6
Research and Development;

Indeed, what is there that does not appear marvelous when it comes to our knowledge for the first **time? How many things, too, are looked upon as** quite impossible until they have been **actually effected?**

—Pliny the Elder

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6. Research and Development

INTRODUCTION

"Research, development, and diffusion" is a shorthand phrase for a diverse and complex process of creating, producing, and delivering technologies. The research and development (R&D) system is an intricate arrangement of public and private organizations. These include Federal, State, and local governments; individuals; companies; universities; and a host of other participants.

The research, development, and diffusion of technologies for disabled people covers an extremely broad range of conditions. The National Institute of Handicapped Research (NIHR), for example, includes the following in its research plan: mental retardation, mental illness, and physical disabilities—i. e., paraplegia, arthritis, sensory deficits (blind, deaf, deaf-blind), epilepsy, heart disease, cancer, stroke, amputations, multiple sclerosis, cerebral palsy, muscular dystrophy, osteogenesis imperfect, spina bifida, cystic fibrosis, chronic respiratory dysfunction, specific learning disabilities, and many other categories (52).

Each of these conditions alone could easily consume a major part of the research attention of the agencies involved in this area. The research task is further complicated by the varying severity of disabilities present in the population. Between the individuals of near "typical" functioning and those with extremely severe disabilities are the majority who require widely varying amounts of assistance, either social or technological, to perform various life functions.

Furthermore, there are thousands of specialized technologies to assist disabled individuals. Such technologies range in complexity from $25,000 computerized reading machines for blind people to $3 specially designed utensils for easier gripping. In addition to devices for the individual, technologies include "system" technologies that make public transportation, buildings, and communication networks more easily accessible. "Service" or process technologies are equally diverse. Programs to assist disabled people include rehabilitation therapy provided by health care organizations, job counseling, sheltered workshops, independent living centers, traditional medical care, income assistance, and a number of other services. Disability-related research encompasses all of these diverse and interlocking technologies,

CURRENT ACTIVITIES AND PROGRAMS

The Federal Role in R&D

Funding Levels of Disability-Related R&D

The amount of funds devoted to R&D in the disability area is quite small in comparison to the number of people affected, the complexity of the research problems involved, and the total health care R&D budget. A recent White House study estimated that approximately $40 million to $50 million was spent annually by Government agencies responsible for various forms of disability-related research (181). A more current survey conducted by Richard LeClair of NIHR estimates the amount spent in fiscal year 1979 to be about $66 million (126). A breakdown of the survey and the agencies involved is presented in table 1.

An important addition to the research more traditionally thought of as disability related is the general research of the National Institutes of Health (NIH). Much of NIH's research aims at preventing, treating, or diagnosing the diseases and conditions that directly or indirectly contribute to disabilities. The expenditures and resource allocations of NIH—especially those of the Na-

Table 1 .—Science Information Exchange Grants Awarded for Disability-Related Research by Federal Agencies, Fiscal Year 1979

	Vocational/ educational	Management/ service delivery	Physical restoration (medical)	Behavioral/ social	Rehabilitation engineering	Total
Office of special education. .	$4,255,550	$ 1,949,207	$ 2.551.993	$3,071,609	$ 781,372	$10,619,731
Veterans Administration. ...	—	400,000	1 ,550; 000	750,000	3,886,011	6,586.011
National Institutes of Health .,	50,000	321,404	7,660,022	3,024,373	1,039,165	12,094,964
Department of Commerce,	—	—	—	—	160,000	160,000
National Institute of Handicapped Research	1,532,358	9,346,536	7,976,239	3,879,114	9,465,753	31,700,000
National Science Foundation .	—	59,000			1,941,000	2,000,000
Department of Defense,	—	—			183,331	183,331
Department of Agriculture ., . .	50,000	50,000			—	100,000
Bureau of Occupational and Adult Education .	540,049	—			.	540,049
Department of Labor.	50,000	100.000	50,000		—	200,000
Social Security Administration	—	100,000	—	—	—	100,000
Health Care and Financing Administration	—	—		37,436	38,000	75,436
Department of Transportation	—	300,000			238,037	538,037
Smithsonian Institution .,	—	50,000			—	50,000
Department of Justice.	—	246,580			—	246,580
Department of Housing and Urban Development. ...	—	—			500,000	500,000
Totals . . .	$6,487,957	$12,922,727	$19,288,254	$8,762,532	$18,232,669	$65,694,139

NOTE These figures are within 10 to 20 percent of the actual expenditure levels Differences indefinitions, account ing procedures, etc all con t ri but e 10 variat ions in estimates

SOURCE. Richard LeClair, National Institute of Handicapped Research

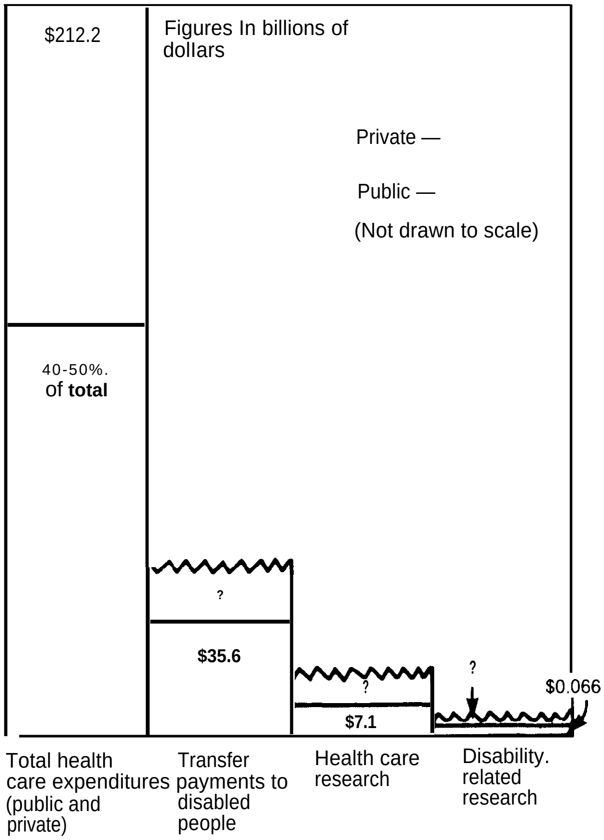
tional Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; the National Eye Institute; the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS); the National Institute of Child Health and Human Development; and the National Institute on Aging —and of the Alcohol, Drug Abuse, and Mental Health Administration within the Department of Health and Human Services (DHHS) all play a role in research aimed at lessening the incidence and severity of physical and mental conditions present in the population as a whole and in the population of disabled individuals specifically. Even if a more inclusive definition of disability-related research is used, the *total Federal level of involvement is still rather small compared to health care expenditures in general, health care research efforts, and money spent on transfer programs for disabled people.* Figure 2 and table 2 illustrate these comparisons. Note that if figure 2 were drawn to scale, the amount for disability-related research could not even be seen.

The Federal Government is responsible for an estimated 66 percent of all health research in this country (163). As a result, the Federal Government is the major force in setting research priorities for health care research in general and also for disability-related research. The figure and tables mentioned above help provide an overview of the Federal R&D effort and the complex network in which biomedical, health care, and disability-related research exist. They also provide an indication of the general direction the Federal Government has established for the national research effort.

The Federal Government's Involvement in Disability-Related R&D

The official role of the Federal Government in vocational rehabilitation, prosthesis research, and other disability-related research dates back to the 1930's and 1940's. The presence of the Federal Government as a purchaser of devices to aid disabled people reaches back even further to the years following the Civil War (210). Much of the groundwork for the current system of rehabilitation research was laid in the 1940's by the National Academy of Sciences and the armed services in

Figure 2.—A Comparison of Public and Private Expenditures for Health Care, Transfer Payments to Disabled People, Health Care Research, and Disability-Related Research, Fiscal Year 1979



SOURCE Office of Technology Assessment

response to the postwar needs of veterans. A large share of the initial research was conducted by the Department of Defense (DOD) and the Veterans Administration (VA) on prosthetic devices. Prosthetics research, along with an expanded focus on other areas of disability-related research, still continues in the VA system. The present day Rehabilitation Services Administration (RSA) had its beginning as the Office of Vocational Rehabilitation within the then Department of Health, Education, and Welfare (DHEW) in the early 1950's (210). Since these early efforts, the range and depth of the Federal initiative have expanded markedly. In addition, this area of R&D has steadily gained increased attention and recognition by the Federal Government over the years, though it remains small in comparison to the im-

Table 2.—National Funding for Health R&D, 1980
(millions of dollars)

Total funding	$7,891'
Government:	
Federal	4,723
State and local	455
Industry	2,391[b]
Nonprofit organizations	322[b]

[a] Includes expenditures for drug research.
[b] Estimates

SOURCE Office of Program Planning and Evaluation. National Institutes of Health

mensity of the problems involved. The private and nonprofit sectors of our society have also become increasingly involved in disability-related products and services. These two areas are examined more closely later in this chapter.

Earlier, in table 1, Federal spending levels were used to illustrate the level of Government involvement in disability-related research. * Naturally enough, levels of spending correlate very closely with levels of involvement and commitment to research. With research budgets as the measuring stick, four organizations stand out prominently: the Office of Special Education (OSE), VA, NIH, and NIHR. The National Aeronautics and Space Administration (NASA) is also involved in this area as a result of technology transfer efforts stemming from its primary aeronautical and space mission.

The Interagency Committee for Handicapped Research is responsible for reviewing proposed research projects and for identifying areas that overlap with ongoing projects. The committee must include the Director of NIHR and representatives from RSA, NASA, NIH, the Department

* There is a lack of consistent definitions for the terms rehabilitation research, handicap-related research, biomedical research applied to the disabled, and similar terms. Each term means something different to different people, and they carry different connotations and emotional undertones. Often, definitions of research in this area primarily include the rehabilitation engineering efforts (hardware-oriented) efforts of the **VA,** NIHR, **NASA,** and NSF. Other definitions expand the hardware orientation and include the services and methods efforts of various organizations; for example, OSE or NIHR's research training centers. Still **others** include **the** biomedically focused efforts of NIH, or the "systems" research of the DOT and so **on,** A large number of agencies and organizations do some amount of research, most of which is narrowly focused in rather specialized areas. These efforts are included in some definitions and excluded from other.

of Transportation (DOT), the National Science Foundation (NSF), VA, and the Department of Education (DOE). A member of the National Council on the Handicapped also sits on the committee. Representatives from the nonprofit and private sectors are also included.

Another mechanism that NIHR and other Federal agencies involved in this area use is the Interagency Committee on Rehabilitation Engineering. This working group, composed of representatives from NSF, the National Council, the National Bureau of Standards (NBS), NASA, VA, NIHR, the Department of Housing and Urban Development, DHHS, DOT, NINCDS, and the Senate Committee on Labor and Human Resources, has been meeting for the last 5 years. It was instrumental in the development of NIHR's Long-Range Plan.

National Institute of Handicapped Research.—NIHR, a major source of disability-related research funds, is an "old" program with a new name and a new location. The Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Public Law 95-602) removed the engineering and training programs previously administrated by RSA in DHEW and placed them, as NIHR, in the newly reorganized DOE under the Office of Special Education and Rehabilitative Services, along with the restructured RSA.

NIHR was a response to a need for a centralized and more visible focus on rehabilitation research and engineering. The agency was given the mandate to establish a comprehensive and coordinated approach to the development of a rehabilitation research program. It was also charged with facilitating the dissemination of information concerning developments in rehabilitation procedures and devices to professionals and disabled individuals. In addition, NIHR was directed to help improve the development and distribution of technologies to disabled people and to increase the scientific and technical base currently existing in the area (10).

NIHR has an extensive mandate considering its size and funding levels. Its fiscal year 1981 budget is $35 million. Its closest competitors for research funding are NIH, OSE, and VA, all of which have smaller research budgets directed toward disability-related research.

NIHR has developed a number of mechanisms to implement its congressional mandates. To approach the critical research issues confronting disabled people, it has developed a three-step process (52): 1) identification and establishment of priorities for research programs for the application of technology to the needs of disabled individuals; 2) development of the technologies that have been identified; and 3) evaluation, verification, and demonstration of the research results and the dissemination of information and technology to the rehabilitation practitioners.

From this process, NIHR has developed a research plan that it has stated in terms of categories of "needs." Each of the general areas of need is further subdivided by functional categories and then once again divided by disability group. These categories are also examined and divided according to age categories, severity of disability, and so on. The general functional areas of research needs, with specific examples, that NIHR has identified are the following (52):

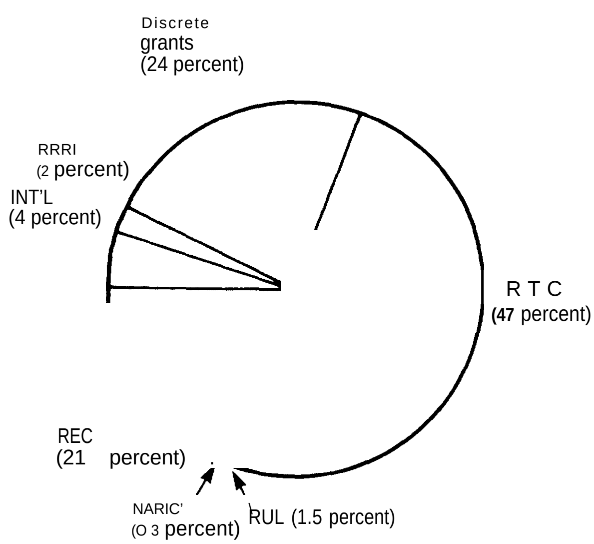
- Mobility: locomotion, wheelchairs, personal licensed vehicles, and public transit.
- Housing: accessibility (architectural barrier removal), and appropriate fixtures and furniture.
- Communication: reception and expression of information (interpersonal communications in person and through telecommunication and access to stored information).
- Function/physical restoration: orthotics, prosthetics, functional electrical stimulation, tissue mechanisms (e.g., pressure on tissue), biomechanics (joint replacement), surgical procedures and equipment (therapeutic), sensory stimulation substitutes, and diagnostics.
- Education: specialized equipment (equipment for delivery of services for diagnostics, and for therapeutics).
- Employment: job station adaption, job modification, specialized equipment, and physical adaption for work.
- Recreation/physical education: specialized equipment.

- Activities of daily living: environmental control systems, medical self-care (monitoring of one's condition and progress), feeding and hygiene devices.

NIHR translates these research goals and needs into practice via: 1) rehabilitation research and training centers (RTCs), 2) rehabilitation engineering centers (RECs), 3) spinal cord injury rehabilitation centers, 4) centers for deaf-blind youths, and 5) coordination with the international rehabilitation research centers (55). A breakdown of the budget levels and grant allocations that NIHR devotes to these various areas is shown in figure 3.

The RECs grew out of the major research and training programs in prosthetics and orthotics at RSA and its predecessor agencies. The REC approach was initiated in the early 1970's and was designed to encourage the application of technology to improve the quality of life of physically disabled people. This goal was to be reached by combining medicine, engineering, and related sciences to form a coherent and total rehabilitation effort (51). Since 1971, 12 RECs have been established in the United States, with three additional collaborating centers overseas. Each center has its own research agenda, developed within the general context of NIHR's long-range research plan.

Figure 3.— NIHR Grant Allocations by Program, Fiscal Year 1979



Key

INT'L — International centers and programs
NARIC — National Rehablllitatlon Information Center
REC — Research engineering centers
RRRI — Regional rehabi(ltation research Institutes
RTC — Research and training centers
RUL — Research utilization laboratories

SOURCE NIHR research and demonstration grants awarded [n fiscal year 1979

NIHR also funds a number of other centers that address a range of disability-related issues. Among these are 21 RTCs: 11 medical RTCs, three mental retardation rehabilitation RTCs, three vocational rehabilitation RTCs, two deafness rehabilitation RTCs, a blindness rehabilitation RTC, and a mental health rehabilitation RTC. These centers pursue research that deals with problems pertaining to employment, living skills, rehabilitation personnel training programs, discrimination, service delivery models, consumer involvement, etc. In addition to supporting research on the topics just mentioned, RTCs have responsibility for conducting training programs for rehabilitation and health care professionals.

The legislation that created NIHR also established a formal mechanism for setting research priorities and for coordinating activities among the various agencies that support disability-related research. The 15-member National Council on the Handicapped, for example, is to perform the following tasks (10):

- establish general policies for, and review the operation of, NIHR;
- provide advice to the Commissioner with respect to the policies and conduct of RSA;
- advise the Commissioner, the appropriate Assistant Secretary, and the Director of NIHR on development of programs to be carried out under the Rehabilitation Act, as amended;
- review and evaluate on a continuing basis all policies, programs, and activities concerning disabled individuals and persons with developmental disabilities conducted or assisted by Federal departments and agencies in order to assess their effectiveness in meeting needs;
- make recommendations to the Secretary, the Commissioner, and the Director of NIHR respecting ways to improve research

concerning disabled individuals, and the methods of collecting and disseminating the findings of such research and to make recommendations for facilitating the implementation of programs based on such findings; and

- submit annually a report to the Secretary, Congress, and the President containing: a) a statement of the current status of research concerning disabilities in the United States; b) a review of the activities of RSA and NIHR; and c) such recommendations concerning (a) and (b) as the council considers appropriate.

Since the National Council was not appointed and confirmed until September 1980, it has only begun its work. Its first task was a review and revision of NIHR's 5-year plan.

Veterans Administration. -As mentioned earlier, VA has been involved in disability-related research since the late 1940's. For many years, VA was the primary supporter of federally sponsored research in this area, especially in the field of prosthetics research. Since 1947, VA has spent over $25.5 million on prosthetics research alone, not including the money devoted to the support of the VA Prosthetics Center on the VA Research Center for Prosthetics in New York City (152). In the last few years, VA has expanded its disability-related research focus to include a broader range of areas. The establishment of the Rehabilitation Engineering Research and Development (RER&D) program is the VA's response to the increased research and service needs of the veteran population and of disabled people in general.

The VA health care system is the largest health care delivery organization in the Nation. It encompasses 172 medical centers, 100 nursing homes, 16 domiciliaries, and 229 outpatient clinics. VA employs the full-time equivalent of approximately 181,440 physicians, dentists, nurses, and administrative and support personnel (218). Further, there are an estimated 28 million veterans over age 40 who are eligible for health care services should the need arise (151). VA presents a unique example of a system that includes the continuum of clients, needs, facilities, money, personnel, and the mandate to develop, deliver, evaluate, and support a full range of technologies and services to disabled individuals. It also provides an excellent setting for the evaluation of medical technologies. Neither VA, the private sector, nor any of the other Federal agencies has made much use of this system for such evaluation. The service aspects of the VA system are discussed in greater detail later in chapter 9.

VA has three centers that perform or support varying types of rehabilitation R&D. One, the VA Prosthetics Research Center in New York City, is organizationally separate from the RER&D program. The two other centers are directly tied to the VA RER&D program: one located in the Palo Alto VA Medical Center in California, and one in the Hines VA Medical Center in Chicago. The RER&D program is also establishing university-affiliated research engineering programs to help support qualified engineering graduate students and faculty who undertake rehabilitation engineering projects (37). The thrust of this program is twofold: 1) to interest engineering students in rehabilitation engineering (a critical shortage of trained rehabilitation engineering professionals exists in this country*); and 2) to infuse new ideas and concepts into the VA RER&D program by having a flow of information on program needs and possible solutions between academia and VA. In addition, the RER&D program supports investigator-initiated projects, both intramurally and extramurally, that are outside the efforts of the two RER&D centers. With the strengthening of in-house capabilities at the RER&D centers and in the university-affiliated programs, however, it is moving away from extramural support.

The RER&D program is a result of the increased focus on rehabilitation research and engineering needs at VA and at the national level in general. In 1973, this program was separated from the general R&D efforts of VA and given the mandate

*In 1976, a workshop held at the University of Tennessee recommended that a master's degree in rehabilitation engineering be established for qualified engineers and that it include training in computer science, anatomy, clinical medicine, and appropriate engineering disciplines. These recommendations were made with the following factors in mind: 1) there are currently (in 1976) only 50 individuals designated and functioning as rehabilitation engineers; 2) the current estimated need is for 250 rehabilitation engineers; and 3) the projected need for rehabilitation engineers is 1,ooO in 5 years and 2,000 in 10 years (123).

to improve the quality of life and facilitate greater independence for physically disabled veterans. The program is to do this through research, development, and evaluation of new devices, techniques, and concepts in rehabilitation. In addition, the RER&D program is required to coordinate and cooperate with NIHR and to support RECs. (This does not mean that VA is obligated to assist these centers financially. Rather, support takes the form of information exchange and consultation regarding ongoing efforts at both agencies.) The RER&D program is primarily a hardware—sophisticated technology—oriented effort that has as its major goal the development of usable devices that assist individuals, have an impact on the delivery of clinical services, or assist in increasing the availability of new devices on the open market. The RER&D budget was $8.1 million in fiscal year 1980 and is estimated to be $8.8 million in fiscal year 1981. The personnel ceiling is 143—including centers, university programs, and RER&D staff. Table 3 summarizes the budget distribution and the priorities and research goals established by VA. Table 4 provides an overview of the RER&D budget in relation to the VA's overall medical and health services research effort (37).

Table 3.—Veterans Administration RER&D Budget Distribution (thousands of dollars)

	Fiscal year 1980	Estimated fiscal year 1981
RER&D centers and affiliations	$2,425	$2,450
Amputation/surgical procedures	1,483	1,547
Prosthetics/orthotics	910	1,045
Blindness and visual impairment	749	823
Hearing and speech impairment	729	804
Kinesiology (Gait analysis)	543	682
Mobility	524	576
Spinal cord injury	269	297
Maxillofacial restoration	212	230
Robotics.	165	196
Functional electrical stimulation or neural control	119	134
Total ., ... , ., ...	$8,085	$8,784

SOURCE. Veterans Administration

Other Federal Agencies .—NASA and NSF are also involved in hardware-oriented research in this area. NSF's authorizing legislation (Public Law 95-434) for fiscal year 1979 included $2 million for disability-related research programs in the Applied Sciences Research Applications Directorate. NSF has supported grant requests dealing with various aspects of disability-related research. Two examples are: 1) the Johns Hopkins University project on personal computing to aid disabled people—a project in conjunction with the Tandy Corp. to develop computer-based programs and ideas to aid disabled individuals; and 2) a project to develop a graphic computer display that blind and visually impaired people can use to create, edit, interpret, store, and retrieve full page braille and tactile programs. Other projects include "Micro-Processor-Based Prosthetic Controls" and a "Needs and Design Concepts for Voice-Output Communications Aids" grant (157). Given the current budget situation and research goals of NSF, however, it is unlikely that this program and NSF's interest and involvement in disability-related research will thrive.

In the late *1970's,* Congress formally expanded the mandate of NASA by adding bioengineering for disabled people to its functions (Public Law 95-401). Congress felt that (211):

> The general welfare of the United States requires that the unique competence of NASA in science and engineering systems be directed to

Table 4.—Veterans Administration R&D Budget Overview (thousands of dollars)

	Fiscal year				
	1977	1978	1979	1980	1981
Medical research program	$101,567	$108,153	$118,016	$122,745	$129,943
Staffing. ., ., ...	4,220	4,367	4,217	4,171	4,171
RER&D program	4,419	5,502	7,191	8,085	8,784
Staffing.	69	90	112	143	143
Health services R&D program	3,604	2,996	3,004	3,153	3,083
Staffing.	45	90	105	104	104

SOURCE: Veterans Administration

assisting in bioengineering research, development, and demonstration programs designed to alleviate and minimize the effects of disability.

NASA has been involved in transferring technology and information gained from its bioengineering efforts, as well as its general research efforts, to the health care sector since the late *1960's.* Biomedical applications teams attempt to: 1) identify and interpret national trends in medicine as well as technology-related problems in health care delivery, and 2) develop potential solutions to these problems through the use of aerospace technology *(227).* NASA tries to pursue technology transfer opportunities when it finds that: 1) a problem is recognized as significant by medical agencies; 2) a solution in the form of a commercially available product is not available or anticipated; 3) a solution would make a significant contribution to medical research or to clinical practice; 4) the problem can be defined in terms that indicate the applicability of aerospace technology; 5) the solution requires application engineering rather than basic research; and 6) the application has a high probability of success in the marketplace (227). Figure 4 illustrates the process that NASA employs to implement these guidelines. It also provides a model that might be useful as a general guide to the technology transfer process of other Federal agencies involved in disability-related research, development, and diffusion.

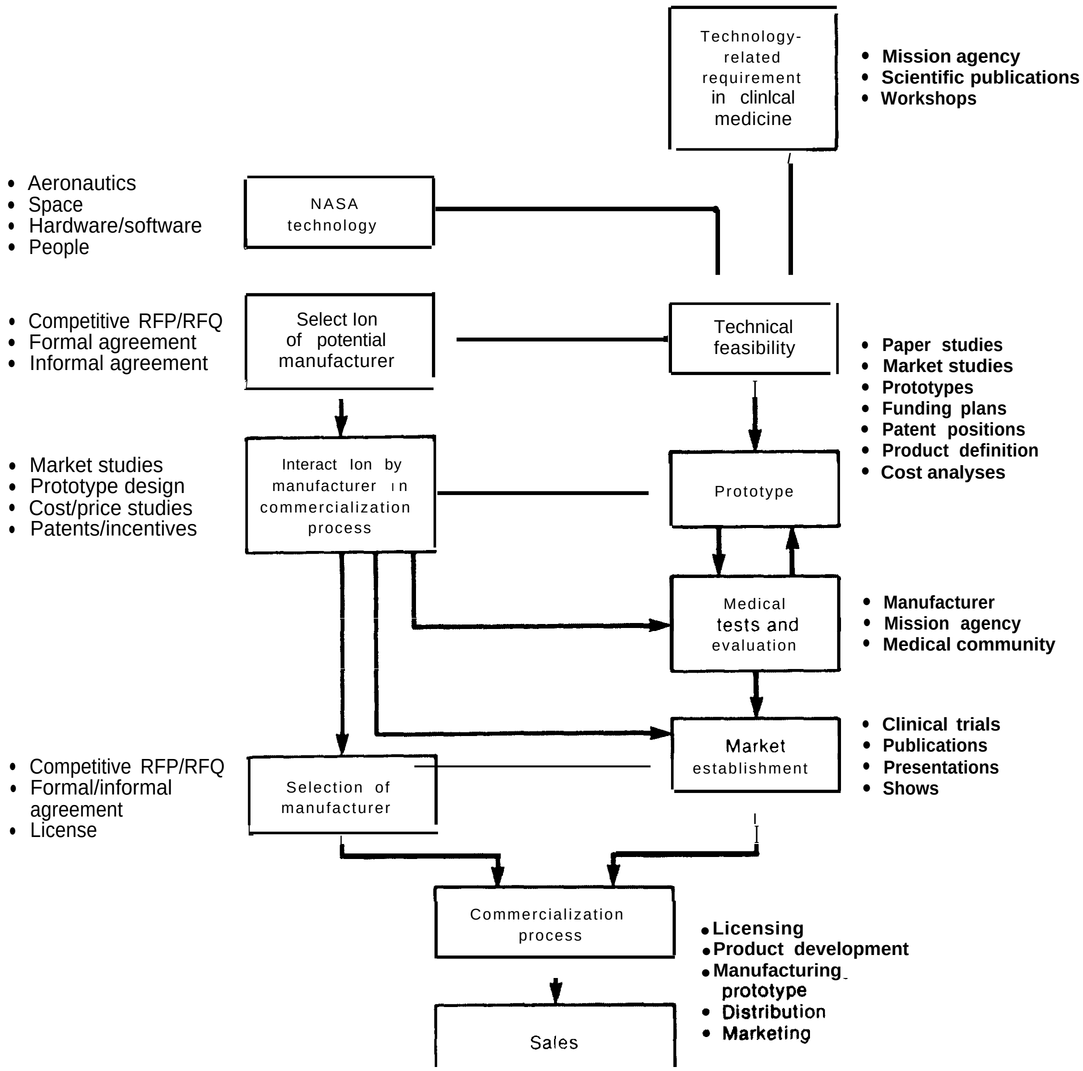
NASA has attempted three types of bioengineering applications projects—commercial, institutional, and demonstration. Commercial projects are those that directly involve a manufacturer; institutional projects are those developed by a Federal agency; and demonstration projects are ones for which NASA develops the prototype on its own *(227).* An example of a commercial project is the fully implantable, programmable, rechargeable human tissue stimulator that was developed in conjunction with the Johns Hopkins Applied Physics Laboratory. An example of an institutional project is the Autocuer, an automated speech analyzer developed as a joint venture between NASA and VA, on the basis of initial work sponsored by NINCDS, with the involvement of NSF, the Research Triangle Institute, RSA, Bureau of Education for the Handicapped, and a Gallaudet College scientist. The liquid-cooled garment used for temperature control is an example of a demonstration project that NASA pursued as a result of its research that had potential in the biomedical/disability area. Other examples of NASA's technology development and transfer efforts are the rechargeable cardiac pacemaker battery, heat activated switches, **a** hand-finger flexor, and biocompatible pure carbon that has proven very useful in prosthesis attachment materials *(226).* Obviously, research in the area of disabilities is not NASA's primary focus; rather, it is **a** lower level priority to be pursued as part of NASA's overall research and technology transfer efforts. NASA devotes about $600,000 to $750,000 to projects related to disabilities, and less than $2.5 million to its entire bioengineering applications programs.

Other Federal agencies that fund R&D programs in the disability-related area are DOT, the Department of Labor, NBS, the Department of Commerce, the Food and Drug Administration, the Health Care Financing Administration, the Social Security Administration, and DOD. These and other agencies have varying degrees of involvement in research on disability-related issues. Recent legislation and the increasing militancy of advocacy groups have forced many Federal and State agencies to examine a wide variety of issues in this area.

RSA is primarily oriented towards the delivery of services at the State and local level via its matching grants programs, which include a small percentage of funds for innovative programs to improve the quality and delivery of services. Most of its research programs were shifted to NIHR when that agency was created in 1978.

OSE still retains a significant research budget that is geared mostly toward the "soft" research areas (i. e., nonhardware directed areas of research). OSE is the third largest Federal supporter of disability-related research and the largest in the area of educationally related efforts. OSE's research priorities include programs for deaf-blind, severely disabled, and gifted and talented persons, for early childhood educational programs, for media and research uses, and for special education personnel development projects.

Figure 4.— NASA'S Technology Transfer Process



SOURCE R P Whitten Technology Transfer NASA s Bioengineering—Applications Program, " *Medical Devices and Diagnostic Industry Monthly* September 1980

NIH presents an interesting definitional problem. A very good argument could be made that most of its basic and applied biomedical research directly *or* indirectly affects currently *or* potentially disabled people. NIH then becomes the runaway leader in the disability-related research area. Using a more restricted set of criteria still puts NIH near or at the top in terms of resources devoted to research in this area.

NINCDS is currently supporting research on regeneration of spinal cord, or the central nervous system (CNS) nerve tissue. Such research is potentially of great value to the population with spinal cord injuries (103). NINCDS also has a Neural Prosthesis Program that is currently working on a project involving artificial control of the bladder through electrical stimulation (103). Persons with muscular dystrophy, multiple sclerosis, cerebral palsy, speech, and other communication impairments, as well as accident victims, may benefit from a device developed at the University of Idaho with funding from the Division of Research Resources at NIH. This device allows a nonvocal individual to work with a computer and video screen to communicate (67). These examples illustrate the NIH involvement in a mixture of biomedical and, to a degree, engineering projects that are very relevant to disabilities.

The Private Sector Role in Disability-Related Research

It is difficult to characterize the "private sector" involvement in disability-related research. The private sector may mean a large, multinational, multiproduct, billion-dollar-a-year company like the Johnson & Johnson Corp., or it may mean a small, single-product firm like Amigo Sales Co., or possibly a private nonprofit organization such as the Cystic Fibrosis Foundation or Muscular Dystrophy Association. These diverse organizations provide a wide variety of products and services to disabled people. However, each is quite different from the others in terms of priorities, resources, and function. Manufacturers of health-related devices that specifically serve disabled people are frequently referred to as part of the medical device industry. In addition, there are thousands of agencies that derive their funds from charity or provide philanthropic services; these may be foundations, service organizations, funds, or associations. The medical device industry and charitable foundations and related organizations are both extremely diverse groups that exist to serve an equally diverse "market ."

The value and impact of voluntary contributions to the health care sector of society are significant. In 1980, Americans contributed a record $5.95 billion to health causes and hospitals (3). Table 5 provides a breakdown of the major health-related organizations (3). Most, if not all,

Table 5.—National Health Agencies

Agencies	1979 Total	1979 Contributions	1979 Beauests	1978
American Cancer Society, Inc.	$142,138,732	$102,778,011	$39,360,721	$126,106,570
American Heart Association	82,938,148	59,594,573	23,343,575	73,801,722
The National Foundation	65,170,640	63,765,738	1,404,902	64,692,941
Muscular Dystrophy Association, Inc.	65,016,996	62,736,755	2,280,241	57,635,996
National Easter Seal Society	52,000,000'	46,323,000[a]	5,677,000*	46,921,946'
American Lung Association	47,000,000*	45,500,000[a]	1,500,000[a]	45,548,629'
Planned Parenthood Federation of America, Inc.	35,000,000*	34,500,000*	500,000*	29,334,747[c]
National Association for Retarded Citizens	34,465,963*	33,851,235*	614,728*	30,605,321'
National Multiple Sclerosis Society	27,242,099	26,052,827	1,189,272	25,206,469
United Cerebral Palsy Association, Inc.	24,888,956*	24,274,853*	614,103*	20,010,219[c]
The Arthritis Foundation	18,000,000*	14,000,000*	4,000,000*	17,109,399C
Mental Health Association	15,000,000*	14,640,000*	360,000*	14,811,703'
Cystic Fibrosis Foundation	14,500,000*	14,450,000*	50,000*	12,723,617[c]
American Diabetes Association, Inc.	11,996,043	11,433,379	562,664	10,945,701[c]
Leukemia Society of America, Inc.	11,314,627	10,850,156	464,471	10,757,023
National Kidney Foundation	9,306,368	9,088,429	217,939	7,739,719
National Society to Prevent Blindness	5,600,000*	3,600,000*	2,000,000*	4,799,622'
Epilepsy Foundation of America	4,800,000*	4,500,000*	300,000*	4,755,719'
Recording for the Blind[b]	3,642,594	2,928,619	713,975	3,384,646
Juvenile Diabetes Foundation	3,261,061	3,261,061	—	2,498,083
The National Hemophilia Foundation	3,100,000*	3,100,000*		3,500,000
American Foundation for the Blind, Inc.	2,459,967	1,131,515	1,328,452	3,875,444
Damon Runyon-Walter Winchell Cancer Fund	1,009,225	140,452	868,772	2,498,083
National Council on Alcoholism	845,582	783,272	62,311	966,425
Total	$680,697,001	$593,283,875	$87,413,126	$622,229,744

[a] Estimate
[b] Educational Organization
'Revised

SOURCE American Association of Fund Raising Council, Inc , *Giving U .S A 1980 Annual Report,* 1980 of the top 24 health-related agencies deal directly, or certainly indirectly, with a range of disabling and handicapping conditions. Many of these organizations support ongoing R&D efforts in their areas of interest. Often, these organizations are primary actors in the development, delivery, and purchase of new technologies for their constituent groups. With yearly budgets in total exceeding $680 million, these organizations are powerful forces in the disability-related R&D system and are significant contributors to the service delivery system as well.

The general medical technology industry is a collection of over 3,000 firms responsible for over 12,000 products at an annual sales level of over $9 billion (34,221). In terms of firm size, 80 percent of the medical technology companies have annual sales of less than $20 million; the remaining 20 percent are much larger and, in almost all instances, are multiproduct companies (221)—e.g., Johnson & Johnson had total sales in 1975 of $2.25 billion, American Hospital Supply Corp. claims to distribute over 57,000 different products, and Everest & Jennings had gross revenues of $51 million in 1975 (34). One study, by Wenchel, found that there are essentially two types of companies in this industry: large, multinational and multidivisional companies with a variety of products; and smaller, single- or several-product firms (221).

Several studies have indicated that the industry is somewhat noncompetitive (34,221). Yet, Wenchel points out that in the realm of technical innovation (rather than in the cost of products), there does seem to be some competition (221). She further states that the market is highly responsive to new products, with a high entry and exit rate among new firms, especially among the smaller firms. The small, single- or several-product firms are often the ones introducing innovative technologies into the marketplace; this is their ticket into the arena (221):

> The measures of R&D and patent activity reflect a higher level of innovation than can be found in most industries in the U.S. economy . . . The medical technology industry appears to have maintained its levels of R&D by providing funding that the Federal Government had previously provided. Further, the level of patent activity is twice that existing in other industries throughout the U.S. economy.

A great deal of debate surrounds the issues of how much R&D is enough, who should do it (e.g., should Everett & Jenning support more R&D on wheelchair design, or just wait for and use the results of the numerous federally sponsored studies in this area?), and who should benefit financially from the complex interaction of private/public/nonprofit sponsored research efforts.

It is difficult and perhaps deceptive at times to use an industrywide description-medical devices industry-to characterize the efforts of a single firm or a specialized group of firms. The industry is too diverse, even if one can narrow the category to disability-related firms. Perhaps one good indicator of what and how much activity is going on is the visibility and frequency of articles in general circulation publications. When innovations or trends reach this level of the business community's or the public's awareness, especially in a specialized area such as this, then there may be a significant level of activity below the visible surface.

Articles in *Business Week* (24,25), Medical *World News (139,140), The New York Times (160), Discover (220),* and the Wall *Street Journal* (190) are representative of the "general circulation" accounts of the increase in corporate interest, investment, product development, and marketing of technologies for disabled people. Most of the activity that has reached this level of recognition, though, has been in the area of fairly sophisticated technology. It is almost a certainty that by far the largest share of corporate interest is geared toward the application of emerging technologies that are hardware based. Examples of the types of technologies that have received media attention are the Kurzweil Reading Machines, electronic communication devices, voice-command control systems, new types of wheelchairs, (the Amigo, the Levo chair, and battery-powered chairs), the Lifeline Emergency Alarm and Response System, the Autocom, environmental control systems, bionic prostheses, robotics, television captioning systems, microcomputer controlled implants, the Optacon, and artificial organs. Obviously, these technologies are the "gee-whiz" offerings that are in, or coming into, the marketplace, This observation does not mean to say that there is no activity in the more mundane, yet critical, areas of disability-related R&D—but the latter type of activity is not as evident or glamorous, and possibly not as rewarding (intellectually, scientifically, or financially) to many scientists and investors.

DISCUSSION

The research goals and priorities in the disability-related R&D process are, to state it mildly, diverse and challenging. The Federal agencies working in this area have extremely broad mandates to address very complex and difficult problems. The research agenda of NIHR alone is overwhelming. The agencies will not be able to do it alone. Private and nonprofit organizations are key components in the R&D process. To date, Congress has recognized great potential in R&D related to disabilities, but the organization of the R&D effort has been inadequate for substantial results. The Federal Government devotes approximately 0.7 percent of the total amount of health-care related research funds to research directly related to disabilities. The annual expenditure for direct disability-related R&D has been estimated to be between $1.00 and $2.92 per disabled person (210). The private sector's contribution is very difficult to determine, but it, too, appears to be less than the amount that could profitably be used. The purpose, though, is not to arrive at precise figures, but rather to obtain and provide a general sense of the level of public and private commitment to the needs of disabled people. The R&D activity is a very important component of the effort to meet those needs. The current research needs are extensive. The ability of the Federal Government to reach those goals, given current outcomes of R&D, is limited.

It is possible that the combined efforts of NIHR, VA, NASA, RSA, DOD, the many other agencies that are involved in this process, and the private sector will be able to make a significant contribution to the population of disabled people. There is reason for some optimism. The focus of R&D, while still firmly entrenched in the "hardware" approach to solving problems, is slowly changing to incorporate and value the work in services, delivery systems, appropriate technology solutions to problems, evaluation of R&D efforts, and the other inputs that are necessary to the "total" rehabilitation of the individual. The research network is being formed to combine these varied fields of investigation. The challenge is to fit the parts together to make a coordinated, comprehensive, and effective research effort that will respond to the changing needs of increasingly active and independent disabled people.

The use of the peer review and advisory council system to assess the value and performance of research products and the likelihood of success of research proposals, deserves attention. Various agencies have different approaches to making use of committees of experts and in-house professionals to judge the quality of the programs and research proposals being funded and the resulting research products.

VA uses a combination of in-house professionals, the directors of its various departments and programs, in conjunction with a panel of non-VA experts drawn from a range of disciplines. This two-level process is used to help set research priorities and to conduct reviews of research proposals and results. The NIH dual advisory/peer review system is well known and does not need elaboration here. The existing peer review systems in other agencies are usually variations on the NIH system.

The RSA peer review system has been an "on-again, off-again" system over the last decade. Currently, it is an "on-again" system that uses the "project announcement in the Federal Register" system as the first step in the process. From there, proposals submitted are routed to internal RSA staff and, if appropriate, to relevant regional rehabilitation officials. There is also a peer review process for research proposals that is conducted by non-RSA, non-Federal Government experts (97).

NIHR also goes through the program announcement process in the Federal Register. In the past, this process was followed with a weak, infrequently applied peer review process. The agency is now in the process of implementing a formal peer review process in its project/program selection and evaluation process, The VA system is much better established and has been more effective than NIHR's. NIHR, prior to the recent changes, concentrated most of its priority-setting efforts in the long-range plan development process.

It should also be noted at this point that announcing project proposals in the Federal Register may satisfy public notification requirements, but it does not guarantee quality research. Often these announcements can be so vague and all-inclusive that the agency discretion retained in the selection process is almost unbounded. Peer review systems are workable and effective only if the spirit of the process is honored rather than just the letter of the law.

An idea suggested to OTA is the removal of much of the peer review process in favor of much stronger program and project manager systems. To a large degree, this idea follows the administrative model used by NASA—i. e., a very goal-oriented, results-directed approach where the various program and project directors are given significant leeway within the general goals of the project being conducted. The effectiveness of the personnel involved and the quality of work being conducted are measured in terms of the performance and success of the program and project. The advantage of a system such as this, especially in an applied research setting, is that once the program or project goals are established (possibly the most difficult part of this approach), the various administrators and scientific personnel are left to reach their goals in the most effective and efficient means at their disposal. There are many obstacles to using this approach, but it is worth noting and perhaps considering (at least on a pilot or demonstration basis) for certain projects. This system seems less appropriate for the setting of research priorities or the awarding of initial R&D contracts and grants.

The disability-related R&D system at present is primarily operating on a basic research model—i.e., one where the funding agencies react rather than act. This approach seems appropriate for basic-research-oriented programs and projects. However, a large part of this R&D area is geared to applied research goals and needs. OTA was frequently told that there are numerous, potentially useful devices in existence: "We are overwhelmed by available technology; we just need to get it to the consumers so they can adopt it to their uses at a price they can afford."* Having Federal agencies or researchers attack these "applied research" problems a piecemeal and basic research approach only exacerbates the view that little of value has resulted from the money, time, and efforts of the myriad research centers and programs supported by the Federal Government.

The alternative to the "goal-oriented" approach is a system of rigorous peer review. The NIH dual review system has served the biomedical and health care systems well. By adopting a similar, though modified, system in this area, the resulting information and products that come out of the federally supported disability-related R&D process may be of a higher quality and thus useful to a wider range of consumers, researchers, manufacturers, and others. On the basis of its research and the results of its public outreach survey, OTA finds that there is a common perception, though certainly not a unanimous one, on the part of consumers and the scientific and professional communities that much of the research conducted in this federally supported system is of poor quality. Strengthening the formal peer review systems of this process could help to alleviate some of these problems. However, effective evaluation mechanisms are very much dependent on the "state-of-mind" in an organization and should be more than a pro forma attempt at satisfying a legislative or agency requirement.

* Other people, however, believe that "overwhelmed" is a deceptive term. They believe that there are some technologies ready for diffusion but that other existing technologies need to be better developed prior to widespread use.