

gap, discussions have been held with industrial leaders who have offered advice on the nature of the rehabilitation market, which is just one impediment. Based upon the input of these industrial leaders, commercial availability is being attacked on two fronts.

First, an interagency agreement with the Department of Commerce has been developed to assist small minority business firms in tooling-up for offering new products as a part of their commercial lines. Specifically, the interagency agreement provides for the study of marketing and development methods to fully utilize the research and development of new devices for the disabled. The purpose of this interagency agreement is to utilize existing programs in the Minority Business Development Agency (MBDA) and stimulate marketing for devices that result from VA-sponsored R&D.

The National Commission of Technology Transfer, of the Department of Commerce, is in the process of offering funding in order to:

- plan for an international conference on making prosthetic and orthotic devices and sensory aids readily available to the handicapped population;
- identify and develop potential markets and financing for such devices;
- examine the use of microcomputers and other high technology areas;
- examine the impediments to obtaining funding for high-technology products; and,
- develop a process that leads to the commercialization of technology researched and developed by the VA, with emphasis on providing access to these markets for minority entrepreneurs.

Arrangements have been made to encourage private industry to adopt the results of individual research products which are judged to have particular merit. As a result of these efforts, the Johns Hopkins Manipulator will soon be commercially available. Other negotiations are continuing. To facilitate this process, VA Rehab R&D has assisted in the creation of a National Commission for Technology Transfer, which is concerned with making research results commercially available to handicapped people.

New Directions

Future plans by VA Rehab R&D to assist in the transfer of technology from research to clinical practice are as follows:

- Continued publication of the *Journal of Rehabilitation R&D* and the *R&D Progress Reports*;
- Publication and distribution of papers on subjects potentially relevant to future clinical practice (e.g. training manual for use of robotic systems for the severely disabled);
- Design and implementation of a formal research program, based at the Office of Technology Transfer, to evaluate and improve the transfer of technology, including:
 1. The collection of clinical practice data from VA facilities to give a chronological picture of the gap between state-of-the-art devices and actual clinical practice;
 2. A series of consumer surveys to determine their needs and to uncover problems or frustrations with existing rehabilitation procedures and equipment; and,
 3. A series of surveys among clinical practitioners to collect data on clinical needs, problems and priorities.
- A periodical and/or a technical communication in existing periodicals for clinicians, designed in cooperation with PSAS, the Academy, AOPA, AAOS, Paralyzed Veterans of America, Disabled American Veterans, National Institute of Handicapped Research, and other organizations to further enrich the transfer of new research findings to clinicians in a format tailored to their practical needs. In the long run, a computerized reference system may be developed;
- Seminars on selected topics between recognized clinical leaders and senior researchers who have achieved scientific breakthroughs relevant to clinical practice; and,
- Access to national and international scientific and clinical literature.

These thrusts are ambitious and will take time, but they convey the depth of Rehab R&D commitment to technology transfer.

Prosthetic-Orthotic Research—A New Thrust is Needed: A Clinician's Perspective

Charles H. Epps, Jr., M.D.*

Since the prime supporter of research, the federal government, has sharply reduced some areas of funding, the efforts of many established investigators and programs have been curtailed. Hardest hit has been the young aspiring investigator without a track record, who has found it virtually impossible to acquire funding for initial research efforts. Basic research as well as clinical research has suffered. Prosthetic and orthotic research programs which have never had abundant or even adequate funding also have been adversely affected.

In the area of upper extremity prosthetics, much research remains to be done. For the patient who wears a prosthesis, cosmesis is still a major concern. Cosmetic acceptability must be improved and sensory feedback must be developed; sockets must be made more comfortable and suspension must be improved. Myoelectric con-

trol systems and other methods of external power must be made more functional, more compact, and more economical.

In the lower extremity, newer materials and techniques must be developed to make prostheses lighter in weight, especially for the geriatric wearer. Although there seems to be less enthusiasm today for skeletal attachment of prostheses, the concept remains a challenge. The mechanical integrity and durability of knee devices can be improved along with fitting and alignment techniques.

Because of basic lack of knowledge about the effects of forces on bone, ligaments and tendons, the need for orthotic research is even greater than in prosthetics. More

*Division of Orthopaedic Surgery, Howard University Hospital, Washington, D.C.

needs to be known about the magnitude and patterns of forces that are necessary and safe to orthotic applications. Workers in kinesiology and gait laboratories around the country are endeavoring to find more answers to diagnostic problems and to collect useful data for orthopaedic assessment and even surgical treatment. New materials offer the orthotist new versatility. The pneumatic orthosis, a new concept, is ready for full development. Electrical applications are at an embryonic stage in the stimulation of paralyzed muscles, inducing therapeutic exercises, and providing afferent or feedback systems. New interest has developed to improve powered mobility devices to replace the conventional electric wheelchair for the high level spinal cord injured patient. Specially adapted vans can be operated safely by paralyzed, limb deficient patients and other severely handicapped. In view of the potential offered by computer applications and rapidly improving robot technology, environment control devices are on the threshold of great advances. So much remains to be done in prosthetic-orthotic research that even the casual observer must be concerned.

At the same time that public research dollars have decreased, private research dollars have not increased sufficiently to fill the void. Obviously, research needs offer a challenge to orthopaedic surgeons who must increase the amount of personal time and funds given for research. At least one encouraging sign of private sector philanthropy exists. Bristol-Meyers/Zimmer U.S.A. has donated 1.2 million dollars to the Orthopaedic Research and Education Foundation (OREF) for the 1983-1984 Campaign. To date, more than 150 orthopaedic surgeons have given \$1,000 each to OREF for the current campaign. This is in sharp contrast to the previous years' total of \$200,000 from all sources. Other members of the industrial community should duplicate and even surpass the example set by the Zimmer group.

If this instance of giving by the orthopaedic surgeons and a prime industrial supplier is replicated by prosthetic-orthotic practitioners and members of the corresponding industrial manufacturing community, the funding for prosthetic-orthotic research can be adequately raised to support needed research programs.

From Research Lab to Consumer: The Manufacturers' Point of View

Carlton Fillauer, CPO*
Charles H. Pritham, CPO†

The matter of transferring new developments from the researcher to the consumer is one that has bedeviled the American prosthetic-orthotic establishment for years. The researcher, the agency that funds the research, the manufacturer, the clinician, and the patient are all, of course, interested in seeing new products brought to market, and all stand to benefit. Financially, the manufacturer is the one who stands to benefit the most from the successful introduction of a new product. Only by such means does a manufacturer expand his base and increase earnings. If the incentives are greatest for a manufacturer, the risks are also proportionately greater. In making a decision to produce a new product, the manufacturer must weigh the risks against the potential benefits and make a decision about committing his resources. It should be obvious that once resources of time, effort, and money are lost backing an unsuccessful product, they are lost forever. What is not so obvious is the fact that the loss is threefold.

Potentially, at least, the resources expended for backing a losing product could have been invested in a successful one, turning a loss into a profit. Also, in making the decision to back a new product the manufacturer commits his prestige and credibility. A positive result resounds to his credit, attracting new attention to products currently being produced and assuring a positive reception for future products. A negative result has the opposite effect, tarnishing the image of other items in the manufacturer's product line and damaging his credibility. That the investment in a new product can be a high one should not be discounted, therefore.

A small group of highly skilled and motivated individuals (or an inventor working alone) can, with a relatively low investment in machinery, produce complicated prototypes efficiently and with a low rejection rate. When

the time comes to produce the same object in large numbers, the factors are fundamentally different. Production workers are seldom so skilled or motivated. Oftentimes, to overcome bottlenecks in production and to achieve consistent results, a product must be redesigned. The cost of this redesign must be borne by the manufacturer. To achieve productivity and consistent results, the manufacturer will develop tools, dies, and molds with which to produce a device. Resorting to such an alternative can enable relatively unskilled personnel using inexpensive materials to produce products of great appeal and excellent quality. While the material costs of such objects can be measured in the cents, the cost of the molds and dies can frequently run in the thousands of dollars each. If it is necessary to produce the device in a range of sizes and in right and left, the cost can be prohibitive. It should also be borne in mind that the researcher or inventor frequently has only partially tested the prototype and further testing and development must precede redesign for production. The direct expense of manufacturing an object, however, is only a portion of the cost.

In order to sell a product it must be promoted and advertised. The total expense of attending a convention (often far from home), renting space to exhibit, and obtaining a suitable display is not cheap. Commissioning the art work and copy of an advertisement, and obtaining space for it in a journal are, similarly, of considerable expense.

The organization that makes all this possible (research and development, production, and promotion) can fre-

*Vice President, Durr-Fillauer Medical, Inc., Orthopedic Division, 2710 Amnicola Highway, Chattanooga, Tennessee 37406.

†Technical Coordinator, Durr-Fillauer Medical, Inc.