

Appendix D.— Medical Technologies and Innovation

Introduction

In some respects, the innovation process for medical technologies parallels that for other technologies. Although there are many variations, the basic process is as follows. 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 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. The final stage before widespread utilization of an innovation is its introduction into the market.

It is at this point that the innovation process for medical care technologies differs from that for most other technologies. Drugs must meet premarket approval requirements for efficacy and safety. Medical devices, depending on their classification, must either meet general controls, adhere to performance standards, or meet premarket approval requirements for efficacy and safety. New medical and surgical procedures, though not subject to the same regulatory requirements as drugs and devices, are increasingly subject to more systematic applications of clinical testing to evaluate their efficacy and safety; and decisions to pay for their use are also increasingly being subjected to more systematic analyses by private and public health insurers.

Definitions of Innovation

The basic criterion for an innovation is “newness,” or “differing in significant ways” from previous products or programs (213). In its most limited definition, an innovation is an invention that is regarded as novel, independent of its adoption or nonadoption (405). But in other definitions, inventions are not considered innovations unless the adopting system perceives them as such—i.e., innovation involves the process of conceptualizing a new idea, finding the solution to the problem, and *using* a new item of economic or social value (256).

These different concepts of innovation impinge on the question of whether regulatory and reimbursement policies inhibit the innovation process. One might find, for example, that regulation reduces the number of new patents. Using the invention concept of innovation, one might then conclude that innovation has been hindered. Patents, however, offer little insight into the value of inventions. Even innovations that have achieved widespread use are not necessarily beneficial

(252). From that standpoint, inventions that do not show social utility as well as economic worth are not innovations. Thus, it could be argued that inventions that do not meet regulatory or reimbursement criteria (representing collective judgments on social utility as well as economic worth) are not innovations.

Research on Innovation

There are four principal approaches of research for understanding the innovation process: 1) statistical studies, 2) contextual comparisons, 3) critical incident studies, and 4) case studies.

National level statistical studies concerning innovation might include the contribution to gross national product, rates of diffusion, effects of legislation, etc. Such studies suffer principally from a lack of differentiation. Innovations vary enormously in terms of complexity, radicalness, compatibility, etc., and organizations and industries vary in size, technology, history, culture, etc. However, most statistical studies generalize on the basis of an assumed homogeneity.

Contextual comparisons are made by selecting and comparing organizations that are similar along several dimensions (e.g., size, technology, product range) but differ in terms of success at innovating (or some similar dimension). From contextual comparisons, it may be possible to extract a list of factors common to the successful innovators but not to the others. Given large samples, the regularity with which some factors appear confirms their importance in the innovation process. Contextual comparisons cannot account for all the local sources of variation, however, and remain at a general and somewhat superficial level.

Critical incident studies deal with individual recollections about important stages in the development of various innovations. The problem here is one of subjective emphasis and bias, rich in detail but not necessarily giving the whole story. Critical incident studies also tend to deal with major innovations only and to provide little information about incremental changes, the total contributions of which may equal or exceed the contribution of single radical innovations.

Case studies are a frequently used approach in medical technology assessments. An attempt is made to get close to the process for a long period of time from an involved but neutral viewpoint. Case studies represent an attempt to understand the dynamics of a process which is naturally changing in character and content all of the time, something very few of the other types of studies consider. But case studies lack a developed methodology, and, although they may be able to ac-

count for the behavior of one specific organization, there is no basis for generalizing beyond that to others.

The limitations of these four basic approaches are: 1) they either provide general data which are limited in applicability to specific circumstances; or 2) they give a highly specific account of one organization or invention, identifying most of the factors which influence the innovation process but with no direct general applicability (27).

Since such studies attempt to place a rational, predictive framework on creativity, it is not surprising that they provide an enormous amount of descriptive detail but do little in the way of establishing cause-and-effect relationships. Innovation *seems* to be the result of many interrelated factors and not of any particular factor. Nevertheless, it is useful to review the available research findings to help gauge what effects regulatory programs and changing governmental reimbursement policies can or might have on the innovation process.

The next section of this appendix summarizes what is known about the factors that affect the innovation process for drugs, devices, and medical and surgical procedures. The second section discusses regulatory mechanisms and medical care reimbursement policies and draws inferences concerning their possible effects on the innovation process.

Factors That Affect the Innovation Process

Characteristics of Successful Innovations

When successful innovations are examined for their key characteristics, certain recurring factors are commonly found in all industrial areas. Their relative importance varies from industry to industry and even between specific innovations in one industrial area, but together these factors provide a composite picture of the conditions under which the innovation process thrives.

Personnel of five types contribute to successful innovations (313). "Idea-exploiters" (as opposed to "idea-havers") not only think up new ideas but also do something about them. "Entrepreneurs" (or "product champions") advocate and push for change and innovation. "Program managers" (or "business innovators") handle the supportive functions of planning, scheduling, business, and finance related to the developmental activities of their technical colleagues. "Gatekeepers" (or "special communicators") are the links who bring information from outside sources, joining technical, market, and manufacturing sources of information to

the potential users of the information. Finally, "sponsors" or ("coaches") are senior people not carrying out the research or advocating the innovation, but providing junior people with the resources necessary to move technological advances forward in the organization.

Motivating forces for the initiation of innovative activity are roughly divided into "technology-push" and "market-pull" theories. The former reflect the belief that pushing technology through basic research will eventually result in significant technological development. The latter reflect the belief that the market, through recognition of a need and creation of a demand for *new* products, is the dominant factor in producing successful innovations.

The general industrial literature supports the theory that market-pull is the primary influence. From 60 to 80 percent of important innovations across the industrial spectrum have been related to market demands (375). In a study from West Germany, 70 percent of successful innovations originated from market-pull and 80 percent of failures began with technology-push (156). However, it is apparent from this literature that it is not an either/or situation between technology-push and market-pull.

Comroe and Dripps (64) argue that in the area of biomedical technology, technology-push is a more important factor. In studying the 10 most important clinical advances against cardiovascular and pulmonary diseases from 1945 to 1975, these investigators reviewed 529 publications considered to be the key research articles leading to these advances. They concluded that 41 percent of the key articles "reported work that, at the time it was done, had no relation whatever to the disease that it later helped to prevent, diagnose, treat, or alleviate."

As for **sources of effective technical solutions**: "In most industries, no single firm commands a majority of the resources available for research, nor can any one firm respond to more than a portion of the needs or problems requiring original solution. It is not surprising, therefore, to find that most of the ideas successfully developed and implemented by any firm came from outside that firm" (375). Moreover, the predominant route of information is personal experience and contacts, not the scientific literature.

An effective technical solution may be an original innovation or one adopted or adapted for a particular problem. About 20 to 30 percent of significant innovations are adopted or adapted ones (219,256) and, as might be expected, a new technology has a greater propensity to be adopted or adapted for a new use when it has passed through the initial and developmental stages into the late maturity stage (376).

Finally, the user or the manufacturer may be the source of the solution, and studies have shown that in many industries (e.g., computers, specialized machinery, scientific equipment), a user came up with the solution, which was then adopted and turned into a product by the manufacturer. Roberts (313) believes that in the medical devices industry, the manufacturer's role is primarily one of adoption and broad-based distribution.

Channels for exploitation is the stage that precedes widespread diffusion. In medicine, the typical mechanism is the clinical trial, and the evidence concerning whether clinical trials function effectively to transfer research results into clinical practice is conflicting (223, 404). In most industrial fields, the nonprofit sector contributes infrequently to innovation. In biomedical innovation, however, universities, medical schools, and hospitals are crucial. Yet few linkages exist in the biomedical area between academia and industry to put innovations into widespread use through commercial marketing. Some linkages may result from a recent change in the patent laws (Public Law 96-517) to enhance commercial exploitation of inventions developed with Federal assistance. And in genetic engineering, universities, medical schools, and hospitals are now forming business relationships with industry, receiving substantial amounts of research funds in exchange for exclusive licenses to market the anticipated innovations.

In the lifecycle of **a technology**, major technological changes occur in the early stages, but incremental technological changes usually dominate the later stages (376). In other words, product innovation dominates in the early stage, with little change in manufacturing process; but as the technology progresses, there is a rapid decline in product emphasis and dramatic increase in process orientation. Finally, small companies contribute most to innovation in the early stages of a technological field, but large companies dominate by the time the field matures. Roberts (313) has observed this pattern in genetic engineering, a new field where small companies are the dominant contributors.

Innovation Process for Drugs and Devices

Although there is little information specifically related to economic factors that affect innovation in the drug and medical devices industries, the following general observations are probably applicable. Innovation is one way to compete in the market and is part of some companies' overall strategy. Basic questions are the extent to which a company pursues long-term v. short-term strategies, and the extent to which competitive success over the long run depends on a company's commitment to technological superiority.

Mansfield, et al. (235), define three probabilities for assessing the importance of different factors at different stages of the innovation process: 1) the probability of successfully completing the technical problem-solving stage; 2) the probability of successfully completing the commercialization stage, given that the technical problem-solving stage has been completed; 3) the probability of economic success, given commercialization. (Economic success means that the project will yield a rate of return which is equal to or in excess of that available from alternative investments.) The product of these three probabilities is the probability that a project which is initiated will be an economic success.

The aforementioned probabilities are affected by both external and internal factors. Externally, a high rate of inflation means high interest rates. These, in turn, make it more expensive to raise capital for long-term investments, and produce large fluctuations in prices, thereby garbling the relative price signals which producers use to determine the kinds of production processes that would minimize future costs. These uncertainties might turn corporate strategy toward a short-term focus.

Corporate strategists also have to choose between long-term technological breakthroughs and short-term, quick-payback product and process improvements. A major innovation of great technical novelty may not have a well-defined market potential. In contrast, a modest product improvement may have a highly predictable market. The major innovation may have a much greater profit potential, but the risk of failure is also much greater. As mentioned above, one study found that 70 percent of successful innovations originated from market-pull and 80 percent of failures began with technology-push (156). Projects that originate with R&D personnel are more likely to be technically challenging than projects that originate with marketing or other company personnel. They also have a lower probability of successful commercialization, because R&D personnel are likely to have less understanding of market potential. But once past the commercialization stage, projects originating with R&D personnel have a higher probability of economic success (235), presumably because they are the most likely to have the combination of technical and economic factors necessary for ultimate success in the market. Whether the greater probability of economic success can offset the lower probabilities for technical completion and commercialization is a matter of judgment. Many projects are not initiated or carried through to completion, because they are judged either to have insufficient market potential or to have risks that are too great.

There is evidence that corporate strategy in the United States has turned increasingly to a short-term

focus, and opinions have been expressed that this is the primary source of our current problems concerning innovation, declining productivity growth, and balance of trade with other countries. Recent investments have been skewed toward equipment and relatively short-term projects and away from structures and relatively long-term investments (231), and an increasing portion of industrial R&D is directed toward relatively short-term developmental work and less toward long-term fundamental research (257). In this vein, some critics have accused corporate managers of relying too much on near-term market considerations in selecting R&D projects. These critics caustically recall that “the initial market estimate for computers in 1945 projected total worldwide sales of only 10 units” (183).

These critics also contend that current management practices in the United States lead to focusing on short-term, low-risk projects. For example, the decentralization of organizational structures requires a greater dependence on short-term financial measurements, such as return on investments, for evaluating the performance of individual managers and groups. In addition, compensation plans for company executives reward shortsighted behavior. In a survey of 174 companies, 79 percent rewarded executives for short-term performance, and only 42 percent offered “long-term” incentives, which were defined as anything over 1 year. In another survey, year-end bonuses were larger than long-term incentive awards; while bonuses amounted to about 50 percent of salary, the median long-term award was only 34 percent of salary (298).

Finally, there is an increasing proportion of corporate presidents with legal or accounting as opposed to technical backgrounds. Critics maintain that this trend reflects a shallow concept of the professional manager as “an individual having no special expertise in any particular industry or technology who nevertheless can step into an unfamiliar company and run it successfully through strict application of financial controls, portfolio concepts, and a market-driven strategy” (183). Such critics contend that although technological issues must be an integral part of broader strategic issues, they cannot be handled by the same methods applied to finance and marketing.

Regardless of the industrial sector, most small manufacturers do not engage in formal R&D. For firms undertaking R&D, innovational effort tends to increase more than proportionately with firm size up to some point that varies by industrial sector. Innovations produced mainly by large firms are typically those in capital-intensive industries. The exceptions are in aerospace, shipbuilding, and pharmaceuticals, where capital intensity is low but development costs for new products are very high. These findings are illustrated in the United Kingdom. Between 1945 and 1970, small manufacturers produced none of the 44 innovations produced by all U.K. pharmaceutical firms, but small manufacturers’ share of net pharmaceutical output in 1963 was 12 percent (151,327).

The U.S. drug industry is also characterized by high and rising development costs for new products and a strong shift toward greater concentration of new products in the very largest of the approximately 600 pharmaceutical firms. Since the late 1950’s, the number of firms producing a new chemical entity has declined, and the development of new chemical entities has been increasingly concentrated in the top four and eight largest firms (see table D-1). In other words, 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.

While the four largest firms’ share of innovative output remained stable from the late 1950’s through the early 1960’s, then accelerated sharply, their share of total prescription drug sales remained fairly constant (see table D-2). Taken together, these findings indicate that the increasing concentration of new chemical entity output in fewer firms has accrued to large firms, mostly at the expense of the smaller firms, in the top 20 innovators. But the four largest firms, despite a near doubling of their share of innovative output, have had essentially the same share of total prescription drug sales during this period. Most of the large drug firms are dependent on a few drugs for much of their income. For example, the three leading products of the companies listed in table D-3 accounted for 22 to 84 percent of their total U.S. pharmaceutical sales in 1979.

These observations probably reflect the following scenario: The vast majority of the 600 U.S. drug firms

Table D-1.—Concentration of Innovational Output in the U.S. Drug Industry, 1957-71

Period	Total number of new chemical entities (NCEs)	Number of firms having an NCE	Innovational output of concentration ratios		
			4-firm	8-firm	20-firm
1957-61	233	51	0.462	0.712	0.931
1962-66	93	34	0.546	0.789	0.976
1967-71	76	23	0.610	0.815	0.978

SOURCE: H. G. Grabowski, et al., “The Effects of Regulatory Policy on the Incentives To Innovate” An International Comparative Analysis, 1976

Table D-2.—Percentage of Innovational Output and Total Sales Accounted for by the Four Largest U.S. Drug Firms, 1957-71

Period	Four largest firms' share of innovational output	Four largest firms' share of total drug sales
1957-61	24.0	26.5
1962-66	25.0	24.0
1967-71	48.7	25.1

SOURCE: H. G. Grabowski, et al., "The Effects of Regulatory Policy on the Incentives To Innovate: An International Comparative Analysis," 1976.

Table D-3.—Percentage Total U.S. Pharmaceutical Sales Accounted for by Three Leading Products, Selected Corporations, Selected Years^a

	1970	1975	1979
Abbot	36	33	28
American Home Products:			
Ayerst	64	74	84
Wyeth	37	44	43
Bristol-Meyers:			
Bristol	69	46	28
Mead-Johnson	40	38	37
Burroughs-Wellcome	NA	56	51
Ciba	47	NA	55
Lederle	48	31	32
Lilly	46	60	43
Merck	35	44	44
Pfizer	52	65	65
Robins	43	45	46
Roche	80	80	70
Searle	45	49	44
Shering	42	48	40
Smith Kline	44	42	66
Squibb	28	31	23
Upjohn	47	50	56
Warner-Lambert:			
Warner	53	NA	NA
Parke-Davis	25	27	22

NA = not available
^aU.S. sales.

SOURCE: Charles River Associates, Inc., "The Effects of Patent Term Restoration on the Pharmaceutical Industry," a report to OTA, May 4, 1981.

are small manufacturers producing primarily generic drugs for limited markets, but also other patented drugs. After patents expire, generics erode some of the market captured by large innovator drug firms and these firms regain their share of total sales through the introduction of new drugs.

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 than 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 high market shares. There are high entry and exit rates in the industry, mostly among small firms (8). Profitability is higher than average in the economy.

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 survey of the industry, for example, did not differentiate between bankruptcy and acquisition in its observation of the 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 medical devices 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 smaller 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). In

other words, a policy of product differentiation and sales promotion may increase a firm's net revenues above the competitive level (288). Profitability measures confirm this viewpoint, indicating a slightly higher profitability in the devices industry than exists throughout the economy. This may explain the observed trend of expansion through acquisition (product differentiation), coupled with major national dealers (sales promotion) either being subsidiaries of large manufacturers or being acquirers of small firms. Product differentiation, distribution, and perhaps the level of new capital investments also appear to act as inhibitors on the growth of small firms (8) and contribute to such firms' failure or acquisition by larger firms.

Innovation Process for Medical and Surgical Procedures

The invention, development, and diffusion of medical and surgical procedures may generally be described by the model of the innovation process developed for products and their manufacturing processes. New procedures usually involve some drug and/or device, and innovations in medical and surgical procedures can be viewed as user-generated innovations, where a previous innovation is adopted or adapted (modified) for another purpose. Regardless of how medical and surgical procedures fit into the model of the innovation process, however, a focus on procedures separate from the drugs and devices that are used in them is necessary, because physicians, as users, are both generators (technology-push) and purchasers (demand-pull) of innovations. Thus, it is crucial to get at least a notion of how they 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.

There are three separate literature sources for analyzing the dissemination of information in medicine. The first comprises sociological research on the diffusion of innovations in social systems (208,317); the second is literature concerned with the effects of communication variables on attitudes and behavior (239); and the third is the scattered, nontheoretical literature in medicine, consisting of descriptive studies of the dissemination and adoption of different medical innovations (62,145,233,331).

The medical literature on the dissemination and adoption of innovations is weighted toward studies of single medical technologies which are diagnostic or therapeutic in purpose. There is a large literature on how physicians learn about and adopt new drugs and a growing literature on specific devices or techniques, but little is known about communication about or the

adoption of complex medical procedures which may not involve drugs or hardware (e.g., psychotherapy).

In practice, however, the crucial distinction is between communication which informs physicians 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 contemplating actual implementation of new procedures (145,233,234).

The importance of informal communication both in the process of scientific discovery and in the diffusion of technological innovations seems to be a feature not only in medicine but in all fields of technological discovery and diffusion (213). Moreover, it may be that there is a prestige hierarchy in which 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 (213).

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.

The following general scenario may help make these theoretical and empirical findings more concrete. Medical and surgical procedures usually begin as user-generated (e.g., physician) innovations. In medicine, an innovative procedure may be in the form of adopting 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 in accompaniment with 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, the "family physician").

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 to present the innovations in a manner that will be technically acceptable, and they also have the prestige which 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 the innovation will revolutionize or at least substantially affect the related area of medical or surgical practice, other academic centers will begin to pursue it, too.

At this point, several Government 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 the Food and Drug Administration's (FDA's) approval. Increasingly, investigational new drug or device uses approved by FDA for limited testing are 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 new procedure and will give great weight to the NIH clinical trials for evidence of safety and efficacy. Meanwhile, 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, also tends to speed up the diffusion of the procedure which NIH may be studying. This result, in turn, places more pressure on HCFA to reimburse for the procedure.

Most of these points are illustrated in the brief case studies in appendix E on: 1) gastric freezing for the treatment of ulcer, 2) hemodialysis for the treatment

of schizophrenia, 3) percutaneous transluminal coronary angioplasty, 4) maternal serum alpha-fetoprotein, and 5) hemodialysis and kidney transplantation.

Funding of the basic research which advances medical care comes primarily from NIH, with smaller but important amounts from private foundations (223). The central role which basic research plays in the process of medical innovation (64) is the justification for the substantial public and private moneys invested.

In the development and diffusion phases of medical innovation, initial findings are translated into clinical procedures. These phases are central to the innovation process, but there is relatively little formal funding. The National Center for Health Services Research (NCHSR) was originally called the National Center for Health Services Research and Development, but its enabling law, when finally passed in 1974, specifically forbade the center to fund development. Although about half of NCHSR's grant awards have been for projects classified as demonstrations, little has been devoted to new medical and surgical procedures.

The primary focus of NIH is research, and there appears to be no systematic or comprehensive policy of NIH support for development. Figures to document the size of NIH's investment in development are not available. Although NIH grants and contracts have been given to support development in a number of areas (e. g., the artificial heart program, cancer screening, cancer chemotherapy, and, in recent years, hemodialysis), the amount invested in development probably constitutes a relatively small portion of the current \$3.8 billion NIH budget.

For developmental costs of procedures used in the prevention or treatment of individual diseases, private foundations have provided important support. A notable example is the generous funding by the Hartford Foundation of Dr. Belding Scribners hemodialysis program in Seattle in the early 1960's. Other examples include grants by the American Cancer Society for cancer screening and treatment programs and by the Jules Stein Foundation for the development of radial keratoplasty (a type of surgery on the eye).

Although there are no explicit data on which to base estimates, the developmental costs of medical innovation are without doubt very large. By and large, 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 came under the aegis of FDA because of the use of the acrylic, methylmethacrylate, in the operating room

construction of the new joint. Despite the artificial hip's clear designation as an experimental device by FDA, the total hip procedure was reimbursed from the outset as an acceptable surgical procedure.

Heart surgery has similarly been reimbursed from the outset through standard medical insurance policies. The single exception was the introduction of heart transplant surgery at Stanford in 1969. Other institutions performing heart transplants have simply charged standard fees. Coronary artery bypass graft (CABG), when introduced in 1969, was considered by its innovators to be standard therapy, despite repeated calls for randomized clinical trials (RCTs) of the new operation (52,358). Clinical charges for CABG were paid via standard policies from the outset and continued to be paid even when, several years later, CABG was finally subjected to RCTs.

Benson Roe, a cardiac surgeon at the University of California School of Medicine in San Francisco, has recently described the historical justification for the "extraordinary" fees in cardiac surgery (316):

Historically, of course, there was justification for extraordinary fees in cardiac surgery. The developmental years of this field were indeed difficult, demanding innovative talent and an enormous amount of time—requirements that many were unable to fulfill. The early cardiac surgeon participated in the diagnostic studies and preoperative preparation, planned and directed the technical details of the cardiopulmonary bypass, conducted the entire longer operation, and personally supervised every detail of postoperative care, often spending late nights at the bedside.

As heart surgery has become, if not routine, at least a great deal more safe and considerably simple, Roe suggests (316):

... one might expect the surgeon's fee to have dropped considerably, but it has not. On the contrary, fees for cardiac surgery have escalated at a rate that far exceeds the inflationary factor.

Much the same pattern Roe has observed in the case of cardiac surgery has been followed for other technologically complex surgical procedures, including intraocular lens implantation and microdissection in brain surgery, as well as orthopedic joint replacements. Not only are the enormous costs of medical and surgical development absorbed by medical insurers (222)—and eventually by the public—but the charges for new procedures, once standard, remain high.

Public Accountability

Regulatory actions and more informed reimbursement decisions are intended to help ensure that new and emerging technologies are efficacious, have acceptable risks, and are appropriately used (e.g., are cost effective). Private industry determines which drugs and

devices it will develop primarily on the basis of market-based criteria. To address perceived deficiencies of the market approach, governmental actions infuse additional criteria based on social and political concerns.

These governmental actions have generally been regulatory in nature, concentrating on the costs to our health, safety, and environment—costs which, because they are diffuse, can best be addressed through collective, governmental actions. Government's role as a purchaser of technologies, of great significance in health care because of Government's role as insurer, has also led to a need to make more informed judgments about the kinds of technologies used in health care. These judgments are needed not only to minimize reimbursing for the use of ineffective technologies, but also to help decide which among the array of technologies are the most appropriate. The regulatory process unquestionably slows diffusion of technologies into the marketplace, and some technologies are filtered out. Slowing the diffusion of new technologies may allow for more informed and timely decisions before widespread use.

Constraining the diffusion of new drugs or devices before they are adequately assessed also affects the conditions under which new technologies are fostered. Meeting regulatory requirements for evidence of efficacy and safety increases industry's costs, for example, by delaying industry's return on capital invested in R&D activities. Factors such as these play a significant role in industry's assessment of whether a new technology could be profitably marketed or in deciding which of several promising technologies to develop further. But the full extent of a new technology's capabilities is usually not known until it is put into use, and use can lead to improvements and, in some cases, further innovations.

The question of the effect on innovation from regulatory and reimbursement policies is not simply one of whether innovation is inhibited, but also whether the alterations in the innovation process are unintended and undesirable. Government support of R&D has long sought to alter the innovation process, most notably to accelerate the pace of innovation and to push it in certain directions. NIH is a prime example of both undirected and directed support for the development of new medical technologies, combining basic research within separate institutes targeted at specific diseases,

As the recent experience of air quality control programs demonstrates, market-modifying factors such as regulation can also alter the direction that innovations take. The kinds of regulations put into effect can force innovation along certain pathways, some of which allow for more maneuvering (e. g., in contrast

to specifying the kinds of pollution control devices to be installed to achieve air quality standards, the “bubble” concept of regulating air pollution sources, where a maximum air pollution level is set, leaves it to pollution sources to stay within those limits by whatever techniques they can muster). Restraints on the marketing end of the innovation pathway confront innovators with new conditions, and the hallmark of innovation is to generate new answers when conditions change. Although there will be industrial losers and winners under these regulatory rules, that does not necessarily mean that innovation has been hindered. It may instead have its direction altered, much as Government attempts to alter innovation at the R&D end for similar social purposes.

There is general agreement that competition among medical care providers is typically not based on price (331); under current reimbursement policies, there are incentives to adopt all available diagnostic tools and to pursue any therapy anticipated to have any value. This is particularly true for hospitals. Third-party coverage currently accounts for about 90 percent of expenditures for hospital care. As the price of technology has little effect on providers and patients under existing health insurance arrangements, a greater adoption of technology can be expected to occur under these arrangements than would occur under more price-competitive reimbursement arrangements.

At a simple level of comparison, recent changes in current regulatory and third-party reimbursement policies can be thought of as approaching some middle ground from opposite ends of the spectrum. Regulation purposefully slows down the innovation process, particularly at the early diffusion stage, and modifications are now being sought (e.g., in premarket approval requirements for drugs) to ensure that this slowing of the innovation process is no more than necessary to achieve the regulatory program’s objectives. Current reimbursement policies, on the other hand, are seen as boosting the diffusion of new medical technologies and modifying existing technologies beyond what would take place under more price competitive systems, and reforms are being aimed at constraining the adoption process.

Because the purpose of regulation is to infuse social criteria into judgments of a new technology’s worth, conclusions based on the economic impact of regulatory requirements must be reached with caution. Regulation is expected to change the innovation process. The issues are whether the specific changes were intended and whether the benefits of regulations are worth the price paid in resulting alterations of the innovation process.

Present reimbursement policies tend to reward the use of technological innovations and discourage less technologically oriented patient care activities (2). Thus, there is a need to infuse more price sensitivity into the reimbursement system. Taken together with the regulatory approach, changes to infuse price sensitivity would theoretically: 1) allow market entry of innovations which have met social criteria of worthiness, and 2) make it possible for those new technologies which have passed the regulatory test to then compete with one another on a price basis. Curtailing excessive demand by a more price-sensitive approach, however, means changing the conditions of the current medical technology innovation process. Again, the question here is whether such major changes in the demand for new medical technologies will affect the innovation process in unintended and undesirable ways.

Regulation

The purpose of regulation is to guide the course of technical change in such a way that, over time, new technologies are responsive not only to the cost and performance characteristics valued by the marketplace, but also to the social values that motivate regulation. Regulatory requirements become added conditions for successful completion of the innovation process.

There are three possible approaches to regulation:

1. **precluding** technologies deemed socially-undesirable by either banning or selectively restricting their use;
2. **deflecting** technologies by forcing their development or diffusion (e.g., through uniform requirements) into technologies with performance characteristics deemed socially desirable; and
3. **using market-like mechanisms** (e.g., pollution fees or marketable pollution rights) to encourage producers to economize on the use of common resources such as air and water (244,283).

Of these regulatory constraints, preclusion and deflection are the methods currently used to regulate biomedical technologies. Prescribing how a product is to be made is preclusive, while specifying the qualities the product must have is deflective. The difference is between standardizing the product (preclusion) and standardizing its performance (deflection).

In addition to these purposeful constraints, regulation requires compliance outlays and introduces a number of other factors which can indirectly constrain the innovation process. Compliance outlays include such direct costs as efficacy and safety testing, legal fees, and employee time spent on regulatory matters.

Greater R&D costs are usually associated with the more technically demanding regulations, such as those applied to drugs. These are resources that could be spent in other areas (e.g., development and marketing) or could enhance profit margins.

Uncertainty discourages risk-taking and prolongs decisionmaking, and regulation can introduce uncertainty over how to comply with the regulatory requirements, which may constitute a “moving target.” For example, additives are not allowed in foods if they are found to cause cancer. But technical advances in detecting smaller and smaller concentrations of one substance in another (in some cases, at the level of 1 in 1 billion), coupled with the regulatory interpretation that any amount detected is illegal, mean that complying with the law depends on the latest advances in detection methods, even if the best method of keeping the banned substance out of the food has lowered concentrations below that detectable by the previous most sensitive method of detection.

Delay is an inevitable result of certain types of regulation, as in those areas requiring premarket approval. Delay also occurs administratively—e.g., when shortages of qualified personnel or turnover in personnel prevent prompt review of applications, or when a regulatory reviewer is unsure of what decisions to make and consults extensively within the agency before reaching a decision. Litigation over an agency’s decisions and judicial review of these decisions impose further delays. These delays can be significant enough to affect the expected economic return on an innovation, which might cause the petitioning company to abandon the product and make investments elsewhere. Delay, may, in effect, extend the life of already approved products, and, if costly, can impede the entry of small businesses into the particular market. Delay can also reduce the effective patent life of a new product, affecting its return on investment.

Regulation can also have other effects on innovation. It can affect the psychology of officials of private firms in conscious ways (e.g., when officials make decisions with an eye toward the likely reactions of the regulating agency) and unconscious ways (e.g., because officials have been accustomed to having to meet regulatory requirements). Furthermore, disclosure of data in support of an application for a new product approval can help another manufacturer compete with the original manufacturer.

REGULATION OF DRUGS AND MEDICAL DEVICES

The responsibility for Federal regulation of drugs and medical devices rests with FDA. FDA’s regulatory modes are: 1) the establishing of standards, 2) the pre-

market notification process, 3) the premarket approval process, and 4) policing.

Policing typically occurs in lawsuits by FDA against violative products or firms. This mode is employed, for example, in the regulation of the labeling of medical devices. Establishing standards is a way of prescribing requirements for products or processes. For example, regulations governing “good laboratory practices” specify the mandatory, or in some cases the recommended, characteristics of the well-designed, properly conducted preclinical study. The premarket notification process gives FDA the opportunity to veto a firm’s plans before they can be implemented. The 1976 Medical Device Amendments require that a firm intending to distribute a device for the first time notify FDA 90 days in advance to permit the agency to determine whether the device requires premarket testing and evaluation.

The premarket approval process is used by FDA to regulate drugs and certain devices. In the case of prescription drugs, a manufacturer must conduct tests for efficacy and safety on the drug, submit the data to FDA and obtain its approval before the drug can be marketed (244). FDA becomes officially involved in the development process for a new drug when its sponsor files a “notice of claimed investigational exemption for a new drug” (IND) for permission to test it in humans. There are three phases in the clinical investigation, and each phase must have been preceded by specified animal tests. (Animal 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 50. 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 are designed to demonstrate effectiveness and relative safety of a new drug and 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. Phase II 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). At least two well-controlled clinical trials, accompanied by complete case records for each pa-

tient, are usually required by FDA for approval of a “new drug application” (NDA).

If these clinical trials are successful, the drug’s sponsor may file an NDA. An NDA is a request for FDA’s permission to market the drug. Chronic animal toxicity studies (1-year dog, 18-month mouse, and 2-year rat studies) must be completed by the time of NDA submission. If the FDA review finds the effectiveness and toxicity data acceptable, the application is approved. Since 1962, FDA has reviewed over 13,500 applications for INDs and has approved about 1,000 NDAs (154).

The Medical Device Amendments of **1976** to the Food, Drug, and Cosmetic Act greatly expanded FDA’s role in regulating medical devices. Prior to the **1976** amendments, FDA had classified devices such as soft contact lenses, pregnancy test kits, intrauterine devices, nylon sutures, and hemostats as “drugs” (359). The U.S. Supreme Court ruled in 1969 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 on medical devices. Class I devices are subject to general controls only; Class II devices must meet performance standards; and Class III devices must have premarket approval.

Class I devices are subject primarily to the Food, Drug, and Cosmetic Act’s basic prohibition against misbranding and adulteration. 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 controls are placed on devices for which general controls alone are judged insufficient, but about which sufficient information exists or could be developed to establish performance standards for the device. Under the 1976 amendments, existing voluntary standards could be used, but legal counsel advised that such actions would violate due process, as the “voluntary” standard might become essentially “mandatory” with the FDA stamp of approval, circumventing the opportunity for public comment and discussion (**247**).

Class III controls are comparable to the premarket approval process for drugs. These controls are applied when general controls or performance standards may not provide reasonable assurance of the safety and efficacy of a device which is life-sustaining, life-supporting, implanted, or presents a potential unreasonable

risk of illness or injury, or when performance standards cannot be developed. Any device which was classified as a “drug” before the amendments is automatically assigned to Class III unless reclassified. Any device developed after the enactment of the amendments which is not judged by FDA to be “substantially equivalent” to a preamendment device in Class I or Class II 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 (260).

The Medical Device Amendments also allow FDA to permit developing and marketing approval of a Class III device under a “product development protocol,” where FDA and the manufacturer agree in advance on a plan for the development, testing, and release of the device. This approach has not been implemented.

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 in its marketing strategy. All results of clinical investigations will ultimately be included in a package insert, product data sheet, or physicians’ brochure, which are FDA-approved generators of promotional claims (300).

MEDICAL AND SURGICAL PROCEDURES

Except insofar as State laws require that medical and surgical procedures be performed by physicians and that hospitals have certain facilities if they are to carry out certain procedures, medical and surgical procedures are essentially unregulated. State licensing statutes that define who can and cannot practice medicine (dentistry, etc.) preclude other technical personnel from performing many such procedures. Laws that restrict the performance of procedures to licensed facilities such as hospitals deflect from these settings innovative organizational arrangements such as home birth delivery and outpatient surgery.

Regulation of the practice of medicine is a State function carried out by State medical licensing boards.

However, State medical licensing boards primarily regulate entry into the practice of medicine and do little to monitor the continued competence of licensed physicians beyond assuring that they meet requirements for continuing medical education. However, a Federal program, the Professional Standards Review Organizations (PSROs), was enacted in 1972 to review medical care delivered to persons eligible for Medicare or Medicaid coverage. (As this program's functions relate more to Federal reimbursement for medical services, it will be described in the section below on reimbursement).

REGULATION OF CAPITAL INVESTMENTS

Three related Federal programs have been enacted in an attempt to regulate capital investment: 1) section 1122 review, 2) State certificate-of-need (CON) laws, and 3) the National Health Planning and Resources Development Act.

Since 1972, section 1122 of the Social Security Act has required the Medicare and Medicaid programs to withhold funding for depreciation, interest, and return on equity capital for certain investments found inconsistent with planning objectives by a health planning agency. The provision 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. Health maintenance organizations (HMOs) are included, but private physicians' offices are explicitly exempted. In 1977, 37 States had contracted with the Department of Health and Human Services* to conduct section 1122 reviews.

The effect of section 1122 review is controversial. Since the statute excludes operating expenses and physicians' services, only a small percentage of a provider's total revenue may be at risk of scrutiny or control. For example, the operating expenses of computed tomography (CT) scanners account for as much as 50 to 75 percent of the technical expenses (279).

State CON laws, in effect, constitute a franchising process for potential adopters of expensive medical technologies. Enacted by 35 States by 1977, these laws require prior approval by the State of investments above a certain threshold (now usually \$150,000 or more). Local health systems agencies have responsibility for areawide planning and initial CON review. Although the laws vary, most apply to hospitals and nursing homes. Like section 1122, most CON laws exempt private physicians. Sanctions include denial of operating licenses, court injunctions, and fines.

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

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 Service Act, the Community Mental Health Centers Act, and the Alcohol Abuse and Alcoholism Act. The 1974 planning act generally applied to the same facilities covered by section 1122 review. However, the 1979 planning act amendments exempted HMOs from having to secure a CON for inpatient investments because of a belief in HMOs' efficiency.

In an early study of CON laws, Salkever and Bice (333,334) reported reduced hospital expenditures on beds, but unchanged overall hospital investment. Faced with greater control over beds, hospitals may have channeled their investments to other technologies. Furthermore, as Ginsburg (162) had found earlier, occupancy was positively associated with bed expansion, although occupancy rates had no apparent effect on total hospital investment.

Cromwell, et al. (75), investigated the effect of CON laws on the adoption of specific technologies. CON appeared to reduce adoption rates for expensive, widely adopted technologies—namely, X-rays and cobalt and radium therapies—but did not affect other technologies examined.

The existence of planning legislation was not correlated with interstate differences in the adoption of the CT scanner (392). In fact, impending legislation may have spurred adoption as providers rushed to place orders before the law applied to CT scanners. Such an effect may have occurred in California, whose 1976 law exempted equipment already ordered (12,19).

Reimbursement Policy

In contrast to regulation, which is often seen as having constraining effects, 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 (142,331). It is important to keep in mind, however, that just as regulation is but one influence on innovation, reimbursement policy is but one contributor to the overall tendency to adopt and use medical technologies at excessive levels. Other 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.

There are two basic forms of payment mechanisms in the U.S. medical care delivery system: cost-based and charge-based (306). Government programs, primarily Medicare and Medicaid, were developed to “buy into” what was then perceived as a market pricing system. When the statutes were enacted in 1965, the legislation 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 assumption was that Government was buying at the margin and would not affect the average costs of the system.

The 1972 amendments to the Social Security Act reflected a growing understanding that purchases of medical services were sufficiently large to affect purchase price and costs. Consequently, limits were placed on the amount which would be paid by Medicare to both institutional providers and physicians. Rather than being related to efficiency, these cost limits reflected rates of increase in charges over time.

PSROs were enacted into law in 1972 and consist of areawide groupings of practicing physicians responsible for reviewing care delivered to persons eligible for Medicare or Medicaid coverage. They help assure that services provided and paid for by Federal beneficiary programs are medically necessary and of a quality that meets locally determined professional standards, and that they are provided at the most economical level consistent with quality of care. PSROs are separate, independent, nonprofit organizations located in a number of designated geographic areas of the country. They are physician-dominated organizations; upward of 50 percent of all practicing physicians in this country nominally belong to the PSRO in their area, although usually only a small fraction of these members participate regularly in PSRO activities.

For a variety of organizational and legislative reasons, PSROs have first concentrated on reviewing inpatient care provided in short-stay hospitals. One of their hospital-review activities is traditional utilization review intended to reduce unnecessary hospitalization. A second review activity is profile analysis, by which PSROs retrospectively review patient care data (aggregated by, for instance, provider or physician characteristics) to highlight patterns of care. Such analyses allow PSROs to identify problems in the use of services and to set objectives for changing the use of services. A third major type of hospital review activity is the “medical care evaluation” study which focuses more on quality of care than on cost containment.

Some PSROs, especially those with long experience in hospital utilization review, have moved beyond these activities to take on utilization or quality of care

review in other facilities or medical settings. The major topics of such studies are ancillary services (virtually all services except for room and board, and nursing, dietary, or physician services in the hospital), long-term care review, and ambulatory care review. All three types of studies have been done in demonstration projects during the late 1970's and have been carried on since then by some PSROs, often as “special initiative” studies. At one time or another, as many as one-quarter to one-third of all PSROs had engaged in ancillary services or long-term care review; ambulatory care is, so far, a less well-developed field.

Several PSROs (or separately incorporated analogs) do utilization review for private firms on a contract basis. Perhaps as many as one-quarter of PSROs were engaged in such review as of 1980, and they covered patients whose care was financed by private insurance companies, self-insured corporations, the Civilian Health and Medical Program of the Uniformed Services, labor unions, and municipal governments.

In addition, several PSROs over the past few years have engaged in cooperative research projects, including projects related or analogous to technology assessment. One example of such a project is an ongoing RCT to evaluate different educational interventions intended to reduce the use of an outmoded obstetric practice (X-ray pelvimetry) in hospitals during deliveries. Other PSROs have collaborated in studies of variations of hospital use for several conditions such as myocardial infarction (heart attack) or gall bladder surgery.

Although the PSRO program pursues many objectives and tasks, the most visible have been those related to utilization and costs of hospital care. The 8 years of the program have not produced the desired reductions in hospital stays or, especially, in the costs of Federal health programs such as Medicare. Improvements in quality of care, although less well documented than the effects on costs, suggest that PSRO activities have ranged broadly across diagnoses and services. Currently, the Reagan administration is deemphasizing PSROs by defunding those thought to be ineffective and by consolidating areas.

There are two widely used mechanisms to set reimbursement levels in the “private” sector of the medical care market. One mechanism is the cost-based Blue Cross/Blue Shield reimbursement system. In many ways, this system is 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. This approach is used by some Blue Cross/Blue Shield plans and in all contracts established between patients and other insurers. Under this ap-

preach, 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. There are also patients not covered by Government or other insurers who 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 yet 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 services, thus placing the provider of care at financial risk.

INFLUENCE OF REIMBURSEMENT ON THE DEVELOPMENT, ADOPTION, AND DIFFUSION OF MEDICAL TECHNOLOGY

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

Several examples have been provided by Blue Shield of California (40). 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 attempted to charge 25 to 30 percent more for the new procedure than they charged for the older one. The Blue Shield Medical Policy Committee disallowed the increase. Another example is the flexible fiberoptic endoscope. This new instrument is easier to use than the standard rigid instrument, yet physicians introducing the new procedure attempted to charge 25 percent more. Similarly, orthopedic surgeons who introduced arthroscopic meniscectomy for torn knee cartilage wished to charge the full fee for the standard open arthrotomy and an additional fee for 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 carrying out 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 results in questionable increases in physicians' fees. In the example just cited, the large difference in allowable charges when an operative pro-

cedure 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 import. 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 \$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 also is 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 with 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 the new one. This 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. Whatever the motives, the net result 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). It is estimated by the medical director that 1 percent of the errors involve the use of existing codes for procedures to which new codes have not been assigned.

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 which deviate the least from existing procedures which are already being reimbursed. 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 coverage 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 much 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 they penetrate the market, the magnitude of their commercial success is greater than for minor innovations. Fourth, as discussed above, a technology-by-technology approach to coverage decisions, with priorities determined by how radically each technology differs from existing ones, may lead 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 cost 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, interstate analysis (75) found that the percentage of revenues from third parties significantly and positively related to a hospital's adoption of expensive technology. Russell (331) found that 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 to 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 also 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 affected the source 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. Non-profit hospitals in the Boston area were using automated analyzers, patient monitors, and, in teaching hospitals, diagnostic X-rays, at only about 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 have 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.

Discussion and Conclusions

No one factor seems to distinguish successful from unsuccessful innovations (252). The key events identified in studies of successful innovations depend on the choices of innovations for study. Failure to find a cause-and-effect relationship between one variable and success in innovations is not surprising, however, given the multiple factors in the innovation process.

It is therefore also not surprising to find that the impacts of regulatory and medical care reimbursement policies on the innovation process are difficult to separate from the impacts of other factors. In the regulation of drugs, for example, the evidence points toward regulation as contributing to, but not as being the sole or primary determinant of, higher R&D costs, greater concentration of new drug development in fewer and larger firms, and an orientation toward the epidemiologically and commercially more important diseases.

The impacts of regulatory policies are not well understood. The availability of data on R&D costs, number and size of firms producing new products, the number of new products, etc., almost compel researchers to focus on these parameters in their evaluative work. Quantitative rather than qualitative analyses are what most people expect in order to translate complex relationships into simple terms such as “bottom line” numerical estimates of how regulation affects the innovation process. The result is a focus on easily identifiable costs and a neglect of difficult-to-quantify benefits, and most of the controversy centers on whether these identified costs are due to regulation or other factors such as, for example, existing trends in the drug industry at the time of the 1962 drug amendments.

On the other hand, the studies that focus on costs might be thought of as providing presumptive evidence of the costs of regulation, thereby shifting the burden of proof to regulation’s advocates to counteract the evidence with findings on the benefits of regulations. The problem with this approach is not only that health impacts cannot be measured adequately, but that even if they could be, there are no unambiguous methods to compare the costs and benefits (270).

Regulation is meant to alter the market forces controlling the innovation process, so it should come as no surprise that observable economic measures are altered. The fundamental question underlying the debate over the absolute or net costs (where benefits are considered) is whether the achievement of the social purposes of regulation is worth the costs. With respect

to drugs, even when evaluation of the impact of regulation focuses on absolute costs, most critics of the current regulatory process call for marginal alterations, not radical changes. Such changes include more flexibility in efficacy and safety testing, speeding up of the premarket approval process, and the use of postmarketing surveillance systems.

For regulation of medical devices, there seems to be no major opposition to the law per se, only a wait-and-see attitude and differences of opinion as to how FDA is implementing certain provisions of the Medical Device Amendments of 1976. For example, FDA has proposed six broad categories of devices which would be subject to premarket testing: 1) invasive devices intended to pierce the skin or mucous membranes; 2) implantable or prosthetic devices; 3) energy-introducing devices; 4) medicinal gas devices; 5) devices, other than in vitro diagnostic products, that are intended for use in diagnosing of disease or monitoring physiological functions; and 6) in vitro diagnostic products intended to provide information which will be used, interpreted, or analyzed by a health professional.

Industry associations, such as the Health Industry Manufacturers Association, urge continued case-by-case determinations and are opposed to these broad categories, because they believe that there is no demonstrated need for the rule and point out that FDA has not conducted cost-impact studies (176).

Much as an IND does, “investigational device exemption” (IDE) regulations describe the requirements for clinical investigation and the responsibilities of the manufacturer, clinical investigator, and the institutional review board. None of this documentation was previously required, and industry has protested that the mandated process would simply give rise to additional costs and delays as well as automatically trigger an FDA inspection of facilities, if one had not been previously done, when an IDE was submitted. Therefore, FDA has been requiring IDEs only for devices which require premarket approval (Class III devices) (359).

A proposed “mandatory experience reporting” rule would require manufacturers, distributors, and importers to report to FDA any device which may have caused injury or death, has a deficiency that could result in death or injury or give inaccurate diagnostic information, or is the subject of remedial action. The proposed rule would require those covered to report device-related deaths within 72 hours after receiving a complaint, injuries within 7 working days, and remedial action or communication with distributors, health care practitioners, or users within 2 working days (8). In response to FDA estimates of \$20 per report, the Health Industry Manufacturers Association

estimates that the entire industry would incur a total annual cost in excess of \$400 million (177).

The wide availability of medical insurance contributes to overadoption of many new technologies, but other factors in the medical care delivery system have significant influences. Some of these other factors can add incentives to overutilize new technologies, but additional factors seem to be keeping the rate of adoption of new technologies below the level expected if costs were the only or primary criterion influencing adoption. Thus, just as regulation has contributed to existing trends in the drug industry, current reimbursement policies also have contributed to overadoption of new technologies but cannot be credited as the determining factor.

In addition to its contribution toward excessive demand for new technologies, current reimbursement policy has another significant effect on the innovation process. Radical innovations, which by their very definition often fall outside generally accepted medical practice, tend not to be reimbursed and thus may be less likely to be developed. The current system discourages the identification of new procedures as such.

This appendix has described the effects of regulation and reimbursement policies on the innovation process as separate issues, but they clearly are interrelated. As new medical procedures develop, they often make use of new drugs and devices or use existing ones in modified ways. In either case, the drugs and devices generally have to pass through the regulatory process. Until they are approved, regulatory review acts as a constraint on the adoption and dissemination of the procedures in which they are used.

Regulatory review is generally limited to the technical questions of safety and efficacy, without consideration of the costs or relative values of the proposed drug or device once it reaches the market. In some cases, however, it goes beyond these questions. For example, in reviewing the injectable contraceptive Depo Provera, FDA used marketing as well as safety and efficacy criteria to deny approval. In that case, FDA denied approval not only because of 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

had become increasingly available and accepted (193). Nevertheless, the more usual circumstance is such as that found in the approval of the catheter used in percutaneous transluminal angioplasty (PTCA). In that instance, FDA released the catheter from investigational device status and approved its marketing for PTCA while the procedure itself was still considered by many to be experimental. Thus, while regulation of the accessories (i.e., drugs and devices) acts as a constraint on the adoption of the medical and surgical procedures in which they are used, once these accessories are released into the marketplace, they can act to stimulate use of procedures which are still experimental and not accepted medical practice.

Does this observation point to a strategy for medical technology assessment in which the criteria are similar for both regulatory and reimbursement purposes? From the review of the regulatory process, it appears that the system for regulation of drugs and devices meets certain social goals. Although economic considerations are important, these considerations point toward specifying how the present regulatory process can be improved, but not toward the infusion of economic measures into the regulatory criteria themselves.

The infusion of economic measures into the regulatory criteria themselves may be arbitrary and counterproductive. Users of innovations are important contributors both in determining the full extent of an innovation and in developing new innovations as spin-offs, the exact results of which can never be determined beforehand.

The current regulatory process for medical technologies may need marginal changes, but the consensus seems to be that its social usefulness is worth the costs which it places on an innovation process dominated by a market approach. This conclusion is compatible with the common sense notion that society should focus on the use of the tools and not on the tools themselves to keep the constraints on the innovation process at a minimum while also addressing the issues of cost, quality, and appropriateness of medical care.

Current reimbursement policies both stimulate and constrain the development of new medical technologies. Possible modifications of these policies might well be examined for their potential.