INFLUENCES ON INNOVATION:
EXTRAPOLATIONS TO BIOMEDICAL TECHNOLOGY

by

Edward B. Roberts

Working Paper #1193-81 March 1981

To be published in Roberts E.B., Levy R.I., Finkelstein S.N., Moskowitz J.A., Sondik E.J. (editors). Biomedical Innovation (Cambridge: MIT Press, forthcoming 1981).

INFLUENCES ON INNOVATION: EXTRAPOLATIONS TO BIOMEDICAL TECHNOLOGY

Edward B. Roberts

PERSPECTIVES ON INNOVATION

The process of innovation takes into account all steps leading to the generation and initial utilization of a new or improved invention. In the biomedical area an "invention" might relate to a product, a manufacutring process, or a clinical practice. Innovation requires invention plus exploitation, which comprises such activities as the evaluation of the technology; the focusing of technological development efforts toward particular objectives; the transfer of research results; and the eventual broad-based utilization, dissemination, and diffusion of research outcomes. All of these activities are potential areas of managerial or policy concern for enhancing the rate of outcomes derived from technological innovation. This chapter summarizes the existing empirical literature on the factors influencing successful innovation and extrapolates where possible to the biomedical field.

Innovations can be classified into the following overlapping set of typologies:

Products vs. processes vs. practices

Radical developments vs. incremental changes

New items vs. modifications of existing items

Industrial goods vs. consumer goods

Services

The typologies are a potentially useful approach for analyzing the influences on innovation. But unfortunately, most empirical work on innovation is outside the biomedical arena, on technologies that have been developed in other fields. Historical investigator bias has led to little research being carried out on the processes that affect the development of biomedical tech-

nologies. The Comroe-Dripps (1977) study in the area of cardiology and pulmonary advances is a welcome exception to this pattern, embodying major and substantive empirical work on biomedical development processes. (The TRACES study (IITRI, 1968) contains some relevant cases as well, but consists of a biased self-serving sample, thereby lacking objective outcomes.) Consequently , to focus on successful biomedical innovation demands the combination of empiricism largely from nonbiomedical fields with speculation on the transferability of ideas across to the biomedical area. Unfortunately, this lack of systematic empirical understanding restricts the basis on which either biomedical research programs or policy formation relating to biomedical research and technology can be advanced.

For example, different factors must affect product innovation--such as in clinical devices or drug entities--than innovation in clinical practice--for example, surgical technique or diagnostic approach or therapeutic regimen. Yet the latter area has not received even cursory attention from empirical researchers. Studies of technological developments in nonbiomedical areas indicate that incremental changes rather than radical innovations dominate. Nevertheless, other than the Comroe-Dripps study, the few innovation studies in the biomedical area have generally taken anecdotal evidence from radical developments and have attempted to draw broad-based policy conclusions about the handling of technology development overall(IITRI, 1968; Battelle, 1973). Such a practice contributes to an erroneous impression that productive biomedical innovation needs to be the same as making a major breakthrough or winning a Nobel prize.

Studies of technological developments in nonbiomedical areas indicate that incremental rather than radical innovations dominate research and developmental outcomes. Research has also been carried out on technological

efforts resulting in new items or new practices versus modifications and improvements of old practices. Again, modification and upgrading activities seem to dominate most fields of endeavor in contrast with the creation of new entities. Differences in innovation patterns also have been found between industrial and consumer goods. Medical devices and prescription drugs fall into the general category of being called "industrial goods"--products that are turned over to professionals for further use rather than being sold over-the-counter directly to the consumer. Finally, few meaningful empirical studies of innovation activities have been conducted in the area of service delivery, generally, and none specifically of medical services. Thus, an attempt to understand what influences the development of technology-based innovation, with empirical evidence as the basis, suffers great weaknesses from lack of data, especially in regard to biomedical technology.

MAJOR INFLUENCES ON INNOVATION

The identifiable influences on innovation can be clustered into four groupings: (1) staffing--the kinds of people involved and the nature of the contribution each kind makes to technological development; (2) structure--issues affecting developmental linkages and development effectiveness; (3) strategic--questions on organizational roles, priorities, resources that affect innovation; and (4) supporting systems--planning, control, and information analysis techniques helpful to organizations trying to develop technology effectively. This chapter presents tentative conclusions about the first three groupings, drawn largely from empirical studies performed outside the biomedical field, and poses questions as to whether these conclusions can be extrapolated appropriately to technological development in the biomedical area. Supporting systems for innovation are not discussed in this chapter as the objective research on this topic is essentially nonexistent. Unanswered questions should become part of an explicit agenda for further research on the biomedical innovation process.

Staffing

A variety of studies in other fields suggest that five types of key staff people have critical roles in achieving successful innovation (Roberts and Fusfeld, 1980). First are the idea generators, the creative contributors often referred to by those involved in innovating and by the literature (Pelz and Andrews, 1966; Andrews, 1981). Empirical research points out the significant differences between "idea-havers" and "idea-exploiters"--those who come up with ideas and those who do something with the ideas they have generated. These differences are now documented in studies of university laboratories and academic departments as well as in industry, and suggest the second key role in innovation that is played by entrepreneurs, called "product champions" in some empirical studies. These people advocate and push for change and innovation; they take ideas and attempt to get them adopted in organizations (Roberts, 1968). The biomedical area has a significant number of entrepreneurs, although the term "entrepreneur" tends to be repugnant in academic medical circles and is usually a perjorative label. In industry, however, it is not perjorative; indeed, in the perspective of economic history, Schumpeter (1934) has defined the entrepreneur as "the engine of economic growth and development". The third necessary contributor to development is the program manager, sometimes regarded as the "business innovator", the person who handles the supportive functions of planning, scheduling, business, and finance relating to the development activities of technical colleagues (Marquis and Rubin, 1966). Gatekeepers, or special communicators, play the fourth role by being the links who bring information messages from outside sources to the inside world of developmental activities. These human bridges join technical, market, and manufacturing sources of information to the potential users of the information (Allen, 1977; Rhoades et al., 1978). In the medical area, Coleman, Katz, and Menzel (1966) identified gate-

keepers as critical to the diffusion of new drug entities throughout the medical community. And finally, empirical studies of technological development identify the role of the sponsor, or coach, the more senior person who is neither carrying out the research itself nor is directly championing the change, but who is providing junior people with the encouragement, support, facilitation, and help in "bootlegging" the resources necessary to move technological advances forward in an organization (Roberts, 1968, p. 252).

Idea Generators vs. Entrepreneurs. Research data are presented here to illustrate influences of entrepreneurs on development, the references cited previously illustrating the extensive empirical research on other key staffing roles. One study of two major MIT laboratories indicates the distinction between having ideas and exploiting ideas (Peters and Roberts, 1969). Table 1 shows that 49% of the laboratory scientists and engineers claimed to have ideas that lay outside the major area of interest of the laboratory and which had commercial implications. However, only 33% of those who claimed such ideas attempted to do anything whatsoever with their ideas, even given the widest range of choices for claiming action. Fully two-thirds of these academically employed scientists and engineers wholly ignored what they claimed to be a significant development.

The same kinds of behavior were assessed in three major MIT academic departments (Roberts and Peters, 1981) (Table 2). Of 66 faculty members statistically distributed to include all major ranks, 47% claimed ideas that they felt had commercial merit but had done nothing whatsoever about those ideas; they had not even tried to publish them. Furthermore, only 38% of the 66 had undertaken strong efforts to move their ideas forward to the point of use. A study underway is trying to replicate this research among several

samples of academic clinicians to better explain the patterns of idea generation and idea exploitation in that community (Finkelstein et al., 1981).

The faculty person who tries to move an idea forward is different behaviorally and sociologically from colleagues who have ideas but do essentially nothing with those ideas. Certain factors of family background, personal persistence, and a drive for tangible outcomes characterize entrepreneurs whose actions may account for the innovations achieved (Roberts and Wainer, 1971). U.S. research is bolstered by U.K. findings that successful, innovative firms have someone who plays the role of "product champion", whereas firms that fail do not (Rothwell et al., 1974). Those among the MIT faculty who undertook exploitative behaviors had characteristics that have been well-documented in previous studies of entrepreneurs: being first-born children, in this case, sons; writing a book; obtaining a patent; understanding the financial community; and being aware of sources of financial support. Most faculty members did not have these entrepreneurial characteristics.

STRUCTURE

Three structural issues in organizations influence innovation: (1) relationships to sources that motivate the initiation of innovative activity, (2) relationships to sources of effective technical solutions, and (3) relationships to channels for successful exploitation. The answers to questions posed here frequently lie in the structural relationships between an organization that is developing a technology and other linked or supporting organizations with which it is working.

Sources Motivating Innovative Activities

Multiple sources are identified as motivating the initiation of successful technological development efforts. The literature reveals extensive controversy among empiricists who divide themselves between the "technology-push" theory and the "market-demand" or "need pull" theory of innovation (Mowery and Rosenberg, 1979). The former believe that pushing technology where technological opportunism seems to exist will eventually result in significant technological development. The latter believe that factors of mission, need, or demand dominate in motivating those activities which eventually produce most successful technological developments. The Comroe-Dripps study (1977) was in part initiated in order to provide evidence for the technology-push theory in explaining the development of biomedical technology. Comroe-Dripps' results did supply some reasonable basis for questioning whether studies in other fields apply to biomedical technology. Other theories of motivation also merit research, however. For example, I believe that potential users of an innovation have great but largely undocumented importance in contributing to biomedical innovation. Finally, of course, the regulatory role needs to be taken into account. Some suggest that regulation stimulates innovation, but those who have had much to do with biomedical technology would find the concept of regulatory stimulus a difficult argument to accept.

Market-Pull vs. Technology-Push. Table 3 lists data from eight studies carried out in the United States and in Great Britain, with different sampling approaches from different industries, during different time periods (Utterback, 1974, p. 622). All draw essentially the same conclusion about the sources that lead to initiation of successful innovation projects: that 60-80% of successful innovations seem to have been initiated by activities responsive to market-pull,

that is, need-oriented forces. Similarly, recent research on West German innovations found that 70% of the successes originated from demand-pull factors, whereas 80% of the failures began with technology-push (Gerstenfeld, 1976).

In further clarifying the role of need-pull, several investigations have described the nature of the user-producer relationship. The British Project Sappho found that companies which generated successful innovations needed less adaptation by users, needed fewer modifications resulting from user experience after sales, had better understanding of user requirements, and recognized user problems earlier than did unsuccessful innovators (Rothwell et al., 1974, p. 265). Several studies focused on the role of explicit customer requests as an initiator of innovations by manufacturers (Table 4). The results show a high degree of variation by industry in the importance of this relationship (von Hippel, 1978, p.6).

Comroe and Dripps argued rather that one could not draw any clean and neat conclusion from the industrial studies that favored the market-pull theory and that other sources of initiation, like technology-push, were also important. But the industrial innovation literature clearly supports the contention that the perception of need that generates response seems to be the principal motivating factor behind successful innovation. More biomedically relevant studies are needed to clarify the possible conflict here.

Government Role. What of the government role as a stimulus to biomedical innovation? Evidence suggests that government regulation sometimes stimulates successful technological innovation, but primarily in areas of environmental and safety regulations (Allen et al., 1978; Gerstenfeld, 1977). When the government pronounces, "You cannot, unless it meets the following specifications," innovation often suddenly takes place to assure meeting those specifications. But in the area of biomedical innovation, the government role is not the setting of performance standards but rather one of regulatory inter-

ference. In drug innovation, where most data exist, the regulatory process adds enormous costs and time delays to the development of new technologies. Increasingly, the evidence indicates that abusive regulatory behavior, particularly in the United States, even denies efficacious entities to clinical practice. Wardell (1978) traced the drugs introduced in the United States and Britain during 1972-1976, documenting the negative consequences of U.S. regulations but also suggesting that some of the regulatory excesses of the United States are now weakening, bringing the U.S. closer to Great Britain in a number of areas of market-available drugs. Although regulation may help in separating good from bad outcomes, the negative influences on developmental quantity, cost, and time make it an inhibitor of biomedical innovation.

Sources of Solutions

Once a program is initiated to solve a need, what are the sources of technical solutions? The answers come from various sources. Inside and outside the organization are distinctly different sources of ideas; much research on industrial innovation demonstrates that key technical answers to major problems come from outside of the organization where the work is underway. These studies also show that personal experiences and contacts are key sources of information whereas the scientific literature yields relatively little productivity, despite the good intentions of the publications and of computer-based information retrieval services such as the National Library of Medicine to provide potentially for better utilization of organized research information. The contrast between original solutions, that is, self-invented answers, and solutions adopted or adapted from existing technology are important to consider, especially in the later stages of an innovation

cycle. Finally, in the area of biomedical technology, research has begun to demonstrate as dominant to innovation the contributions of the user, in contrast with the producer.

Inside vs. Outside Ideas. The development of a successful innovation usually requires multiple ideas for solutions to the multiple technical problems that arise during a project. Several studies point out that for innovations eventually developed within a firm, the sources of initial technical ideas divide between inside and outside origins on about a 2:3 basis (Table 5) (Utterback, 1974, p. 621).

Myers and Marquis (1969, p. 90) studied the sources of information for 567 innovations in five industrial fields with 120 firms. Table 6 lists the sources of technical solutions for the problems dealt with in these successful commercial innovations. Personal contacts generated a total of 25% of the solutions, and personal training and experience produced an additional 48%, clearly the dominant sources of technical insights. The Langrish data (1972, p. 79) (Table 7) also demonstrate that personal contacts, training, and experience dominate the routes for transferring outside ideas into a firm, in contrast with the minor role of the literature and other formal sources.

Does this dominance of personal information transfer also hold true for biomedical innovation? Or does the formal literature convey key scientific and technical inputs to innovative projects?

Original vs. Adopted Innovations. A stereotype of the source of innovative ideas is the inventor transforming technical and market information into a creative outcome. An alternative perspective is that some ideas for technological solutions already exist and the innovating organization merely needs to adopt or adapt them by slight modification for a new purpose. Few studies

illuminate this distinction, but the Myers-Marquis data (1969, p. 20) showed 22% of the key innovations to have been adopted or adapted, and the Langrish U.K. data (1972, p. 79) indicate that 33% of the Queen's Awards were based on adopted innovations. In examining 567 innovations, Myers and Marquis (1969, p. 20) found that only 18% of new products in their sample were adopted whereas 32% of the successful product modifications were adoptions. Reanalyzing a portion of the Myers-Marquis data (77 companies, generating several hundred innovations), Utterback and Abernathy (1975) divided the development of a technology into three stages. Stage I was the initial stage of a new field of technology, Stage II its later development, and Stage III the maturation of a technological area. The researchers found adoption to be present in all stages of development of a new technology, but especially important and concentrated in the late mature stage (Table 8). One small study (Gerstenfeld and Wortzel, 1977) showed adoption to be far more significant in Taiwan, accounting for the bulk of the successes, even to the point of many purchased turnkey technologies.

These data, however meager, do suggest the importance of adopted and adapted innovation in industrial innovation. But how important is this phenomenon in the biomedical area? In the medical field, adoption in innovation for clinical practices may have greater potential than for drugs or devices, but no studies exist to support this speculation.

User vs. Manufacturer Roles. Increasingly, a special case of adoption exists when a user creates and implements an innovation for his or her own purposes, followed by a manufacturer's later adoption of the innovation for large-scale production and distribution. Many but not all of the studies listed in Table 9 demonstrate the significant contributions of the user (von Hippel, 1978, p. 2). As shown, the first two studies, both in the plastics industry, reveal no contributions of users, but in other areas--petroleum and chemical equipment,

computers, specialized machinery, aluminum, scientific instruments, and semiconductor and electronic manufacturing processes--a heavy percentage of innovations were created by the users of the products or processes rather than by manufacturers. In each case, a user came up with the successful solution, implemented it first in his or her own organization for personal use, and made copies available to others on request. Later, a manufacturer discovered the successful development and use, fully adopted the solution, made engineering modifications as needed, and then produced the innovation in large volume, distributing it to industrial customers or to the public at large.

In a recent study, von Hippel and Finkelstein (1979, p.31) sought the sources of innovation for test methods embodied in medical laboratory clinical analyzers. The study focused on how the design of a physical piece of equipment encourages or discourages scientific manipulation and experimentation, and eventually further contributes to the process of innovation. The test methods and origins of the DuPont clinical analyzer and the Technicon machine were studied (Table 10). For the Technicon SMAC, of the 20 most significant test methods used, 14 were successfully developed and initially implemented by users of the equipment. Another method was developed by a reagent manufacturer, a firm supplying chemicals for use with the Technicon equipment. Only 4 of the 20 test method innovations in the Technicon SMAC were generated by Technicon itself. One more method is in question because there were multiple sources of contribution. In contrast, all of the 18 test methods that constitute the principal utilization of the DuPont clinical analyzer were developed by DuPont itself--no contributions by the users. No other evidence is available to establish whether users

or manufacturers are the dominant sources of innovation of biomedical tools and devices. I perceive the role of the manufacturer of biomedical devices as primarily one of adoption and broad-based distribution, not of initial generation of the ideas nor of initial successful solution of the problems involved in those ideas.

Channels For Exploitation

Other structural considerations for research are the linkages for transferring the results of a successful technical development out of the innovating organization to the outside where they can begin to have impact on others. This stage precedes significant external diffusion. The first movement toward use and implementation generally takes place on a pilot or trial basis, especially in medicine, before evidence accumulates that might induce widespread diffusion and dissemination.

Effective linkages are needed between research laboratories and product-line departments in such organizations as pharmaceutical companies. Effective linkages are needed between universities and industry if the university is to be a significant source of original technological development in the biomedical field. Yet no empirical research meaningfully indicates which patterns of transfer presently dominate or which channels might be more effective than others. Apparently, with few exceptions (Chemical Week, 1979), effective linkages do not exist between universities and medical schools and between universities and the industries that eventually must transfer the product results of biomedical technological development. The appropriate structuring of such linkages is a controversial issue, now being tackled in increasing numbers of sites. Theoretically, many different kinds of bridges--procedural, human, and organizational--can be used for technology transfer,

but existing evidence of what occurs is not broad-based (Roberts, 1979) and not without conflict. For example, recent studies by Young (1981) have questioned the effectiveness of clinical trials as a mechanism for transferring research results into broad-based clinical practice. But Levy and Sondik (1981) have evidenced support of the utility of clinical trials as a transfer mechanism. Mechanisms for improving the utilization of research results need major empirical investigation (Roberts and Frohman, 1978), especially with respect to biomedical innovation.

STRATEGY

In the third cluster of influences on the development of technology are strategy issues: How does the stage of technology affect the pace and the nature of technological innovation? Who does the technological innovation? Is successful innovation done more by large companies, by small companies, by individual inventors? Is it done more in universities, in industry, or in government laboratories? Is it done more by outsiders to a given industry? (Schon, 1973) How much technological change is embodied in significant innovations? How costly is the process of technological development? What is the role of patents and trade secrets in these areas? Answers to these questions in the area of biomedical innovation should provide important foundations for corporate and government strategic policy development. All attempts to formulate policy, to regulate, or to influence emerging or existing technologies are based at least implicitly on the answers to these and other strategy questions; yet, again, little empirical research exists in any of these areas.

Technology Stage and Innovation

The changing stages along the life-cycle of a technology suggest different strategies in terms of the nature, direction and frequency of product and process innovation. As shown in Table 11, the Utterback-Abernathy analysis (1975, p. 649) of Myers-Marquis data reveals considerable differences in patterns of success in three stages. The earliest phase of a new technology is dominated by product innovation, with little change in manufacturing process. A rapid decline occurs in the degree of product emphasis in innovative activity as the technology progresses, with dramatic growth occurring in process orientation. Do similar changes occur in pharmaceutical or biomedical device technology?

Identity of Innovator

An often cited but controversial finding is that individual inventors and small firms are principal contributors to product and even process innovation, particularly of radical innovation and especially in the early stages. Data from large-scale industries (Table 12) do indicate rather surprisingly that small companies and individual inventors tend to dominate in the generation of key innovations (Enos, 1962; Hamberg, 1963, 1966; Jewkes et al., 1958; Peck, 1962). Comparable data are not available on medical innovation.

The data become more interesting when examined in regard to the size of the innovative sources as a function of the stage of technological development (Utterback and Abernathy, 1975, pp. 654 and 656). Most companies listed in Table 13 as "unclassified" are in fact privately-owned small companies who would not release their sales data, but are for the most part under $10 million in sales. Combining these "unclassifieds" with those certified as "small" (<$10 million) demonstrates clearly that small companies are the principal contributors to major product and process change in Stage I

of a new technology. By the time a technology gets to Stages II and especially III, the mature stage of a technology, the role of small companies no longer is dominant though still important. Instead, large companies (over $100 million in sales) tend to dominate. Precisely the same pattern appears to be taking place in biogenetic technology; small companies are rapidly becoming the dominant contributors to innovation in this new field. Again, systematic studies are needed on the role of the small firm and the individual inventor in bringing new technologies to fruition in the biomedical area.

And what of the role of the university in this process? In most industrial fields, the nonprofit sector contributes infrequently to innovation, though occasionally with fundamental importance. Yet universities, medical schools, and hospitals appear to be potentially of critical importance in biomedical innovation. For example, the von Hippel and Finkelstein study (1979, p. 32) found that nonprofit organizations were the sources of 18 out of 20 manual clinical test methods adapted to and automated on the Technicon SMAC. The potential consequences for corporate and governmental policy of an important university role in biomedical innovation require careful study.

Embodied Technological Change

The degree of technological change embodied in a successful innovation is also an important question for speculation. The Utterback-Abernathy (1975, p. 651) analysis of the data on 77 companies indicates that 45% of the successful innovations embodied major invention during Stage I. But in Stage III, when a technology has been well-established and well-accepted, only 19% of those innovative successes embodied invention to a meaningful extent (Table 14). Most of the successes in late stages of a technology involve merely incremental technological change.

The Hollander data (1965) on DuPont productivity improvements in rayon plants support the assertion that minimal technological change is embodied in innovations in the mature stage of an industry. Minor technical changes accounted for an average of 78% of the net cost reduction in five plants (Table 15).

This pattern of declining technological change as a function of the stage of a technology is repeated in costs of innovation. The Utterback-Abernathy analysis (1975, p. 653) shows that the costs of Stage I innovations are more or less evenly distributed across cost categories from under $25,000 to more than $1,000,000. On the average, however, Stage I innovations cost more than the incremental changes with high adoption rates that typify Stage III.

Role of Patents

The data on the role of patents in innovation raise further questions about the issues of biomedical technology but also suggest possible differences between biomedical innovation and innovation in other areas. Large numbers of studies of the role of patents demonstrate, almost without exception, that patents have little influence on the successful development or commercialization of technologies (Roberts, 1981). Anecdotal evidence to the contrary about the importance of patents in the great successes of Polaroid and Xerox, the general course of results is that patents are not significant for other firms and industries. The data in Table 16 demonstrate that the one area significantly different from all others is the pharmaceutical industry in that patent royalties for drugs make a three or four times larger relative contribution to profits than royalties in other industries (von Hippel, 1979). Furthermore, the pharmaceutical industry distinguishes itself from other industries by being concerned about patent availability in motivating the direction, character, and budget of research and development (Taylor and Silberston, 1973).

SUMMARY AND QUESTIONS

This chapter has presented a number of major contentions, drawn primarily from data outside of the biomedical arena, about the principal influences of technology development.

1. Five key staffing roles are vital influences in the development of successful technological innovations. The strongest evidence exists on the need for idea exploiters or entrepreneurs (as distinct from merely idea generators). An important need exists for facilitators of communication (the information gatekeepers), and a similarly important need for senior management helpers (sponsors or coaches).
2. Structure exercises important influences on innovation. Ties to the market-motivating forces have been found to be primary in effecting eventual successful technological development. Linkages to outside information sources for initial ideas, for technical solution ideas, and for whole-solution adoption of ideas, are freqeuntly key to the technological development process, with personal contacts and experience as the major mechanisms by which these linkages are effected successfully. Adopted innovation in general, as well as the special role of the innovative user as a source of eventually-adopted innovation, need more attention. Little evidence exists on the differential effectiveness of various channels of research results transfer, even though this may be the most critical stage of technological development. Government regulation is seen as largely inhibitive to innovation in the biomedical area.

3. Different forms of innovation dominate at different stages of a technology cycle; individual inventors and small firms seem critical early in development. Patents, seen as insignificant elsewhere, are important to the pharmaceutical industry, but this does not necessarily mean that patents are important to the medical device industry, given the many distinctions among innovation in the areas of drugs, devices, and clinical practices.

The findings cited here rest largely on empirical studies done primarily outside of medicine; therefore, some key differences between biomedical research and technology and other fields deserve mention.

1. The uncertainties involved in natural science research and development are far greater than in the physical sciences, including problems of biological variability as well as efficacy determination. These problems are far more significant to biomedicine than to other areas of research and technology.
2. The federal government is an exceptionally high sponsor of biomedical technology research but, unlike defense research, is not the direct customer for the implementation of R&D results. This difference in research utilization has critical consequences for successful development and use of biomedical technology.
3. Relative to any other scientific or technical field, biomedical technology has the highest degree of academic involvement in and domination of research.
4. The highest extent of government regulation of product acceptability and of product diffusion is encountered in the biomedical area.

5. Strong emotional market factors affect involvement with innovation in and utilization of products, processes, and practices that influence health and life. This can never be forgotten when trying to understand what affects successful biomedical technology development.

A major research program is needed on the influences involved in all stages of development and dissemination of biomedical innovation. This program should be supported by the federal government and by foundations. This program should be initiated promptly, to begin building an empirical basis for managerial direction, policy formation, and regulatory action in regard to medical technology.

REFERENCES

Allen TJ. 1977. Managing the Flow of Technology. Cambridge: MIT Press.

Allen TJ, Utterback JM, Sirbu MA, Ashford NA, Hollomon JH. 1978. Government influence on the process of innovation in Europe and Japan. Research Policy 7, No. 2: 124-149.

Andrews FM. 1981. Innovation in R&D organizations: some relevant concepts and empirical results. In Roberts EB et al. (eds.). Biomedical Innovation.

Battelle Memorial Institute. 1973. Interactions of Science and Technology in the Innovative Process: Some Case Studies, NSF-C667. Washington D.C.: National Science Foundation.

Chemical Week. 1979. Industry R&D renews the old campus ties. February 21: 38-39. The article discusses the Harvard-Monsanto long-term medical and biological research program, a potentially important exception.

Coleman JS, Katz E, Menzel H. 1966. Medical Innovation: A Diffusion Study. Indianapolis: Bobbs Merrill Co.

Comroe JH Jr., Dripps RD. 1977. The Top Ten Clinical Advances in Cardiovascular-Pulmonary Medicine and Surgery, 1945-1975, DHEW Publication No. (NIH) 78-1521. Washington DC: U.S. Department of Health, Education and Welfare.

Enos JL. 1962. Petroleum Progress and Profits: A History of Process Innovation. Cambridge: MIT Press.

Finkelstein SN, Scott JR, Franke A. 1981. Diversity as a contributor to innovative performance by physicians. In Roberts EB et al. (eds.). Biomedical Innovation.

Gerstenfeld A. 1976. A study of successful projects, unsuccessful projects, and projects in process in West Germany. IEEE Transactions on Engineering Management EM-23, No. 3: 116-123.

Gerstenfeld A. 1977. Government regulation effects on the direction of innovation. IEEE Transactions on Engineering Management EM-24, No.3: 82-86.

Gerstenfeld A, Wortzel LH. 1977. Strategies for innovation in developing countries. Sloan Management Review 19, No. 1: 57-68.

Hamberg D. 1963. Invention in the industrial research laboratory. Journal of Political Economy 71: 95-115.

Hamberg D. 1966. R&D: Essays on the Economics of Research and Development. New York: Random House.

Hollander S. 1965. The Sources of Increased Efficiency. Cambridge: MIT Press.

Illinois Institute of Technology Research Institute. 1968. Technology in Retrospect and Critical Events in Science (TRACES). Washington D.C.: National Science Foundation.

Jewkes J, Sawers D, Stillerman R. 1958. The Sources of Invention. London: Macmillan.

Langrish J, Gibbons M, Evans WG, Jevons FR. 1972. Wealth from Knowledge. London: Macmillan.

Levy RI, Sondik EJ, 1981. The management of biomedical research: a case in point. In Roberts EB et al. (eds.). Biomedical Innovation.

Marquis DG, Rubin IM. 1966. Management Factors in Project Performance, Working Paper. Cambridge: MIT Sloan School of Management.

Mowery D, Rosenberg N. 1979. The influence of market demand upon innovation: a critical review of some recent empirical studies. Research Policy 8, No. 2: 102-153.

Myers S, Marquis DG. 1969. Successful Industrial Innovations, NSF 69-17. Washington D.C.: U.S. Government Printing Office.

Peck M. 1962. Inventions in the postwar American aluminum industry. In Nelson RR (ed.). The Rate and Direction of Inventive Activity. Princeton: Princeton University Press, 299-322.

Pelz DC, Andrews FM. 1966. Scientists in Organizations. New York: John Wiley & Sons.

Peters DH, Roberts EB. 1969. Unutilized ideas in university laboratories. Academy of Management Journal 12, No. 2: 179-191.

Rhoades RG, Roberts EB, Fusfeld AR. 1978. A correlation of R&D laboratory performance with critical functions analysis. R&D Management 9, No. 1: 13-17.

Roberts EB. 1968. Entrepreneurship and technology. Research Management 11, No. 4: 249-266.

Roberts EB. 1979. Stimulating technological innovation: organizational approaches. Research Management 22, No. 6: 26-30.

Roberts EB. 1981. Is Licensing an Effective Alternative for Achieving Commercial Benefits of R&D Results? Working Paper #1182-81. Cambridge: MIT Sloan School of Management.

Roberts EB, Frohman AL. 1978. Strategies for improving research utilization. Technology Review 80, No. 5: 32-39.

Roberts EB, Fusfeld AR. 1980. Critical Functions: Needed Roles in the Innovation Process, Working Paper #1129-80. Cambridge: MIT Sloan School of Management.

Roberts EB, Levy RI, Finkelstein SN, Moskowitz JA, Sondik EJ. 1981. Biomedical Innovation. Cambridge: MIT Press.

Roberts EB, Peters DH. 1981. Commercial innovations from university faculty. Research Policy.

Roberts EB, Wainer HA. 1971. Some characteristics of technical entrepreneurs. IEEE Transactions on Engineering Management EM-18, No. 3: 100-109.

Rothwell R, Freeman C, Horlsey A, Jervis VTP, Robertson AB, Townsend J. 1974. SAPPHO updated—project SAPPHO phase II. Research Policy 3: 258-291.

Schon DA. 1963. Innovation by invasion. International Science and Technology.

Schumpeter J. 1934. Theory of Economic Development. Cambridge: Harvard University Press.

Taylor CT, Silberston ZA. 1973. The Economic Impact of the Patent System. Cambridge, England: Cambridge University Press.

Tilton JE. 1971. International Diffusion of Technology: The Case of Semiconductors. Washington D.C.: The Brookings Institution. The book describes the role of "new firms" in semiconductor industry innovation and growth.

Utterback JM. 1974. Innovation in industry and the diffusion of technology. Science 183, February 15: 620-626.

Utterback JM, Abernathy WJ. 1975. A dynamic model of process and product innovation. Omega 3, No. 6: 639-656.

von Hippel E. 1978. A Review of Data Bearing on the User's Role in Industrial Innovation, Working Paper #989-78. Cambridge: MIT Sloan School of Management.

von Hippel E. 1979. Appropriability of Innovation Benefit as a Predictor of Functional Locus of Innovation, Working Paper #1084-79. Cambridge: MIT Sloan School of Management.

von Hippel E, Finkelstein SN. 1979. Analysis of innovation in automated clinical chemistry analyzers. Science and Public Policy: 24-37.

Wardell WM. 1978. The drug lag revisited. Clinical Pharmacology and Therapeutics 24, No. 5: 499-524.

Young DA. 1981. Communications linking clinical research and clinical practice. In Roberts EB et al. (eds.). Biomedical Innovation.

Table 1

Individuals Who Had and Exploited Ideas
Whose Scope is Outside the Laboratory

Laboratory	N	Claimed Such Ideas		Attempted to Do Something	
		#	%	#	%*
Lincoln	161	72	45	25	35
Instrumentation	138	75	54	24	32
Totals	299	147	49	49	33

*Percentage based on those who had such ideas.
Source: Peters and Roberts, 1969.

Table 3

Innovations Stimulated by Perceptions of Market Needs[a]

Author	Study	N	% from Market, Mission, or Production Needs
Baker et al.	Corporate research laboratory	303[b]	77
Carter/Williams	British Board of Trade	137	73
Goldhar	"Industrial Research" winners	108	69
Langrish et al.	Queen's Awards	84	66
Myers/Marquis	5 Industries	439	78
Sherwin/Isenson	"Hindsight"--weapons systems	710[c]	61
Tannenbaum et al.	Materials	10	90
Utterback	Instruments	32	75

[a]Source: Redrawn from Utterback, 1974.

[b]Ideas for new products/processes.

[c]Research events used in 20 developments.

Table 4

Manufacturer Innovations Initiated in Response to Customer Request

Author	Study	N	% Requested by Customer
Berger	Engineering polymers	5	0
Boyden	Plastics additives	16	0
Meadows	Commercially successful chemical products	17	53
Peplow	Successfully implemented creative R&D projects on processes and equipment	48	62
von Hippel	Semiconductor and electronic assembly manufacturing processes and equipment	16	38

Source: Redrawn from von Hippel, 1978.

Table 5

Sources of Ideas for Innovations Developed Within the Firm

Author	Study	N	% from Outside the Firm
Langrish et al.	Queen's Award	51	65
Mueller	DuPont	25	56
Myers/Marquis	5 Industries	157	62
Utterback	Instruments	32	66

Source: Assembled from data contained in Utterback, 1974.

Table 6

Key Source of Information Inputs to Successful Innovation

Innovator Got the Key Input From:	No. of Cases	%
Inside the Firm:		
Printed Materials	9	2
Personal Contacts	25	4
Own Training and Experience	230	41
Formal Courses	1	0
Experiment or Calculation	40	7
	305	54
Outside the Firm:		
Printed Materials	33	6
Personal Contacts	120	21
Own Training and Experience	39	7
Formal Courses	8	2
	200	36
Multiple Sources	62	11
	567	101

Source: Myers and Marquis, 1969.

Table 7

Methods of Transfer of Ideas from Outside for Successful Innovations

Method	# of Ideas
Transfer via person joining the firm	20.5
Common knowledge via industrial experience	15
Common knowledge via education	9
Commercial agreement (including takeover and sale of know-how)	10.5
Literature (technical, scientific, and patent)	9.5
Personal contact in U.K.	8.5
Collaboration with supplier	7
Collaboration with customer	5
Visits overseas	6.5
Passed on by government organization	6
Conference in U.K.	2.5
Consultancy	2
Total	102

Source: Langrish et al., 1972.

Table 8

Role of Adoption in Successful Innovation

	% Distribution		
	Stage I	Stage II	Stage III
Original Innovations	84	84	49
Adopted Innovations	16	16	51

$x^2 = 72.8, p < 0.0001$

Source: Utterback and Abernathy, 1975.

Table 9

Users vs. Manufacturers as Sources of Industrial Innovation

Author	Industry	N	% by Source User	Mfr.	Other
Berger	Engineering Polymers	6	0	100	
Boyden	Plastics Additives	16	0	100	
Enos	Petroleum Processing, Major	7	43	14	43
Freeman	Chemical Processes/Equip.	810	70	30	
Knight	Computers, 1944-62				
	Improved Performers	143	25	75	
	Radical Structures	18	33	67	
Lionetta & von Hippel	Pultrusion Machinery	13	85	15	
Peck	Aluminum Industry				
	Joining	52	17	50	33
	Finishing	27	33	48	19
	Fabricating	76	30	49	21
	Alloys	39	3	79	18
von Hippel	Scientific Instruments				
	First of Type	4	100	0	
	Major Improvements	44	82	18	
	Minor Improvements	63	70	30	
von Hippel	Semiconductor & Electronic Assembly Mfg. Equipment				
	First of Type	7	100	0	
	Major Improvements	22	63	21	16
	Minor Improvements	20	59	29	12

Source: Redrawn from von Hippel, 1978.

Table 10

Sources of Test Methods for Automated Clinical Chemistry Analyzers

	N	% by Source: User	% by Source: Equip. Mfr.	% by Source: Reagent Mfr.
DuPont ACA	18	0	18	0
Technicon SMAC	20	14	4	1

Source: Redrawn from von Hippel and Finkelstein, 1979.

Table 11

Patterns of Innovation Along the Technology Cycle

Type of Innovation	Stage I (N=52 firms)		Stage II (N=14 firms)		Stage III (N=11 firms)	
	#	%	#	%	#	%
Product	114	66	46	50	13	21
Component	39	22	8	9	6	10
Process	21	12	39	42	44	70
	174	100	93	101	63	101

$x^2 = 80.7$, $p<0.0001$

Source: Redrawn from Utterback and Abernathy, 1975.

Table 12

Sources of Key Innovations

Author	Study	N	Major Firms	Small Firms and Inventors
Enos	Petroleum Refining, Basic Major Innovations	7	0	7
Hamberg	Steel	11	4	7
Hamberg	Major Innovations, 1946-1955	27	<1/3	>2/3
Jewkes	Major Innovations, 1900-1945	61	<50%	>50%
Peck	Aluminum, Major Innovations	7	1	6

Sources: Enos, 1962; Hamberg, 1963, 1966; Jewkes et al., 1958; Peck, 1962.

Table 13

Firm Size and Successful Innovations

Sales ($000,000)	Stage I		Stage II and III	
	#	%	#	%
Unclassified	12	23	8	32
<10	18	34	0	0
10-100	6	12	2	8
>100	16	31	15	60

$x^2 = 11.2, p<0.01$

Source: Assembled from data in Utterback and Abernathy, 1975, pp. 654-656.

Table 15

Innovation in DuPont Rayon Plants

Plant	Contribution of Minor Technical Change to % of Net Reduction in Unit Costs Due to Technical Change
Spruance II-A	83
Spruance I	80
Old Hickory	79
Spruance III	46
Spruance II	100

Source: Drawn from data in Hollander, 1965.

Table 14

Technological Change in Successful Innovations

Degree of Invention Required	% Distribution		
	Stage I	Stage II	Stage III
Little	14	19	33
Considerable	41	50	48
"Invention" Needed	45	31	19

$x^2 = 19.1$, $p<0.001$

Source: Utterback and Abernathy, 1975.

Table 16

Importance of Patents

Wilson (1971 Royalty Data, U.S.)		Taylor-Silberston (1968 Royalty Data, U.K.)	
Industry	Royalties Paid As % of Sales	Royalties Paid As % of Sales	Industrial Activity
Chemicals			Chemicals
Industrial	0.244	0.042	Basic
Drug	0.745	0.635	Pharmaceutical
Other	0.034	0.044	Other Finished and Specialty
Machinery	0.051	0.255	Mechanical Engineering
Electrical	0.13	0.182	Electrical Engineering

Source: Redrawn from von Hippel, 1979.