testing are increasingly given to the same centers which NIH supports as clinical research centers (or at least to the health institutions in which these designated centers are located).

Sooner or later, the Health Care Financing Administration (HCFA) may receive a request for reimbursement of the procedure and will give great weight to NIH clinical trials for evidence of safety and efficacy. Meanwhile, however, FDA must make a determination of safety and efficacy for market clearance of the drug or device under review. FDA will often have to make its decision long before NIH reaches a decision and terminates funding for the clinical trials. The reason is that FDA must act in a timely manner and reach its conclusion on minimal evidence, while NIH has no similar regulatory responsibilities and is more interested in the cumulative evidence. FDA's decision, moreover, especially in the case of devices, may rest on the narrow question of the efficacy and safety of the device in a particular setting, not of the entire procedure in general use. But release of the device to the general market, once premarket approval is given, tends to speed up the diffusion of the procedure which NIH may be studying. This may place more pressure on HCFA to reimburse for the procedure.

Although there are no explicit data on which to estimate the developmental costs of medical innovation, they are without a doubt very large. Commonly, the costs of the developmental phase of early clinical application have been paid by patients, usually through standard medical insurance policies. Even for procedures that have been clearly designated as experimental, reimbursement has often been provided. Thus, for example, when total hip replacement was first introduced into this country in 1971, it was still an experimental procedure; reimbursement for the procedure was nevertheless provided.

PROGRAMS AND POLICIES RELATED TO THE DEVELOPMENT, DIFFUSION, AND USE OF MEDICAL TECHNOLOGIES

The public and other organizational policies and programs related to the development, diffusion, and use of medical technologies can be broadly classified under four headings; 1) research activities, 2) regulatory responsibilities, 3) reimbursement policies, and 4) coordination of assessment activities and dissemination of information. Some of these policies and programs have been described in previous OTA reports ***(266,270,274,*** 281).

Research Activities

R&D activities are an integral part of the innovation process. Funding for the basic research which advances medical care comes primarily

from NIH, with smaller but important amounts from other Government agencies, industry, and private foundations (222). The central role that basic research plays in the process of medical innovation ***(64)*** is the justification for the substantial public and private moneys invested.

The development and diffusion phases of medical innovation are also central to the innovation process, but for these phases there is relatively little formal public funding. NIH, whose primary focus is research, appears to have no systematic or comprehensive policy of support for technology development. Although NIH grants and contracts have been given to support technology development in a number of areas (e.g., the artificial heart program, cancer screening, cancer chemotherapy, and, in recent years, hemodialysis), figures to document the size of NIH investment in development are not available. The amount invested in development probably constitutes a relatively small part of the current $3.8 billion NIH budget.

In the discussion that follows, the emphasis is on public and private research related to medical technology assessment. Information derived from this research should be useful in setting policies affecting medical technologies.

Federal Research Activities

Medical care research is of two general types: 1) biomedical research, and 2) health services research. More than a dozen Federal agencies are involved in conducting biomedical research, but the 11 institutes of NIH receive approximately ***70*** percent of Federal funds ***(228).*** The primary sponsor of health services research is the National Center for Health Services Research (NCHSR). HCFA sponsors additional health services research, but tends to focus it ***on*** the needs of Medicare and its other operating programs, A fourth Federal agency, the National Center for Health Care Technology (NCHCT), was established in 1978 to support evaluations of health care technologies, but did not receive funding for fiscal year 1982.

NIH and each of its institutes divide their resources among extramural grants, contract research, and intramural projects initiated by scientists within NIH. The Federal agencies that support biomedical and health services research rely on a peer review system to judge proposed projects (270). The peer review system of NIH, for example, consists primarily of non-Federal scientists and lay advisors from across the Nation grouped into 130 peer review groups, advisory committees, councils, and panels (125). They provide NIH with opinions on the scientific and technical merits of grant applications and contract proposals and on program initiatives and policy issues (270).

NIH both conducts its own testing and encourages and funds medical research and testing activities in academic centers and research institutions. It has funded studies of drugs, devices, and medical and surgical procedures, though it generally does not synthesize the evidence garnered from these efforts (266). NIH is the largest single source of funds for the support of RCTs in the country. Such trials, as described in chapter 3, are a key method for obtaining information about the safety and efficacy of certain medical technologies. In 1975, NIH provided approximately $110 million for clinical trials, a figure representing 5 percent of its total budget (266). By 1979, support for clinical trials had increased to over $135 million. Tables 2 and 3 summarize NIH's support for clinical trials during fiscal year 1979.

NCHSR conducts and sponsors a wide variety of health services research. This agency has three principal responsibilities: 1) to develop information that might be used by various decisionmakers in the public and private sectors; 2) to serve as the focal point for coordination of health services

Table 2.—Number and Amount of NIH Support for Clinical Trials Active in Fiscal Year 1979 by Institute

Institute	Number of trials	Amount of support
NIH	986	$136,160,1 16'
NEI	26	8,605,609
NHLBI	20	56,523,501
NIAID	120	6,496,938
NIAMDD.	67	8,240,133
NICHD	32	4,183,244
NIDR	26	1,778,699
NINCDS	40	2,660,949
NIGMS	1	**225,750**
NCI	**654**	**47,445,293'**

'One trial did not report amount of support

SOURCE NIH Inventory of Clinical Trials, 1979

Table 3.—Amount of NIH Support for Clinical Trials Active in Fiscal Year 1979 by Institute for Type of Support

Institute	Extramural support				Intramural Support[b]	Total amount of support
	Grant	Contract[a]	Grant and Contract	Total		
NIH	$47,304,588[c]	$75,738,768	$1,954,960	$124,998,316	$11,161,800	$136,160,1 16'
NEI	3,141,547	5,378,262	–	8,519,809	85,800	8,605,609
NHLBI	4,006,736	50,933,477	159,788	55,100,001	1,423,500	56,523,501
NIAID	2,435,341	3,827,597	–	6,262,938	234,000	6,496,938
NIAMDD	1,927,658	5,226,975	–	7,154,633	1,085,500	8,240,133
NICHD	3,074,448	556,296	—	3,630,744	552,500	4,183,244
NIDR	221,977	557,672	–	779,649	999,050	1,778,699
NINCDS	1,786,449	439,000	—	2,225,449	435,500	2,660,949
NIGMS	225,750	—	—	225,750	—	225,750
NCI	30,484,682[c]	8,819,489	1,795,172	41,099,353	6,345,950	47,445,293[c]

[a]Contract includes interagency agreements without intramural support.
[b]Intramural support includes intramural support in combination with interagency agreements
[c]One trial did not report amount of support.

SOURCE: NIH Inventory of Clinical Trials, 1979

research within the Public Health Service (PHS); and 3) to ensure that results from its research, evaluation, and demonstration activities are disseminated rapidly and in a form which is usable ***(290).***

NCHCT, though not funded for fiscal year 1982, was required as part of its 1978 legislative mandate to undertake and support comprehensive assessments of health care technologies, including analyses of their safety, efficacy, and economic, social, and ethical implications. NCHCT had its own extramural program for awarding grants and contracts for assessments, research, demonstration, and evaluations in the field of health care technology (90,112).

In addition to responding to Medicare coverage questions (see discussion below), NCHCT identified priority technologies for "focused" or "full" assessments. NCHCT selected technologies for these assessments through the advice of the Secretary of Health and Human Services, its National Council, and others. Full assessments were comprehensive, integrated analyses of a technology's safety, efficacy, and effectiveness, and any social, ethical, or economic implications. Such assessments usually involved commissioning an overview paper, establishing a Federal planning group, establishing a full planning group, and convening a conference. Conferences were held on such topics as coronary artery bypass graft surgery, dental radiography, cesarean section, and electronic fetal monitoring (110,111).

HCFA's research objectives and priorities are defined by the information needs of HCFA operating programs. HCFA's research and demonstration mission is to improve the operating effectiveness of the Medicare and Medicaid programs. The agency's Office of Research and Demonstrations is currently conducting over ***200*** intramural and extramural projects on reimbursement issues, coverage eligibility, and management alternatives to present Federal programs, as well as on the impact of HCFA programs on health care costs, program expenditures, access to services, health care providers, and the health care industry.

One focus of HCFA's Office of Research and Demonstrations is on data acquisition and data management systems. Over the past 3 years, grants have been awarded to develop "integrated data demonstration" systems in a number of States, including Iowa, Maine, Massachusetts, Minnesota, Missouri, New York, South Carolina, and Vermont. * Each grantee proposes to develop a central data base—often conceived of as a "clearinghouse" or "data broker''—in which numerous types of billing and discharge abstract data, and sometimes other types of data, will be collected and linked. Although the eventual goal is statewide implementation of a system that collects data on all patients, most grantees propose

● Recent decisions by HCFA have resulted in continued funding of the demonstrations in South Carolina, Maine, Vermont, and Missouri. Demonstrations in Massachusetts and Iowa were up for renewal later in fiscal year 1981.

initial implementation in only a few pilot or test hospitals (32,105,106,107). The Office of Research and Demonstrations has several publications for disseminating research and demonstration findings, which are also available through the National Technical Information Service.

Research and assessment issues are often initially identified by HCFA in the form of reimbursement coverage questions: Is the test, procedure, or treatment regimen provided to a specific patient "reasonable and necessary?" (305). Coverage questions originate when a bill is submitted to the Medicare fiscal intermediary, whose medical director is to determine whether an "unusual" medical event has occurred. In order to make a determination, the medical director checks through a "buddy system," contacting physicians in the local community or recognized experts in the medical field involved. If he or she decides that the intervention was appropriate, the bill will be paid, and this limited review will be the only "technology assessment" the procedure will undergo. If some question remains regarding the intervention's appropriateness, however, the bill will be forwarded to the HCFA regional office, and that office will investigate in much the same manner as the intermediary's medical director. If the intervention is accepted in the region's area, the bill will likely be paid. (Thus, the various regional offices may reach different conclusions on similar coverage questions.) In the event that there is still ***uncertainty,*** however, the regional office will pass the question along to HCFA's central office.

Until early 1980, HCFA's procedures for making coverage decisions were highly informal. The staff of the Office of Coverage Policy, often with assistance from the Health Standards and Quality Bureau, would review the issue, consult experts in the field with whom they were acquainted, and come to a decision. Although a formal agreement between HCFA and PHS had existed since around 1966 (407), a somewhat more formal process involving a panel of physicians within HCFA and from NCHCT was established in early 1980. When HCFA decided that a procedure involved a question of national importance, a request for a technology assessment was sent to NCHCT ***(305).*** Usually, such a request asked NCHCT to determine the safety and efficacy of a particular technology and to recommend whether HCFA should reimburse. Inquiries from HCFA covered the full spectrum of medical practice, ranging from the appropriateness of continued coverage for highly questionable or obsolete to medical technologies questions of reimbursement for new or investigative medical technologies. (Reimbursement policies have profound effects on the adoption and use of medical technologies and are discussed in the section on reimbursement below.)

Private Sector Research Activities

Increasingly, the private sector is involved in evaluating medical technologies, especially to determine their safety and efficacy. Manufacturers of drugs and devices initiate research and are required by FDA to conduct tests for premarket approval of their products. Large private clinics have often led the way in finding effective and efficient applications. For example, the Cleveland and Mayo Clinics were particularly active in the early evaluative efforts of the computed tomography (CT) scanner. The Cleveland Clinic has traditionally supported strong research and assessment programs in cardiovascular diseases, including an artificial heart development program. The Mayo Clinic, long recognized for its contributions to biomedical research, supports a methodologically sophisticated cadre of assessors and recently established a health care studies unit to examine problems in hospital utilization and delivery of medical services in rural areas. The health care studies unit began with $12 million in NIH grants in ***1975.*** By ***1980,*** its total budget approached $41 million, much of it private foundation money. Most of the unit's research can be classified as nonrandomized in design, often relying on careful recordkeeping (11,37,347).

Other research activities have been undertaken by professional associations. The American Academy of Pediatrics has developed recommendations concerning immunization practices. The American Public Health Association periodically compiles a list of effective preventive and therapeutic procedures for infectious diseases ***(266).*** The American Hospital Association and the American College of Radiology have been involved in similar activities ***(306).***

There is also ECRI (formerly the Emergency Care Research Institute), a nonprofit organization primarily involved in comparative product evaluations of diagnostic and therapeutic devices and hospital equipment and supplies. ECRI provides a type of "Consumer Report" service for hospital administrators, which gives ratings to comparable medical technologies based on performance, safety, ease of use, and cost effectiveness. Its emphasis on the larger economic, social, and ethical issues surrounding health care technologies has recently been expanded. Further, ECRI maintains a computerized health devices data base on over ***6,000*** categories of devices and hospital equipment (251).

Some health insurance companies and nonprofit organizations also provide funds for research and technology assessment activities. For example, Blue Cross of Massachusetts has funded the clinical cost of an RCT comparing CT scanning, radionuclides, and ultrasound for the diagnosis of adrenal tumors, pancreatic diseases, and metastatic tumors of the liver (38). The studies were carried out at the Peter Bent Brigham Hospital in Boston and at the Johns Hopkins Hospital in Baltimore, and the cost of analysis was paid by the American Cancer Society. Blue Shield of California, along with the Multiple Sclerosis Foundation, is exploring the feasibility of similar collaborations in a clinical trial of plasmapheresis as a treatment for multiple sclerosis ***(38).***

Approximately 15 years ago, medical insurance carriers became concerned about reimbursing new therapies that were still in the experimental phase. In 1966, therefore, Blue Shield of California established its Medical Policy Committee (primarily composed of physicians but also including members of the public and representatives of the California Podiatry Association) to assess the scope and limits of Blue Shield's standard medical insurance policies with respect to new diagnostic and therapeutic procedures (39).

In 1975, in addition to evaluating new procedures, services, and technologies, California Blue Shield's Medical Policy Committee began to identify obsolete procedures (155). This function was subsequently promoted by the Blue Cross and Blue Shield Associations under the Medical Necessity Project.

One outgrowth of that project has been the Clinical Efficacy Assessment Project (CEAP), undertaken by the American College of Physicians with funding from the Hartford Foundation. CEAP's specific objectives are to: 1) identify and evaluate technologies that are only partially effective, 2) disseminate evaluative information of potential use to health care providers and third-party payers, 3) evaluate technologies that are more efficacious in one setting than in another, 4) obtain such measures as cost benefit/cost effectiveness and marginal utility, and 5) discover how physicians decide about technology use. CEAP's mandate at this time does not include the investigation of new or emerging technologies. For the foreseeable future, therefore, CEAP will review tests and procedures that are in current use (4).

Another important initiative of California Blue Shield's Medical Policy Committee, undertaken in the interests of cost containment, was the Ambulatory Surgery Project. In 1976-77, it identified more than 700 surgical and diagnostic procedures that could normally be performed in an ambulatory setting without admission to a hospital ***(38).***

Regulatory Responsibilities

To regulate effectively, the Federal Government must obtain adequate information in a timely manner. One major regulator, FDA, requires manufacturers of drugs and some medical devices to submit information about their products which is gathered according to approved research protocols. Other regulatory mechanisms, including local health planning agencies, are in need of information but have no particular means to obtain it.

The major Federal health regulatory activities are described briefly below. The reader will note that one primary effect that regulation tends to have on medical technologies is to constrain their development, diffusion, and in some instances, their use.

Federal Regulation of Drugs

FDA becomes officially involved in the development process for a new drug when the drug's "sponsor" (e. g., manufacturer) files a "notice of

claimed investigational exemption for a new drug" (IND) for FDA's permission to test the drug in humans. If FDA approves the sponsor's IND, the sponsor may proceed with clinical testing. There are three phases in the clinical investigation of a new drug, and each phase must have been preceded by specified animal tests. (Test requirements for contraceptives are more stringent than the requirements set forth below for other drugs.)

Phase I studies are investigations of a new drug's clinical pharmacology to determine levels of tolerance (toxicity), followed by early dose-ranging studies for safety (and, in some cases, efficacy) in selected patients. The total number of both healthy volunteers and patients, which varies with the drug, ranges from *20* to *so.* If the drug is found to be safe, the manufacturer can proceed to the next phase of testing. Phase I studies must be preceded by 2- to 4-week studies in two animal species.

Phase II studies, designed to demonstrate effectiveness and relative safety of a new drug, are carried out on 100 to *200* patients under controlled conditions. If the drug's therapeutic value is demonstrated and there are no serious toxic effects, the manufacturer can proceed to the next phase of testing. Phase 11 studies must be preceded by 90-day studies in two animal species.

Phase III studies are expanded controlled and uncontrolled clinical trials, involving 500 to 3,000 patients in usual medical care settings (clinics, private practice, hospitals). After completing clinical testing under IND, the sponsor of the drug may submit to FDA a "new drug application" (NDA). An NDA is a request for FDA's permission to market the drug. At least two well-controlled clinical trials, accompanied by complete case records for each patient, are usually required for FDA's approval of an NDA. Chronic animal toxicity studies (l-year dog, M-month mouse, and 2-year rat studies) must be completed by the time of the NDA submission. If FDA finds the effectiveness and toxicity data acceptable, it approves the NDA. Since 1962, FDA has reviewed over *13,500* applications for INDs and has approved about 1,000 NDAs (154).

Once a drug is on the U.S. market, FDA has little control over its use or evaluation *(274).* Processes for collecting information on the safety (rare adverse reactions, long-term effects) and on the indications for use of drugs on the market are very limited and for the most part voluntary. In recent years, there has been increasing discussion in the United States about relying more on post-marketing controls on drugs and relaxing the pre-marketing controls somewhat. *

Federal Regulation of Medical Devices

The 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act greatly expanded FDA's role in regulating the safety and efficacy of medical devices. Prior to the amendments, FDA had classified devices such as soft contact lenses, pregnancy test kits, intrauterine devices, nylon sutures, and hemostats as "drugs" *(359).* In 1969, the U.S. Supreme Court ruled that this move was justified since Congress intended the public to be protected from unsafe and ineffective devices *(299).* The Medical Device Amendments of *1976* established a three-tiered system of controls: Class I, General Controls; Class II, Performance Standards; and Class III, Premarket Approval. Each device is required to be classified on the basis of the level of regulation needed to ensure its safety and efficacy.

Class I devices are low-risk devices that are not used to support or sustain human health, and these are subject primarily to the Food, Drug, and Cosmetic Act's basic prohibition against misbranding and adulteration. Although Class I controls apply to accuracy in labeling and the sanitation and physical integrity of low-risk medical devices, all devices must meet these minimum standards. FDA also has the power to ban any device, regardless of classification, which presents a substantial deception or an unreasonable and substantial risk of illness or injury that is not correctable by labeling.

Class II devices are those for which general controls alone are judged insufficient and about which sufficient information exists or could be developed to establish performance standards. FDA is authorized under the 1976 amendments to develop and establish performance standards.

* This topic is explored at greater length in OTA's report *Postmarketing* ***Surveillance of Prescription Drugs*** (281).

Class.III devices are those devices that are life-sustaining, life-supporting, implanted, or present a potential unreasonable risk of illness or injury, and for which general controls or performance standards may not provide reasonable assurance of the device's safety and efficacy or for which performance standards cannot be developed. Class 111 controls are comparable to the premarket approval process for drugs. * Any device which was classified as a "drug" before 1976 is automatically assigned to Class III unless reclassified. Any device developed after 1976 which is not judged by FDA to be "substantially equivalent" to a preamendment device in Class I or Class 11 will also be assigned to Class III and require a premarket approval application. In the first 4 years after implementation of the 1976 amendments, about 98 percent of the listed devices in the 10,540 premarket notifications received were declared "substantially equivalent" to a preamendment Class I or Class II device (270).

The 1976 amendments require any distributor of a device intended to be marketed for the first time to file a notice with FDA at least 90 days in advance to permit the agency to decide whether the device needs premarket approval to assure safety and efficacy. FDA permits earlier distribution if it concludes and notifies the distributor that premarket approval is not required. If the ***90*** days pass without comment from FDA, marketing can begin. In 1981, FDA estimated that 2,300 premarket notifications would be reviewed.

Industry often uses FDA approval to advantage for its marketing strategy. All results of clinical investigations will ultimately be included in a package insert, product data sheet, or physician's brochure, which are FDA-approved generators of promotional claims (300).

Other Regulatory Activities

Concerns about premature diffusion of the more expensive devices and other capital investments led to the enactment of three overlapping Federal programs: 1) section 1122 review, ***2)*** the 1974 National Health Planning and Resources Development Act, and 3) State certificate-of-need (CON) laws. Concerns about the utilization of health care services by beneficiaries of the Medicare and Medicaid programs led to the development of Professional Standards Review Organizations (PSROs).

The first State CON law was enacted by New York in 1964. This law, subsequently followed by similar laws in other individual States, empowered State planning agencies to deny reimbursement to hospitals for large capital expenditures unless the planning agency found a "need" for the service to be provided. In ***1972,*** section 1122 of the Social Security Act similarly authorized the Medicare and Medicaid programs to withhold funding for depreciation, interest, and return on equity capital for certain investments found not necessary by a health planning agency. State CON laws and section 1122 review, in effect, constitute a franchising process for potential adopters of expensive medical technologies.

Section 1122 applies to investments of more than some specified amount (initially $100,000) and covers changes in beds and services that are provided by certain health care facilities, such as ambulatory surgical facilities. Private physicians' offices are explicitly exempted. In 1977, 37 States had contracted with the Department of Health and Human Services (DHHS)* to conduct section 1122 reviews.

The National Health Planning and Resources Development Act of 1974 required States to pass CON laws by 1983 as a condition of future Federal funding under the Public Health Services Act, the Community Mental Health Centers Act, and the Alcohol Abuse and Alcoholism Act. The original act applied to the same facilities covered by section 1122 review. However, 1979 amendments to the act exempted health maintenance organizations (HMOs) from having to secure a CON for inpatient investments.

PSROs, enacted into law in 1972, are areawide groupings of practicing physicians responsible for reviewing services provided and paid for by Medicare and Medicaid, The purpose of their review

● The 1976 amendments also allow FDA to permit developing and marketing approval of a Class 111 device under a "product development protocol, " where FDA and manufacturer agree in advance on a plan for the development, testing, and release of the device. This approach has not been implemented.

*Then the Department of Health, Education, and Welfare.

is to help assure that these services are: 1) medically necessary, 2) of a quality that meets locally determined professional standards, and 3) provided at the most economical level consistent with quality of care. However, the primary operational mission of PSROs has been to constrain excessive utilization of health care services which is fueled by the reimbursement incentives discussed in the next section of this chapter.

Other regulatory-type mechanisms that have been instituted because of the high demand generated by third-party payment include State hospital rate-setting programs, increasing Medicare deductibles, setting low reimbursement levels for the Medicaid population, decreasing Medicaid benefits, and raising Medicaid eligibility requirements. All of these affect the diffusion and level of use of medical technologies.

Reimbursement Policies

Reimbursement policies have profound effects on the adoption and use of medical technologies. Reimbursement also influences the innovation process, especially for medical and surgical procedures. With the increasing costs of medical care continuing to cause concern, reimbursement policy is becoming even more important. Informed coverage decisions may require even more detailed information concerning medical technologies than regulatory decisions. Whereas regulatory decisions tend to be *more* of a "go," "no go" nature, reimbursement decisions are, or at least could be, more related to appropriate use of technologies, a much finer distinction.

The growth in third-party coverage of medical care is seen as a major cause of the excessive adoption and use of many medical technologies (142, 33 I). It is important to note, however, that factors other than reimbursement policy contribute to the overall tendency to adopt and use medical technologies at excessive levels. Such factors include competition among hospitals to achieve quality and prestige to attract patients and physicians, public demand for sophisticated technologies, increasing specialization within medicine, physicians' desires to do as much as possible for their patients, uncertainties related to what constitutes appropriate use, and the defensive overutilization of medical tests and procedures because of the threat of malpractice suits.

Variations of Reimbursement Mechanisms

There are two basic forms of payment mechanisms in the U.S. medical care delivery system: cost-based and charge-based (305). Government programs, primarily the Medicare and Medicaid programs, were developed to "buy into" what was then perceived as a market pricing system. The statutes enacted in 1965 established the principle that the Government purchaser would pay institutional providers the costs of services to patients. Physicians were to be paid their "usual, customary, and reasonable" fees. The original assumption was that the Government was buying at the margin and would not affect the average costs of the system. Subsequently, however, it came to be recognized that Government purchases of medical services were sufficiently large to affect purchase price and costs. Thus, the 1972 amendments to the Social Security Act placed limits on the amount that would be paid by Medicare to both institutional providers and physicians. Rather than being related to efficiency, these cost limits reflected rates of increases in charges over time.

In the "private" sector of the medical care market, there are two widely used mechanisms to set reimbursement levels. One, the cost-based Blue Cross/Blue Shield reimbursement system is in many ways similar to the Medicare program. Hospitals are reimbursed the "reasonable" cost of providing care to patients, and physicians are paid "reasonable" fees. The second mechanism is payment for billed charges and is used by some Blue Cross/Blue Shield plans and in all contracts established between patients and other insurers to pay the bills generated by the patient. Under this approach, all or some of the charges of hospitals and other medical providers are paid through insurers, unless there are copayments and deductibles which are paid by the patient. Patients not covered by Government or other insurers are responsible for their own bills. Billed charges are more like a market mechanism, except that demand is not directly affected by the income or wealth of the patient.

A third payment mechanism, not very widespread, is cavitation, whereby a fixed amount is paid for each patient per time period, regardless of the health services provided. The cavitation method generally involves the integration of financing and the delivery of services, thus placing the provider of medical care at financial risk.

Influence of Reimbursement on the Development, Diffusion, and Use of Medical Technologies

When coverage for new and experimental medical and surgical procedures has been offered from the outset, a high level of reimbursement has been justified on the basis of the special skills and large amounts of professional time required, and perhaps on the basis of increased risk. When such procedures have become routine, requiring less time and skill and posing lesser risks, however, professional fees have usually increased rather than fallen ***(316).***

Several examples have been provided by Blue Shield of California (39). Phakoemulsification of the crystalline lens, introduced as an alternative to lens extraction for cataract, is—once learned—shorter and no more complex than standard lens extraction, yet surgeons initially charged ***25*** to ***30*** percent more for the new procedure than for the older, more costly procedure. In this instance, California Blue Shield's Medical Policy Committee disallowed the increase. Another example is the flexible fiberoptic endoscope. Although this new instrument is easier to use than the standard rigid instrument, physicians introducing the new procedure charged 25 percent more. A third example is arthroscopic menisectomy for torn knee cartilage. Orthopedic surgeons introducing this procedure wished to charge the full fee for the standard open arthrotomy and an additional fee for the arthroscopy. In this instance, Blue Shield of California agreed to pay the full arthrotomy fee and an additional ***50*** percent of the arthroscopy fee. The rationale for Blue Shield's concession was that the performance of the simpler procedure might eliminate the need for many days of hospitalization and laboratory tests, with a considerable net savings in total charges.

Allowing a simpler procedure to be billed as a more complex procedure has resulted in questionable increases in physicians' fees. In the example of arthroscopy of the knee, the large difference in allowable charges when an operative procedure is added to a diagnostic procedure offers a strong invitation to remove some tissue during arthroscopy. During the diagnostic examination of the knee, a small piece of redundant synovial membrane may be seen—a finding of no great importance. Removing a piece of this tissue makes the procedure a "synovectomy," for which the customary charge is $1,300, rather than simply a diagnostic arthroscopy, for which the customary charge is only $500. The above scenario presents a situation that may be reasonably justified medically, but, even interpreted generously, there is a clear fiscal invitation to perform a procedure that is more, rather than less, complex.

There is also a much more serious consequence of the manner in which charges are submitted for experimental procedures. With increasing scrutiny by third-party payers of bills submitted for new procedures and more than occasional denial of payment for such bills, there is a strong incentive for physicians to request payment for a standard procedure rather than a new one. This practice is also encouraged by the fact that new procedures often do not have a procedure code number, by which most bills are processed. Requesting payment for a standard procedure may simply reflect an honest effort to use whatever code number seems most nearly to approximate the procedure actually performed. The net result, however, is that the identity of the new procedure may be concealed, and the fact that an experiment has been carried out may not emerge.

In bills submitted to Blue Shield of California, there is an approximately 15-percent error rate in the coding of all procedures (39). The medical director estimates that 1 percent of the errors involve the use of existing codes for procedures to which new codes have not been assigned. Any innovation that falls outside of "accepted medical practice" is particularly vulnerable to being mislabeled. Because it is difficult to define exactly what constitutes accepted medical practice, the new procedures that have the best chance of being reimbursed are the ones that deviate the least from existing procedures which are already being reim-

bursed. The Federal Government, for example, has traditionally favored coverage of new technologies perceived to be modifications of existing interventions **(270).** The incentives, therefore, are toward the development of parallel procedures or extensions of existing technologies.

For procedures that deviate substantially from accepted medical practice, the reimbursement system may require considerable testing for safety, efficacy, and costs to determine if they offer sufficient contributions to compensate for their deviation from standard medical practice. These circumstances have several implications. First, when procedures remain outside the coverable range, they may also suffer the fate of anonymity, neglect, lack of funding, or underutilization. An obvious example is the traditional exclusion from most insurance plans of preventive medical care, most notably screening services. Second, the scrutiny of radical innovations rather than of incremental improvements may be misplaced to the extent that the growth in medical expenditures is the primary reason for such scrutiny. The collective expense of small tests and procedures is arguably far greater than that of a few 'big ticket" technologies **(249).** Third, if radical innovations have the most difficulty in receiving favorable coverage decisions, innovators might be inclined to pursue less radical but more easily accepted innovations. This is a difficult hypothesis to test, as radical innovations have less chance of commercial success than minor innovations; but once radical innovations penetrate the market, the magnitude of their commercial success is greater than for minor innovations. Fourth, a technology-by-technology approach to coverage decisions, with priorities determined by how radically each technology differs from existing ones, may invite those seeking payment for the use of new technologies to submit their claims for payment under the guise of accepted procedures.

Under either cost reimbursement or charge payment, third-party payments generally are intended to cover the full costs of new technologies, including purchase, maintenance, or operation of equipment; the leasing of equipment; the costs of drugs; or the facilities and equipment needed for a procedure (19). One would expect that greater adoption of technologies would occur under these relatively price-independent conditions than would occur under a more price-sensitive system. Cromwell, et al.'s ***(75),*** interstate analysis found that the hospital's percentage of revenues from third parties was significantly and positively related to the hospital's adoption of expensive technology. Russell (331) found that the adoption of cobalt therapy and electroencephalograph occurred faster when the level of insurance coverage was higher and proceeded more rapidly as that level grew. She also found that a greater contribution of hospital costs by Medicare was associated with increased adoption of cobalt therapy, intensive care beds, and diagnostic radioisotopes. And Willems ***(392)*** concluded that open-heart surgery spread more quickly in areas with faster growth in insurance coverage.

Third-party reimbursement can indirectly affect the adoption of technology by changing the availability of financial capital to potential adopters. A prominent example is the Medicare program, which reimburses institutional providers for capital as well as operating costs. Medicare payment for allowable capital costs such as depreciation and interest provides a source of internally generated funds ***(28).*** Third-party coverage, especially by Medicare and Medicaid, has also reduced hospitals' risks of bad debts, thereby improving their standing as credit risks to private lenders. Other changes in governmental programs, such as the Hill-Burton program for funding medical facility construction and modernization, as well as various tax-exempt bond programs, have also affected the sources of financial capital.

In addition to affecting the adoption of technologies, the extent of third-party coverage would be expected to affect the use of technologies. Data on the use of specific technologies are generally lacking, however. Cromwell, et al. (75), found that many hospital technologies are underutilized after being adopted. Nonprofit hospitals in the Boston area were using automated analyzers and patient monitors (and, in teaching hospitals, diagnostic X-rays) at only half of capacity. Willems ***(392)*** considers such underuse as presumptive evidence of the hospitals' overinvestment in new equipment.

It is not clear how this relatively price-independent adoption of medical technologies is used by medical care providers to compete with one another. As summarized by Banta, et al. (19):

> Studies of hospitals found no definite relationship between measures of competition and adoption. The situation is complex, because the characteristics of the market may relate not only to competitiveness, but also to the availability and sharing of information and to local standards of practice. The evidence conflicts, depending on the characteristic used and the technology studied. Russell **(331)** found that concentration of market power among a few large hospitals did not appear to influence the adoption of three common and two prestige technologies, but that hospitals in more concentrated markets were less likely to adopt open-heart surgery. Prior adoption in a locality reportedly speeded the adoption of intensive care units and electroencephalographs, but not diagnostic radioisotopes, open-heart surgery, renal dialysis, cobalt therapy, and computers (75,331). In urban areas, greater adoption of radioisotopes and electronic data processing occurred where there were many hospitals per capita, the hospitals were of similar size, and they were close to other hospitals (212,301).
>
> Different patterns have also been observed between adoption and the number of physicians per capita. Facing a low physician-population ratio, hospitals may compete for physicians through technology adoption. On the other hand, fewer physicians may exert less pressure for adoption. The adoption of CT scanners and radioisotopes appeared unrelated to the physician-population ratio (301,392). However, greater adoption of intensive care units, open-heart surgery, cobalt therapy, and renal dialysis occurred among States with higher ratios **(75).**

Thus, even though current payment mechanisms for medical care services can lead to excessive adoption of medical technologies, there are still constraining factors which make it clear that cost is not the only factor which influences adoption.

Coordination Efforts and Dissemination of Information

Federal Activities

The Technology Coordinating Committee of DHHS served as an interagency forum for the identification and discussion of problems and issues associated with health care technologies (110,111,112). This committee, previously chaired by the Director of NCHCT, fostered information exchange and interagency cooperation on health care technology matters and has served as the department's principal mechanism for joint action on appropriate issues. Now that NCHCT is no longer funded, DHHS is studying whether to keep the Technology Coordinating Committee and, if so, how to organize it.

NCHSR has responsibility for coordinating health services research within agencies of PHS. To coordinate this research, NCHSR chairs the PHS Health Services Research Coordinating Committee, which includes representatives from each of the PHS agencies. * NCHSR also meets regularly with HCFA to review research priorities and to determine how each organization's research activities might contribute to the other's programs. In fiscal years 1980 and 1981, NCHSR and HCFA produced a joint health services research strategy and budget (113).

NCHSR also disseminates research results to relevant Government agencies, the research community, and other interested parties by means of publications, press releases, conferences, and workshops. In 1978, the legislation authorizing NCHSR was modified to require that at least $1 million or 5 percent of its budget, whichever is less, be used for dissemination activities. In response, NCHSR established a User Liaison Program, aimed at providing substantive assistance to non-Federal health care leaders concerned with critical policy issues and operational problems in the organization, administration, regulation, and delivery of health care services at the State and local level. In ***1979,*** NCHSR's User Liaison Program conducted nine workshops that were attended by users of health services research such as State legislators, executives of State health agencies, leaders of both the insurance industry and hospital sector, and city health officials ***(113).***

● NCHSR'S Health Care Technology Study Section, which served as the scientific peer review committee in the grants review process for NCHSR and NCHCT, provided an additional formal coordination link.

The Office for Medical Applications of Research (OMAR), established in the NIH Director's Office in *1978,* monitors, facilitates, and evaluates NIH research, technology assessment, and technology transfer activities. As noted in chapter 5, OMAR coordinates NIH consensus development conferences. The OMAR Advisory Committee—consisting of representatives from the bureaus, institutes, and divisions of NIH and from other Federal agencies, including FDA, the Centers for Disease Control (CDC), and the NCHCT (while it was funded) —assists OMAR in its planned consensus development activities. The committee also assists OMAR in the exchange of information relating to other NIH involvement in assessing biomedical technologies *(228).*

The consensus conference panels of NIH are composed chiefly of medical experts, although they also include members of the lay public and selected professions (e.g., clerical and legal). The technologies these panels examine may be emerging technologies or technologies in general use and may be drugs, devices, or medical, surgical, or dental procedures. (As described in ch.5 , there have been over *30* consensus conferences since the first on breast-cancer screening in September 1977. The topics and dates of all conferences from *1977* through the end of 1982 were listed in table 1.) On topics representing areas of mutual interest and concern, consensus conferences have been sponsored by NIH in conjunction with NCHCT, in collaboration with an agency outside NIH, or under the cosponsorship of two or more institutes within NIH.

An essential part of the OMAR consensus development program is the dissemination of consensus statements and supporting materials to practicing physicians and others in the health care system, the biomedical research community, and the public. It is hoped that by supplying medical practitioners with critiques of complex medical technologies, dissemination of these reports will contribute to an improvement in the quality of medical practice. OMAR has compiled a mailing list of over *21,000* names. Consensus materials and information have been published in three major American medical journals *(Journal of the American Medical Association, New England Journal of Medicine,* and *Annals of Internal Medicine),* as well as in State medical society periodicals and the general press *(229,287).*

NCHCT initiated the proposed development of a Clinical Data Acquisition Plan, a conjunctive effort with both public and private group support to develop a model method for collecting clinical data on emerging technologies. Under the model process, third-party payers would provide interim reimbursement for appropriate technologies and related services to those providers who agreed to submit certain prescribed data (110,372).

As called for by its 1978 authorizing legislation, NCHCT also compiled an annual "emerging technology list. " All DHHS and other relevant agencies submitted a list of candidate technologies, including background information and a preliminary assessment of each. Although the "emerging technology list" was intended only to identify emerging technologies, not necessarily to assess them, it came under increasing attack by industry as a threat to innovation. The mere appearance of a technology on the list, it was argued, increased managerial reluctance to develop the technology because it created additional uncertainty in further marketability (111).

Other Processes

Apart from those mechanisms involving Federal agency interaction, various other mechanisms by which medical technology information is distributed include: 1) the public media, 2) the mail, 3) advertising, 4) personal contacts, 5) the educational process, and 6) libraries and other types of information providers, including Federal information centers and private for-profit and not-for-profit organizations. While the relative importance of each is arguable, the appropriateness of individual mechanisms may partly depend on whether the information is to be used in conducting an assessment of a medical technology or is to be used in conveying the results of a medical technology assessment.

The popular print media, including daily and weekly newspapers and journals, are a primary channel of information on health, including medical technology assessment, for the general public. At times, they also serve a similar function for physicians, nonphysician health profes-

sionals, legislators, and others in the health field. Joining the mass circulation publications are an increasing number of biweeklies and minimagazines serving special interests, regions, and even localities (37o). Many of the mass circulation publications employ a trained science/health columnist at regular or occasional intervals. In addition, news reports of immediate happenings in health, health advice columns, retrospective analyses of technologies, and more often, predictions about the future of new technologies are found in all forms of print. Indeed, some popular publications are devoted exclusively to health and/or specific aspects of health.

The diversity in the print media is paralleled in *radio* and *television*. Some networks and/or stations, especially publicly owned or operated outlets, occasionally explore a medical technology in depth. One can question whether the 5-minute-or-so news programs provide health information of any real value, but such programs usually carry spot announcements about health fairs and the need for their listeners to take advantage of technologies, such as immunizations and high blood pressure medications. Health fairs also supply information about medical technologies, as well as how and where professional assistance can be obtained.

Mailings are a common mechanism for disseminating both unsolicited and solicited information for and about medical technology assessment. Unsolicited information is that which is received without having been requested or paid for by membership or subscription. Among the materials available by this mechanism are direct mailings about medical technologies (e.g., newsletters from drug companies) and advertisements from product distributors. Unsolicited information through the mails is an important source of health information for both lay people and health professionals. Most Federal agencies dealing with medical technology use the mails for sending literature in response to direct requests or to people on their mailing lists.

Advertising of drugs, and to a much lesser extent of other medical technologies, is prominent in all the popular media. The large budgets that most pharmaceutical companies allocate for this purpose seem presumptive evidence that there is a market for this source of information among the general public. Advertising is termed education by the companies involved, especially when the target audience is physicians and other health professionals. Pharmaceutical manufacturers spend several hundred million dollars a year in advertising their products to the medical profession in professional journals, at professional meetings, and through their representatives ("detail men"). These expenditures would not be likely to continue if they did not bear results ***(65).***

Recently, some drug companies have been supplying hospitals and other medical facilities with video cassettes that contain information on various aspects of health care including medical technologies. They also are producing closed circuit television programs on similar topics to be received at medical facilities that have video tape receivers (214).

For a discussion of the ways in which physicians keep informed about, and are influenced by, new developments of medical technologies, the reader is also referred to an earlier section of this chapter concerning the diffusion of medical technologies.

CONCLUSION

This chapter has discussed the innovation and diffusion of medical technologies, especially medical and surgical procedures, and policies that affect the innovation and diffusion process. Many of the points raised in this chapter are discussed at greater length in appendix D,

The innovation process is complex and not well understood, but is certainly important to an assessment strategy. Most regulation is intended to substitute for an imperfect market. Government has adopted a general sense of public responsibility by seeking to ensure that unsafe and inef-

ficacious drugs and medical devices not be allowed on the market. The thrust of nearly all FDA regulations is to require manufacturers of new drugs and certain medical devices to test their products for safety and efficacy according to approved protocols. FDA then synthesizes this information, decides whether to approve the marketing of the technology, and then regulates the labeling process. Thus, FDA is involved with all stages of medical technology assessment as defined in chapter 1 (i.e., identification, testing, synthesis, and dissemination). However, FDA's involvement is limited to certain types of technologies-emerging and new drugs and devices. Also, FDA's activities are generally limited to assessments of safety and efficacy; cost, cost effectiveness, and other social/ethical effects are generally not explicitly considered. *

The information requirements of FDA tend to slow the innovation and diffusion of certain medical technologies. Industry, especially the medical devices industry, is concerned that FDA's information requirements unnecessarily threaten innovation. A major problem in analyzing industry's concerns, however, is the difficulty of determining the costs and benefits of testing requirements.

Reimbursement policies also distort the innovation process. In general, it appears that the wide availability of medical insurance contributes to the overadoption and use of many medical technologies. In many cases, the lack of technology assessment information at the point of reimbursement tends to speed up the diffusion process. As suggested earlier, however, the diffusion of truly innovative technologies that fall outside generally accepted medical practice may actually be discouraged by the present reimbursement system.

This dichotomy seems to be related to the lack of adequate scientific evidence of the value of new technologies. When a new technology is an add-on (i. e., when it does not directly substitute for an existing technology), produces more information, or for some reason captures the imagination of the medical profession, the technology tends to be accepted and even encouraged by the medical profession without substantial evidence of its value. On the other hand, radically new technologies that challenge preexisting beliefs—or in some cases merely the status quo—are less likely to be acceptable to the medical profession without very strong evidence of their worth. Since present reimbursement policy rests in large part on accepted medical practice, these more radical technologies tend not to be acceptable for reimbursement, and their innovation may thus be discouraged.

The effects of regulation and reimbursement policies on the innovation process are clearly interrelated. As new medical procedures develop, they often make use of new drugs and devices or use existing ones in modified ways. Such drugs and devices generally have to pass through FDA's regulatory process. Until these technologies are approved for marketing, regulatory review acts as a constraint on the adoption and dissemination of the procedures in which they are used. Once these accessories are released into the marketplace, however, they can act to stimulate use of procedures which are still experimental and not accepted medical practice. For example, FDA released the catheter used in percutaneous transluminal coronary angioplasty (PTCA) from investigational device status and approved its marketing for PTCA while the procedure itself was still considered by many to be experimental.

The Federal agencies responsible for medical research, regulation, and financing engage in a variety of technology assessment-like activities. Although there are increasing efforts to improve coordination between these agencies and collaboration with the private sector, these efforts currently fall short of a strategy for medical technology assessment as discussed in chapter 1. Current coordinating efforts are heavily oriented toward the question of reimbursement. One of the former NCHCT's formal responsibilities was to advise HCFA on coverage decisions. Current efforts such as NIH consensus development conferences are oriented toward determining the efficacy, safety, and appropriate use of medical and surgical procedures, but they can also help to pro-

* Sometimes, however, its review extends farther. For example, in the case of the injectable contraceptive Depo Provera, FDA based its decision to deny market approval, not only on safety criteria (i.e., its concerns over Depo Provera's cancer-causing potential), but partly on the basis that the patient population originally targeted for Depo Provera had diminished substantially as other methods of contraception and sterilization became increasingly available and accepted (193).

vide information for HCFA's decisions regarding the reimbursement of new technologies. A major weakness of all these activities is that no body is charged with evaluating the economic and social/ethical effects of medical technologies. In contrast, the regulatory agencies, principally FDA, have limited roles in current coordinating efforts. Although FDA's regulatory responsibilities make FDA an important generator and repository of assessment data, there is little coordination of its functions with those of the other governmental health agencies.

The next chapter presents OTA's critique of the current system for the identification and testing of medical technologies and the synthesis and dissemination of technology assessment information.