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Diffusion and Marketing of Technologies

Grace is given of God, knowledge is bought in the market.

—Arthur Hugh Clough

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INTRODUCTION

Often, the research, development, marketing, and diffusion continuum is characterized as being loosely woven aspects of a single effort. To a degree, this is correct. However, it is also accurate to describe the diffusion and marketing aspects of technology delivery as ones requiring quite different methods, goals, and information than the research and development (R&D) efforts that have gone on before. For example, most disability-related researchers (as well as most scientists in general) have basic research orientations, training, and value systems that focus on conducting research to further the knowledge in their professional areas (147). As Dr. Goodgold of the New York University Institute for Rehabilitative Medicine explains (147):

> We're certainly concerned with utilization, but not from the point that we have a profit motive. Our profit motive is the advancement of science while agreeing that there is a need to transform research ideas in order to increase their acceptance and put them in a form which decision makers could understand and accept.

This is a point that is often overlooked in criticism of the performance of the National Institute of Handicapped Research's (NIHR's) research and training centers (RTCs) and rehabilitation engineering centers (RECs). Their mission encompasses a good deal more than product development and commercialization. In addition to having a commitment to basic and applied research, these centers are responsible for training new and existing professionals, delivering services to patients, evaluating research products developed in-house (as well as those from other RECs and RTCs), and finally, working with private firms or organizations to manufacture and market the R&D products that they have developed. Therefore, it is not entirely fair to measure their success or failure in terms of device development alone.

Even though R&D, diffusion, and marketing process can be, and is, broken up into distinct, but overlapping, approaches, there must still be a continuity to the process that allows and requires a look at the system as a whole. Any description of the entire process will be deficient in one area or another. The process is a complex one whose performance is the result of a myriad of factors, many beyond the control or predictions of the scientists, the administrators, Congress, or the market analysis. At best, a descriptive guide can be provided to cover the more generalizable features of the research, development, diffusion, and marketing process.

Many steps are involved in developing and marketing a technology. The factors affecting adoption of innovations are equally numerous and involved. An organization's potential for innovation is related to its environment—the econonomic, social, and political factors involved, the state-of-the-art of technology, and the availability of useful information (216). If barriers exist that impede the flow of information between the organization and its environment, the innovation, diffusion, and marketing process is hampered. Government (via its programs, incentives, and regulations) and the firm (using its resources, personnel, and patterns of communication and decisionmaking) are both responsible for the degree to which those barriers are overcome and innovations reach and satisfy the demands of the marketplace (216).

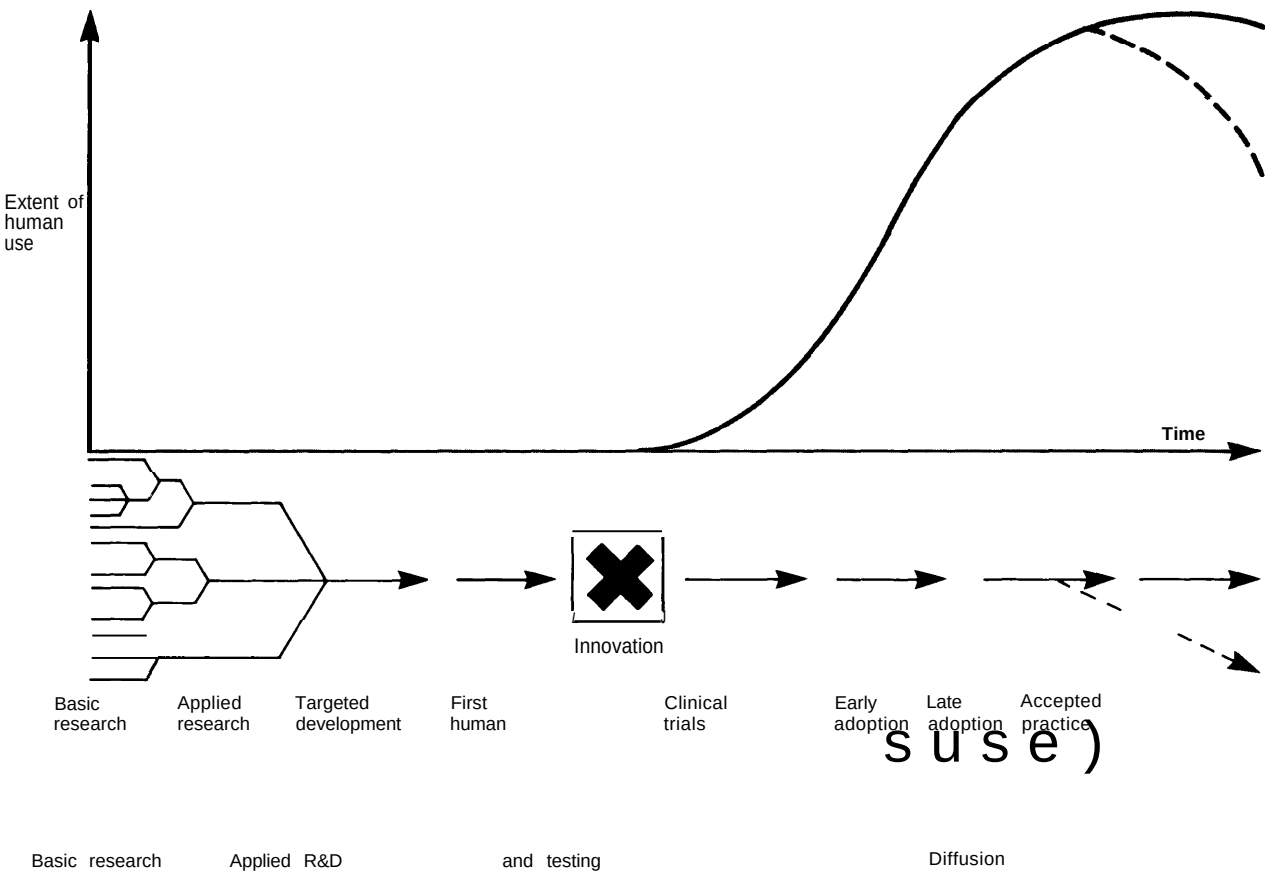
Combining the diffusion and marketing models used to characterize the health care system and the private sector innovation process may provide a useful guide to the vagaries of marketing of technologies for disabled people. The disability field provides an example of R&D that is stimulated by personal, economic, social, and political incentives; funded to a large degree by public and

nonprofit sources; and then, usually late in the process, grafted onto the manufacturing and marketing systems of the private sector. This forced marriage is often difficult and unsatisfying to both partners, as well as to disabled people. However, when this union is successful, it is a productive, efficient relationship deserving of praise. Figure 5 depicts a typical diffusion pattern for medical technologies (165). This model may be inadequate for some disability-related technologies, but in general serves as a useful description of the process.

An ideal, or model, development and diffusion process by which technology would pass through the necessary stages to reach the consumer is as follows (164):

- discovery, through research, of new knowledge, and relation of this knowledge to the existing knowledge base;
- translation of new knowledge, through applied research, into new technology, and development of a strategy for moving the technology into the delivery system;
- evaluation of the safety and efficacy of new technology through such means as controlled clinical trials;
- development and operation of demonstration and control programs to demonstrate feasibility for widespread use;
- diffusion of the new technology, beginning with the trials and demonstrations and continuing through a process of increasing acceptance into practice;

Figure 5.—Stages in the Development and Diffusion of Medical Technologies



SOURCE Off Ice of Technology Assessment U S Congress Development of *Medical Technology Opportunities* for assessment (Washington, D.C U S Government Prlnting Office August 1976

- education of the professional and user communities in use of the new technology; and
- skillful and balanced application of the new developments to the population.

Muthard cites a number of studies of utilization patterns in the rehabilitative system that were designed to determine the types of factors that have been most effective in increasing the chances of an innovation being adopted (147). Below are the factors that Havelock has suggested that account for most dissemination and utilization phenomena (105,147).

- Linkage—reciprocal relationships between resources and user systems.
- Structure—the resource system must plan its activities in a structured sequence and the user system must be organized to receive input.
- Openness–the resource system must be willing to be influenced by user needs and expose its new knowledge to inspection; the user system must actively reach out for new ideas.
- Capacity—both resource and user systems require the amount of wealth, intelligence, etc., needed to deal with a given innovation.
- Reward—both resource and user systems need kinds of positive reinforcement or benefits from the innovation to warrant the investment of time, money, and effort.
- Proximity—proximity facilitates linkage.
- Synergy—several inputs of knowledge, working together over time, through different channels and formats (purposeful redundancy) facilitate adoption.

The two lists presented above are quite different in the types of factors involved. The first set is more a description of *how* **an** innovation winds its way through the process, getting the appropriate and necessary "stamps of approval" along the way. It provides the framework that allows the second list of factors to operate. The second is a list of criteria that explain *why* a given innovation is used and assimilated into the system. And obviously the attributes of a technology will enhance or impede its adoption. According to Muthard, adoption will be facilitated when a technology is (147):

- inexpensive;
- time-saving;
- easy to use;
- easy to explain;
- easy to understand;
- consistent with the consumer's value system; and
- observable (its workings or effects can be demonstrated in advance to consumers).

Perhaps implicit in Muthard's list, and as mentioned in chapter 5, additional factors that could be included are perceived and actual cost effectiveness, ease of repair, and low frequency of replacement or maintenance.

CURRENT ACTIVITIES AND PROGRAMS

In the process of developing and distributing disability-related technologies, the public-private relationship is very complex and close. Each sector brings with it a full complement of beneficial and negative characteristics. These attributes assist and impede the process and require the presence of compromises and insight to make the system work. Each partner has its own set of agendas, mandates, and constituencies that it must satisfy. Often, the organizational goals of the various actors are not even close to being compatible, even when the basic *intentions* are similar. Federal agencies are, among other things, creations of the political process. The political process has goals and requirements that are often unique to that process. Studies, as well as common sense, tell us—not surprisingly—that private sector firms tend to innovate primarily in areas where there is a reasonably clear, short-term profit potential (216). In an area such as handicap-related innovation, where the market population is ill-defined and where, on average, the economic status of

users is far below the median, the stimulus for private investment and involvement is sometimes very weak.

The imperfections in the existing market structure are numerous. Flaws in public-private sector relationship are equally abundant. NIHR, along with many others, has identified the major barriers in both the marketplace and the public-private sector relationship (52). That agency is also attempting to identify solutions to many of these problems. In the following paragraphs, the discussion will draw heavily on NIHR's summary of both the recognized imperfections and the suggested solutions to these problems. It is worth mentioning again that the Veterans Administration (VA), the Office of Special Education, and the National Aeronautics and Space Administration (NASA), among others, are also involved in efforts to address these same problems. NIHR's long-range plan is a fair representation of the general approach taking place at the Federal level.

Before turning to the negative aspects of this process and the problems that exist in the public-private relationship, it is worth noting a few of its positive aspects. The Federal Government has a number of programs in place to provide assistance to the private sector in terms of loans, technical assistance, and information transfer. The Food and Drug Administration (FDA) imposes numerous requirements on businesses of all sizes, but the smaller firms are often hit the hardest. Therefore, since 1977 it has maintained an Office of Small Manufacturers' Assistance (OSMA) to provide technical help and other nonfinancial assistance to small firms in the device and drug approval processes (22 I). In addition, FDA is instituting a $100 million program to assist smaller firms financially if they are involved in the rulemaking and administrative procedures at FDA (221). The Small Business Administration (SBA) is also involved in making low interest loans to small, disability-related businesses. Over the period 1973-81, SBA loaned a total of $116 million to a wide variety of firms in the United States.

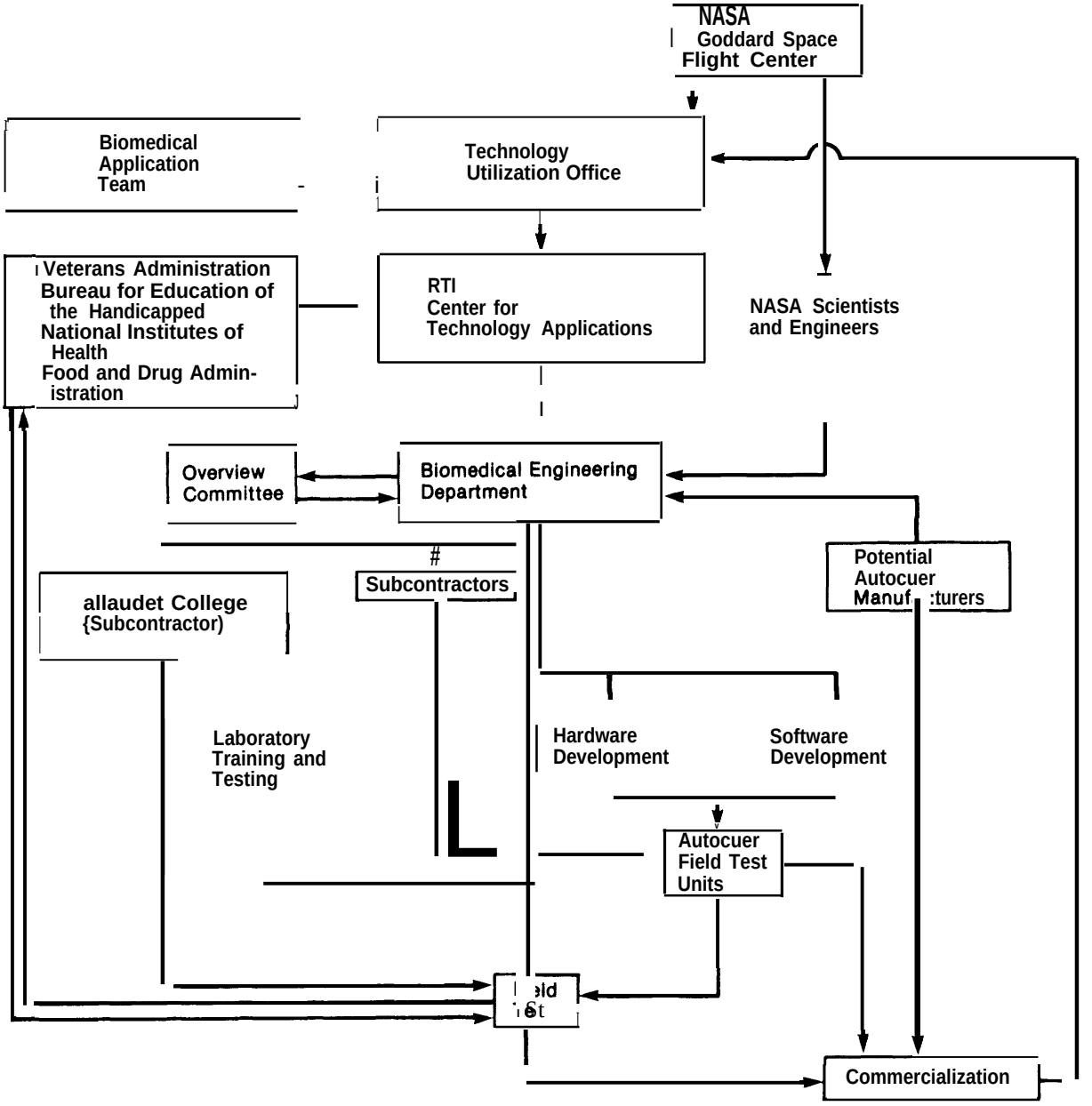
The efforts of VA, NASA, and NIHR have also produced a number of "successes" in terms of taking R&D products from the Government labs to private manufacturers for mass marketing and distribution. The introduction of the commercially produced version of the Autocom, a communications device, is the result of 5 years of initial R&D at the Trace Center at the University of Wisconsin and 2 years of production engineering at Telesensory Systems, Inc. The Autocom is a example of a prototype device proving the validity of a research idea and then being "redesigned" to fit the needs of the manufacturer: 1) mass production, 2) regular production schedules, 3) high product consistency, and 4) adherence to industrial standards of quality control (189).

Rancho Los Amigos has worked with Med General in Minneapolis to transfer its research on idiopathic scoliosis to produce a device—the Scolitron—to put on the market. The University of Michigan REC has also transferred its research on transportation devices and systems to firms like Creative Controls, Inc., and the Amigo Corp. for the development and marketing of mobility technologies to aid handicapped individuals. There are many examples of where and how RTCs and RECs have been effective and successful in working with the private sector to transfer R&D prototypes and information to marketable products. *

A good example of how involved and complex this type of transfer process can be is well illustrated by figure 6, a flow chart of NASA's efforts in bringing the technology that became the *Autocuer* to the marketplace (227). This chart traces the tortuous route that a single project, involving a not unusual number of actors and organizations, took to get to the commercial stage. This schematic is a good model for this type of interagency and public-private process. Since most of the more important technologies tend to follow

*For an interesting account of how the Optacon technology reached the marketplace, see LaRocca and Turem's "The Application of Technological Developments to Physically Disabled People" (LaRocca & Turem, 1978). It was a 10-year project, involving DHEW, Stanford University, the Mellon Foundation, the Stanford Research Institute, and finally, the creation of Telesensory Systems, Inc., to manufacture, distribute, and service the Optacons. More than $3 million was granted to this project, which came to involve a staff of 20 to 30 people, while turning out 13 Ph. Ds. and other advanced degrees for dissertations concerning the Optacon project. A more thorough analysis of the factors associated with bringing a device to market can be found in "A Production and Marketing Strategy for Prototype Devices Developed Under the Rehabilitation Engineering Program, " prepared by the Electronic Industries Foundation, March 1978, for RSA (78).

Figure 6.—Organizational Chart for the Autocuer Project



SOURCE. National Aeronautics and Space Admlnlstratlon

Photo credit' Courtesy of Research *Triangle* Insf/fute, Research Triangle *Park, N. C.*

The Autocuer, a portable minicomputer, mechanically "hears" words spoken to a deaf person and projects symbols onto the lens area of a pair of eyeglasses worn by the deaf person. The symbols, shown above for the phrases "He can go" and "Get a coat," act as visual cues that lessen the ambiguity of words that look similar to a lip-reading person

this type of route, the model is an accurate general indicator of how the process works and why it can succeed or fail.

A major aspect of NIHR's mandate is to "improve the distribution of technological devices and equipment for handicapped individuals by providing financial support for the development and distribution of such devices and equipment" (Public Law 95-602, sec. 200). There are a number of significant obstacles, however, that complicate and prevent the participation of private industry in this process (170):

- lack of adequate demographic data (or market statistics) about the needs for technological aids and devices by disabled people;
- lack of commercial viability of certain ventures because of a small fragmented market and high investment costs; and
- roadblocks caused by the patent system, liability insurance requirements, and the third-party payment system.

Additional factors must be considered to the issues of reimbursement and marketing (see the following chapter). The Government may provide a fairly large guaranteed market for numerous medical and rehabilitative technologies. VA and the vocational rehabilitation systems alone provide a ready market for medical and rehabilitative devices. The Government, as purchaser and as arbiter of performance and design standards, can to a large extent determine what technologies will qualify to enter the marketplace. There is some concern that FDA, the Rehabilitation Services Administration (RSA), and VA accept specification and standards of existing technologies on the market as the criteria for evaluation and (in the case of VA and of vocational rehabilitation systems)

Photo credit Courtesy of the National Institutes *of Health*

An arthritis patient IS being set up to receive radiation treatment from a high-energy X-ray machine. Total lymphoid Irradiation IS currently being tested for its effect on reducing disability of people with severe rheumatoid arthritis

purchase of new rehabilitative devices (141). This situation makes it even more difficult for emerging technologies that are different in design or performance levels to enter the general marketplace, especially the large VA market. If a device can enter into the "medically necessary" category in the Medicaid reimbursement process or be included as a necessary rehabilitative device in the VA or vocational rehabilitation systems, a significant obstacle is overcome for the manufacturer. Reimbursement is then guaranteed for their product. If a technology is not found to be "therapeutic, " "medically necessary, " or does not meet the standards established by FDA, RSA, or VA, then the production and marketing outlook is much less optimistic given the relatively poor financial status, low employment levels, and ill-defined target populations that characterize disabled people as a market.

There are relatively few commercial products available to disabled people despite the millions of public dollars dispersed yearly for handicap-related R&D. A major problem is that the Federal Government does not have consistent, formal mechanisms in place to link research investment to the production and distribution needs of the marketplace. The exception is a formal mechanism for accomplishing this task within NASA that works quite well when applied correctly. One critical aspect of the NASA system is that it sometimes uses a "co-contracting" process with both researchers and potential marketers involved. NIHR and VA are trying to move in this direction, to the extent possible, by redirecting the development process to accommodate and include marketplace considerations. NIHR is examining a number of initiatives to promote and facilitate private sector involvement (170):

- demographic and market research,
- low-cost loans or grants,
- tax incentives,
- studying the experience of European systems, and
- contracting arrangements.

NIHR is also investigating ways to overcome the disincentives that have discouraged private sector involvement, such as patent policy, product liability issues, and the third-party payment system. Patent policy, for example, is seen as a disincentive for many firms who are in, or who might enter, the production of disability-related technologies. The patent process is expensive and lengthy. Numerous challenges of patent rights in court have resulted in a situation of uncertainty regarding the amount of protection of a design afforded by a patent. There is also uncertainty regarding the granting of patent rights to products or techniques developed in whole or in part by Federal funds. These considerations are heightened by the fact that a great many firms in this area are small and cannot easily afford the costs involved in a lengthy patent process. Additionally, in a rapidly evolving field of technology such as this, patents may be out-of-date rapidly, thus lessening the incentives to go through the process of securing them. Nevertheless, a streamlined and less costly patent process, combined with a more consistent and explicit Federal policy toward the assigning of rights to products developed with Federal funding, could make some firms less reluctant to enter the market with new products.

It remains to be seen whether this Federal attention will be translated into federally supported action. One final problem that NIHR has already begun to address is information collection and dissemination. This is not to say that there is, at present, an absence of disability-related information collection and dissemination in this country. On the contrary, there are numerous public and private reference centers, information dissemination networks, nonprofit organizations, bibliographic services, etc., that can provide a wealth of information on a wide variety of topics. Nevertheless, finding product information that is up-to-date, complete, and accurate remains a substantial problem.

The most recent addition to the information collection and dissemination system is the computer network ABLEDATA. This is an NIHR-funded, product information system operated as a service of the National Rehabilitation Information Center based at Catholic University in Washington, D.C. Most product information is available only through manufacturers' catalogs or from distributors. Normally, these data consist of technical specifications, selection choices, etc. The ABLEDATA system collects manufacturers' data and adds updated information regarding local availability of products, names of manufacturers, where the distributors are located, product descriptions, cost information, and any relevant evaluation data that are available. This information is in a computerized data bank that is accessible to information brokers at selected locations around the country. These brokers are in turn accessible to rehabilitation centers, individuals, or anyone who has a need for that information.

Currently there are nine information brokers. In their searches (for information for clients or users), these brokers access the on-line data base as well as conduct manual searches through documents containing information not yet entered into the computer data bank. As of November 1981, information on 3,200 items was entered into the system, and another 2,000 entries were expected shortly. The amount of information that can be entered is constrained by the limited staff time available to obtain the information and process it. There are 15 centers, including private rehabilitation centers and NIHR-funded RECs, that assist the ABLEDATA staff in obtaining manufacturers' literature. For example, the University of Virginia is responsible for contributing wheelchair data to the information bank. The University of Michigan submits information regarding personal transportation technology. The Smith-Kettlewell Institute contributes data regarding technologies for deaf-blind individuals. And, New York University covers environmental technologies for personal use.

The information contributed by RECs will include relevant R&D and evaluation/performance information they have developed in their program areas. Surveys of manufacturers, consumers, and

other relevant persons, will be conducted to supplement these efforts, as well as to keep the product listings and information current. For each product, there will be a section for general comments regarding the technology's use. These comments may include information provided by the manufacturer but not printed in the product's literature, suggestions by consumers and professionals regarding modifications that can be made to the product, and tips regarding the product's safe use.

The concept and approach of ABLEDATA are excellent. However, primarily due to low levels of funding for start-up and for continuing operations, effective implementation of this program is likely to be quite difficult. The number of entries is extremely limited, and the comment and evaluation fields (areas of the forms used) for each product are currently incomplete, Furthermore, there is no procedure in place to systematically update the information. As with the original product entries, the reason for these limitations appears to be a lack of funding for additional staff time. They are not due to a lack of need or to the existence of severely limiting technical problems.

Summarizing NIHR's priority research and demonstration activities in the marketing and diffusion area also serves the purpose of summarizing the major issues that confront the disability-related development and marketing system in general. The research goals and projects identified below represent the distillation of concerns collected from relevant participants in the field (170):

- Conduct a comprehensive demographic survey of the Nation's disabled population to determine the number and the character of subgroups according to precisely defined impairment and/or functional needs.
- Conduct a comprehensive study of incentives to promote business investment in ventures that potentially have high social benefit but which at present are not profitable. Incentives to be studied include: 1) low-cost loans or grants, 2) tax abatement, and 3) contracting arrangements related to Government purchases.
- Conduct a study of disincentives to business investment including: 1) patent policy, 2) product liability, and 3) third-party payers.
- Establish a testing and evaluation program (minimum of two centers per year) to assess suitability of products for use by disabled persons. This program is to include input from disabled consumers.
- Develop and establish minimum performance specifications for products. This will offer producers criteria for manufacturing, and furnish a framework for testing and evaluation.

DISCUSSION

One of the key driving forces usually behind the innovation process are consumer demands and needs as perceived by the Government or private sector. Note that it is not as common for needs as perceived by the user to be a key driving force. To a major degree, new scientific or technological advances and opportunities have also stimulated important innovations (216).

The obstacles to getting new products onto the marketplace are many. Booz, Allen & Hamilton, Inc., found that of every 58 new product ideas, 12 pass the initial screening test, seven remain after a thorough evaluation of their profit potential, three survive the production stage, two survive the test marketing phase, and only one becomes commercially successful (15). Coupling these statistics with the knowledge that 8 of every 10 new small (general) businesses fail within their first 5 years makes it apparent that new business and products (of any type) have very significant survival problems. These statistics are especially relevant to the handicap and disability-related area, since many of the firms that produce technologies in this area are relatively new and very small, with a fragile capital base and narrow market structure. Businesses and products *existing* primarily for disabled persons may encounter additional difficulties due to the sometimes limited and almost always ill-defined market segments

that characterize this area. These factors also present further complications when a business tries to raise venture capital to support an uncertain or risky business proposition. The market demands and needs may be present, but so are a host of other considerations that make the production, diffusion, and marketing of innovations quite difficult. Below is a set of actual or perceived reasons why manufacturers avoid producing disability-related devices (123):

- the cost of design for production may not be recoverable;
- the cost of special modifications that maybe necessary in individual situations;
- the cost of training that may be involved in the use of the technology;
- the costs associated with assuring that the technology meets functional, technical, reliability, and safety requirements;
- liability and legal concerns (lawsuits due to malfunctioning devices);
- the cost of developing maintenance systems for technologies whose market potential is difficult to identify and quantify; and
- fear that informed consumer demand, for better or new products or services, does not exist.

A dilemma that also adds to the uncertainty of being a manufacturer in this area is the occurrence of special problems within existing problem areas for business. Different populations (e.g., children, elderly people, active young adults) may have the same underlying condition or disability, and yet will not share the same lifestyles, educational needs, employment aspirations, and so on. Thus, a technology to assist, for example, a deaf young adult may have quite different demands placed on it than one to assist a deaf or hearing-impaired senior citizen. The specific requirements for an assistive device will often be quite different. Are the "numbers" of deaf people relevant to the manufacturer if that firm does not know the subsets of the market, their various disability levels, and their lifestyle requirements?

Figure 7 provides more graphic illustration of the dynamics and requirements involved in private sector efforts to bring research ideas, information, and products to the consumer (147). Diffusion of information is a critical aspect of any such process. Information transfer needs are found along the continuum of R&D, diffusion, and marketing. Outlets for information include scientific journals, meetings, radio, periodicals, computer networks and data bases, reports, advertisements, catalogs, television, and books. Despite the extensive array of possible information sources, considerable attention has been focused on the many weaknesses of the information transfer system.

The complexity of the general research, diffusion, and marketing process is increased by the special requirements of the area of technology for disabled or handicapped people. If one examines just the engineering obstacles of adapting technologies to the human system, the barriers to diffusion seem monumental. The testimony of James Reswick illustrates the frustration involved in this process (123):

> It is virtually impossible for any one person clearly to state specifications of a device to meet a patient's need in engineering terms. An initial attempt can be made by an effective team which includes medical, engineering and the associated health professionals and technical persons associated with clinical operation and testing. Such a medical engineering team can set down initial performance goals and proceed from these goals to define research and development tasks. Still, the inescapable fact remains that it is not until the device is *first* tried in the clinic on a patient that many aspects of the problems not recognized in the beginning become clear, after which it may be possible to define the specifications in engineering terms.
>
> Inevitably, the first prototype must be redesigned and redeveloped, and it is seldom that only one cycle of this process is required, Rather, the process becomes a continuous one, with new and improved models being worked on and evaluated. It often is difficult for a developer to accept that his designs must be frozen for production at a time when he still is working on various improved versions. But at some point, a manufacturer or other agency must reach a decision that a product or a device has attained a level of development sufficient to warrant production and distribution for profit. It is absolutely vital that this occur if the firm or agency is to be able to encourage a continuing R&D effort in the first place.

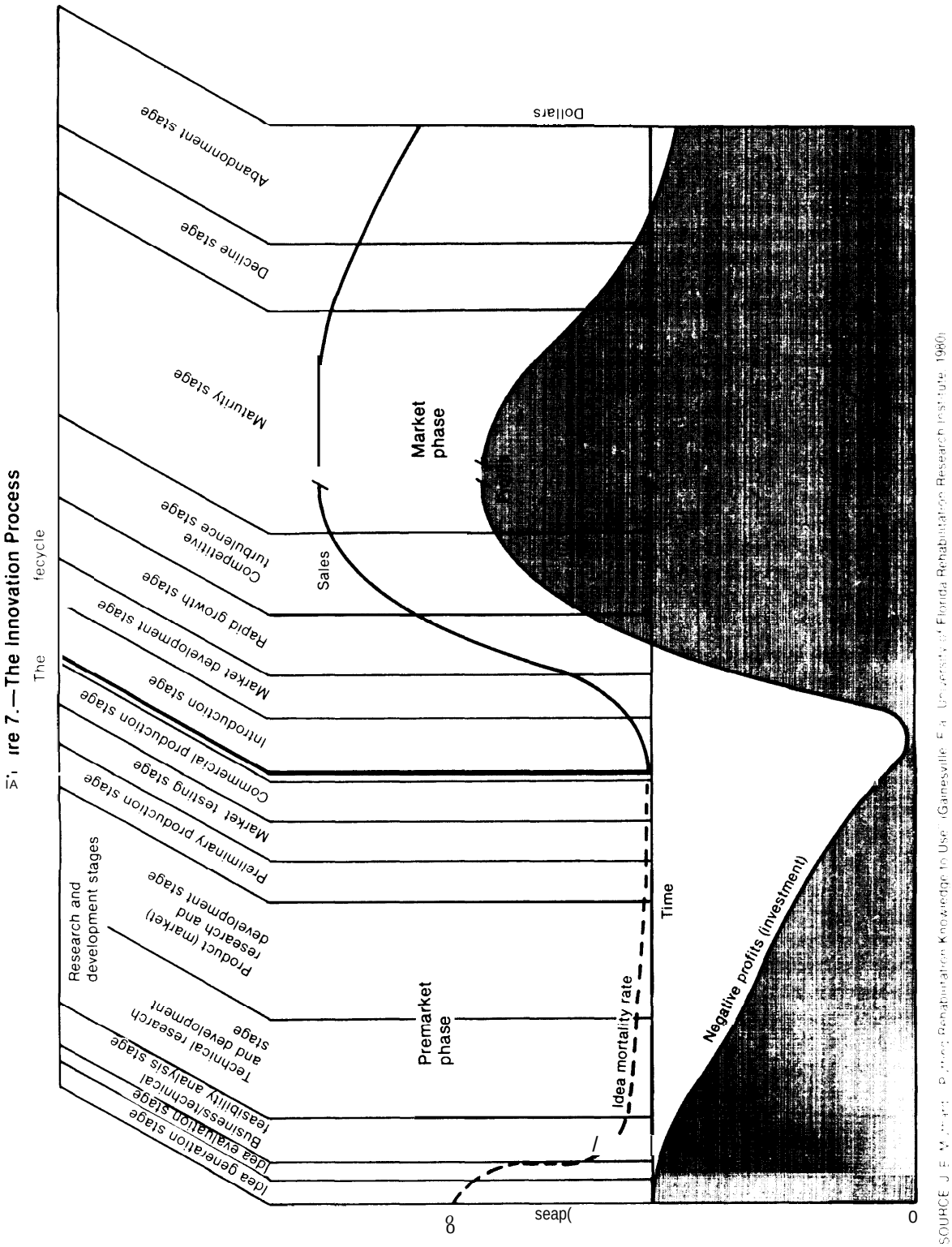


Figure 7.—The Innovation Process

The fecycle

SOURCE J E [illegible] Business Rehabilitation Knowledge to Use (Gainesville FL: University of Florida Rehabilitation Research Institute, 1990)

Presuming that the manufacturer is successful in producing a useful biomedical product, he then faces some additional problems not usually prescribed by a patient's physician. This means that physicians must be educated and trained in the application and use of the devices. Such training and education are costly and the physician must be completely sure of the performance of the device before he can fulfill the ultimate of responsibility which the doctor-patient relationship requires of him. Thus the device development must occur in the context of a respected teaching-clinical facility if reported clinical experience is to be considered reliable by the prospective prescribing medical community.

A second problem facing the manufacturer is the fact that no electromechanical device ever improves with use and age. These devices inevitably require maintenance and repair, and the manufacturer must assume responsibility for this service. The establishment and maintenance of such a service in a limited market may well be too costly to justify. Therefore, many small firms with limited marketing, distribution, and service capability refrain from producing medical engineering devices even though many have the technical capability and interest.

Additional steps in this process are the premarket approval evaluations required by FDA for medical devices. The cost of just the process is considerable. Reswick estimates that the investment required to move a device beyond the prototype stage is as much as four times the original development costs (123). NIHR places this investment at about five times the original cost of research (51).

The issue of rapidly changing technology is a serious problem for manufacturers in this field. Sometimes, though, it can be a benefit as well; especially in those areas served by or related to computer and microcircuit technology. Devices are constantly being made smaller, more sophisticated, more flexible, and cheaper. At the Tufts RTC, researchers and subcontractors have made available an Interactive Communicator for use by nonvocal individuals (147). They never build more than 10 to 20 devices of the same design. The technology changes so fast that each year a new feature is added. As another example, the Kurzweil Reading Machine had an initial cost of $50,000, which fell to $25,000; and there are now plans to reduce the price much further as new technology and "mass" production help lower its cost. The problems created by rapidly expanding technological innovation can be offset by the benefits it helps deliver.