5.

# Survey of Wheelchair Manufacturers

# 5. Survey of Wheelchair Manufacturers

## SURVEY METHODS

Eleven wheelchair manufacturers chosen from a list developed from products listed in the National Rehabilitation Information Center's data bank, ABLEDATA, on about July *1, 1983,* were interviewed between July *15* and August 31, 1983. This list might be imperfect due to lags in updating ABLEDATA about new or discontinued products, but was the best available. Ten of these manufacturers were selected through a sequential sample designed so that the larger the number of products listed for the manufacturer, the greater its chance of being selected (see app. A). This sampling process made the sample less prone to bias from any ability to update the list. (Most updates would probably apply to small manufacturers. ) The principal investigator wrote a letter to manufacturers selected for the survey describing the study and kinds of information sought (history of past innovations and descriptions of R&D activities), and inviting them to participate. When one company declined to participate due to time constraints, a replacement was chosen through the process of sequential selection.

None of the companies chosen at random manufactured power alternatives to wheelchairs. Amigo Sales, Inc., was then chosen as a representative of that group on the basis of its previous work with the U.S. Congress' Office of Technology Assessment (OTA) and the availability of its information on the products. This brought the total to 11 companies surveyed. The officials of selected manufacturers were then interviewed by telephone according to a semi-structured set of questions (see app. B).

## INNOVATIONS OF THE PAST DECADE

Respondents were asked to identify their most significant innovations over the last 10 years. Many such innovations focused on increasing the mobility of wheelchair users (table 5), particularly the active user (table *6)* who is apt to want a chair that is eas, to use (lightweight and easy-rolling); transportable (lightweight, easy to disassemble, folding); durable; and safe to use outdoors. Dynamic brakes, which keep the wheelchair from gaining speed when going downhill, are a helpful safety device to an active person.

Most manufacturers interviewed identified higher cost of an innovative product as the largest impediment to marketing new devices, but surprisingly only one manufacturer specifically identified low cost to the buyer as an advantage to an innovation. One possible explanation is that manufacturers do not perceive reducing the cost of their product as a significant concern to wheelchair users, due to the high percentage of wheelchairs paid for by third-party payers. Perhaps Medicare's prevailing charge system creates a price umbrella. As copayments and competition increase, as seems likely, manufacturers may begin to be more concerned with lowering product cost.

All of the innovations identified by the manufacturers were currently available at the survey date, possibly because manufacturers are eager to sell their present products or because they did not think of or care to mention products that are not current. It may also be that most of the innovations identified are so recent that they have not yet become obsolete. Indeed, all five innovations for which dates reported were developed within the last 4 years (see table 7).

Most of the innovations identified were improvements of existing products (table 8). Seven innovations were based on personal experience and identification of unmet needs; three of them

**Table 5.–Wheelchair Innovations, 1973.83**

| Code[a] | Innovations | Features/advantages |
|---|---|---|
| ***Manual wheelchairs:*** | | |
| M1a | lightweight manual | • lightweight<br>• disassembles |
| M1b | lightweight manual | • serves active user<br>• lightweight<br>• low-friction tires and bearings |
| M2 | compact folding chair | • folds in one piece<br>• lightweight<br>• fits compact car trunk |
| M3 | free-rolling chair | • lightweight<br>• stainless, noncorrosive frame |
| M4 | stainless chair | • stainless, noncorrosive frame<br>• conventional design<br>• Improved bearing construction<br>• lightweight<br>• durable construction |
| ***Power wheelchairs:*** | | |
| P1 | proportional control box | • high-technology joy stick<br>• solid-state circuitry<br>• infinite variability in speed and direction |
| P2 | folding electric chair | • lightweight<br>• electric<br>• folding |
| P3 | lightweight electric | • electric<br>• lightweight<br>• disassembles |
| P4 | power wheelchair | • dynamic brakes<br>• automatic steering correction<br>• lightweight |
| ***Sports wheelchairs:*** | | |
| S1 | sports chair | • lightweight<br>• 16 different seating positions<br>• adjustable seat/back heights<br>• lifetime warranty on frame |
| ***Power alternatives:*** | | |
| PA1a | three-wheel alternative | • three wheels<br>• disassembles<br>• dynamic braking<br>• narrow<br>• usable in planes<br>• extendable wheelbase<br>• adds stability<br>• optional elevating seat |
| PA1b | three-wheel chair | • swivel seat<br>• disassembles<br>• narrow<br>• three wheels<br>• controls on handlebars<br>• ''looks fun' |
| ***Accessories:*** | | |
| Acl | telescoping leg rests | • infinite number of positions<br>• better support |
| Ac2 | solid seat | • better support |
| Ac3 | conversion kit for E&J power drive | • increased speed<br>• durable<br>• simple to service<br>• low cost |

[a] Innovations identified through the survey were categorized as being for manual wheelchairs (M), power wheelchairs (P), sport S wheelchairs (S), Power alternatives (PA) or wheelchair accessories (Ac) Within each category. the products were randomly assigned code numbers Small letters after an Innovation code are used to differentiate between products of similar description

SOURCE D S Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

also used existing technology. Only 4 of the 15 innovations used technology from other fields. They were from simpler fields, such as bicycle and stretcher manufacturing. Many people in Government R&D centers believe that current high technology is not being fully utilized by the wheelchair industry. The survey found no instances of high technology transferred to wheelchairs. The case study of the Power Rolls® IV, however, showed an application of state-of-the-art electronics. It incorporated a wheelchair controller with self-correcting steering on slopes (see ch. *6).* This survey suggests that existing R&D or marketing are often inadequate for the transfer of high technology.

**Table 6.—Frequency of Features or Advantages in Wheelchair Innovations, 1973-83**

| Feature or advantage | Frequency[a] |
|---|---|
| Lightweight | 9 |
| Easily disassembles | 4 |
| Serves active user | 3 |
| Durable | 2 |
| Folding | 2 |
| Dynamic brakes | 2 |
| Low-friction brakes/bearings | 2 |
| Better support | 2 |
| Narrow width | 2 |

[a] Frequency was measured only for those features or advantages with a frequency greater than 1

SOURCE D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

**Table 7.—Length of the Development Process**

| Innovation code[a] | X[b] | Prototype date | y[c] |
|---|---|---|---|
| ***Manual wheelchairs:*** | | | |
| M1a | | NA | |
| M1b | 4 mo. | 9/82 | 11 mo. |
| M2 | 12 mo. | 1979 | >12 mo. |
| M3 | | NA | |
| M4 | | NA | |
| ***Power wheelchairs:*** | | | |
| P1 | | NA | |
| P2 | | NA | |
| P3 | | NA | |
| P4 | 8 mo. | 9/80 | 12 mo. |
| ***Power alternatives:*** | | | |
| Pa1a | 18-24 mo. | 1981 | 12 mo. |
| PA1b | | NA | |
| ***Sports wheelchairs:*** | | | |
| S1 | 12 mo. | 11/79 | <12 mo. |
| ***Accessories:*** | | | |
| Ac1 | | NA | |
| Ac2 | | NA | |
| Ac3 | | NA | |
| **Median** | 12 mo. | 9/80 | 12 mo. |

[a]Categories of innovations were for power wheelchairs (P), manual wheelchairs (M), power alternatives (PAL sports models (S), and accessories Within each category the products were randomly assigned numbers Small letters after an innovation code differentiate products of similar description but different manufacturers

[b]"X" is the length of time in months from the conception of the Innovation idea to the making of the prototype

[c]"y" is the length of time in months, from the making of the prototype to the first commercial delivery of the product

SOURCE D S Shepard Harvard School of Public Health telephone survey of manufacturers 1983 (see app B)

**Table 8.—Source of the Innovative Idea**

| Innovation code | Personal experience | Existing product[b] | Technology transfer[c] |
|---|---|---|---|
| M1a | — | x | |
| M1b | — | x | **X** |
| M2 | x | — | |
| M3 | x | x | — |
| Ma | — | x | |
| P1 | x | **X** | — |
| P2 | x | **X** | — |
| P3 | — | *X* | — |
| P4 | — | **X** | — |
| S1 | x | — | **X** |
| PA1a | — | **X** | — |
| Pa1b | x | — | — |
| Ac1 | — | **X** | **X** |
| Ac2 | — | **X** | **X** |
| Ac3 | x | **X** | — |
| Total | 7 | 12 | *4* |
| Percent[d] | 46,70/. | 80.0% | *26.7%* |

[a]"X" indicates that idea was derived from personal experiences with wheelchairs or from identification of unmet needs

[b]Innovation was a modification or Improvement of an existing product

[c]Innovation was based on a transfer of technology from another health care product or another field

[d]Percent, based on 15 innovations for which the innovation is at least partially attributable to each source

SOURCE D S Shepard Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

## SOURCE OF FUNDING FOR INNOVATIONS

The R&D efforts behind the innovations studied were all privately sponsored. None of the manufacturers interviewed received any Government funding, although some of them do cooperative work with universities on Government-funded research projects. Several respondents expressed interest in Government funding of R&D, They did not seem to feel that the loss of control over patent rights, which often accompanies Government funding of projects, was a major problem. The advantage that comes from being first on the market with a new product was said to be much more important than patent rights.

## REIMBURSEMENT BY GOVERNMENT PAYERS

All of the innovations identified by the study are now reimbursable under Medicare and Medicaid, if they are medically necessary and prescribed by a physician.

The Veterans Administration (VA) takes longer to approve a new product for purchase than it takes to approve one for reimbursement by Medicare and Medicaid. Only 10 of the 15 innovations

identified through the survey are covered by the VA. Of those 10, two are reimbursable only with a waiver. One of those two meets VA procurement standards but is not on the Federal Supply Schedule; the other does not meet standards (table 9).

**Table 9.—Eligibility of Innovations for Purchase by the VA**

| Innovation code | Yes | No | Innovation code | Yes | No |
|---|---|---|---|---|---|
| ***Manual wheelchairs:*** | | | ***Sports wheelchairs:*** | | |
| M1a | X | | S1 | X | |
| M1b | X | | Total | 1 | 0 |
| M2 | | X | ***Accessories:*** | | |
| M3 | | X | Ac1 | X | |
| M4 | X | | Ac2 | X | |
| Total | 3 | 2 | Ac3 | X[a] | |
| ***Power wheelchairs:*** | | | Total | 3 | 0 |
| PI | X | | Grand total | 10 | 5 |
| P2 | | X | Percent of innovations | 670/o | 330/0 |
| P3 | | X | | | |
| P4 | X | | | | |
| Total | 2 | 2 | | | |
| ***Power alternatives:*** | | | | | |
| Pal | | X | | | |
| PA1b | X[a] | | | | |
| Total | 1 | 1 | | | |

[a]Products not on the Federal Supply Schedule purchasing list, but may be bought in individual cases

SOURCE D S Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (seeapp B)

## R&D EFFORTS

All but one of the companies surveyed have their own R&D departments. The one relies solely on outside firms for its R&D. Four of the companies use outside firms in addition to in-house staff, The outside companies generally develop a particular part to be used in the wheelchair, for example a lighter weight alloy or anew controller. The manufacturers pointed out that they and their subcontractors do not do basic research but develop new ways of putting together known materials and ideas.

Although most manufacturers said R&D was a critical part of their operations and success, some were hesitant to specify the size of their R&D operations. The largest R&D budget identified was 5 percent of gross annual sales (see table lo). The limited quantitative responses indicated a median of 4 percent of sales and 9 full-time equivalent employees devoted to R&D.

The areas of R&D tended to parallel the kinds of products already under production. Only a few manufacturers mentioned development in a part of the market in which they did not currently have products.

The most common area of R&D mentioned involved utilization of lighter and stronger materials, Also important were development of better control systems and more esthetic design (table 11).

**Table 10.—Location and Size of R&D Departments**

| Manufacturer code[a] | Location[b] | Size of department: Percent of sales | Size of department: FTE[c] | Size of department: Qualitative |
|---|---|---|---|---|
| 1 | IH | —[d] | 7 | — |
| 2 | IH | — | 9 | — |
| 3 | CT | NA[e] | NA | NA |
| 4 | IH | 50/0 | — | — |
| 5 | IH, CT | 4% | — | — |
| 6 | IH | NA | NA | NA |
| 7 | IH | — | 10 | — |
| 8 | IH, CT | NA | NA | NA |
| 9 | IH | — | | "the main structure of the company" |
| 10 | IH. CT | >2% | | — |
| 11 | IH, CT | | | "absolutely crucial . now more than ever ." |
| Median | | 4% | 9 | |

[a]Manufacturer code numbers were randomly assigned to the companies surveyed The codes used are constant for this and all other tables
[b]IH indicates an In-house R&D department, CT indicates contractual arrangements with other companies
[c]FTE is full-flme.equivalent employees
[d]Dash indicates data are expressed in other terms
eNA Indicates no data are available on Size of department

SOURCE D S Shepard Harvard School of Public Health telephone survey of manufacturers 1983 (see app B)

**Table 11 .—Types of R&D Efforts**

| Manufacturer code | Areas of R&D | Manufacturer code | Areas of R&D |
|---|---|---|---|
| 1 | • control systems<br>• posture support systems<br>• curb-climbing wheelchairs<br>• wheelchair design | 6 | • airline models<br>• rehabilitation models |
| 2 | • style; appearance<br>• attachment to motorize a manual chair | 7 | stronger, lighter materials<br>• electric wheelchairs |
| 3 | • NA[a] | 8 | • NA[a] |
| 4 | • stronger, lighter materials<br>• more efficient design<br>• stronger construction<br>• more cost-effective production procedures | 9 | • stronger, lighter materials<br>• decreased rolling resistance<br>• increased durability and longevity |
| 5 | • improved control mechanisms<br>• stronger, lighter materials<br>• style; appearance | 10 | • improved control mechanism<br>• refinement of current products |
| | | 11 | • style; appearance<br>• stronger, lighter materials<br>• lower rolling resistance |

[a]NA indicates no data available

SOURCE D S Shepard Harvard School of Public Health, telephone survey of manufacturers 1983 (see app B)

## TARGETS OF MARKETING CAMPAIGNS

Dealers are most influential in diffusing an innovation; 9 of the 11 manufacturers surveyed aim their marketing campaigns at dealers. Six of them also target the end user, five the institution (hospital, rehabilitation center, or nursing home), four the foreign markets, three the VA, and two the therapist. Clearly, more than one market may be targeted simultaneously.

It was surprising that only two mentioned the physical therapist because it is often the therapist who decides what kind of chair the user is to have. One explanation for this fact may be that the manufacturers meant to imply marketing to therapists when they said they market to institutions. Another possible explanation is that, although therapists often decide what features are needed on

an individual user's wheelchair, it is the dealer who often decides which brand is ordered. Unless a company makes a wheelchair with unique features of which they need to inform therapists, there may be very little return on these marketing efforts (table 12).

**Table 12.— Marketing Procedures: At Whom Is the Marketing Aimed?**

| Manufacturer code | Therapist | Dealer | Institution | User | VA | Exports |
|---|---|---|---|---|---|---|
| 1 | — | x | x | — | — | — |
| 2 | — | x | x | x | — | — |
| 3 | — | — | — | x | — | — |
| 4 | — | X | X | — | — | — |
| 5 | X | X | — | X | X | — |
| 6 | — | X | — | — | — | — |
| 7 | — | X | — | — | — | X |
| 8 | — | — | X | X | — | — |
| 9 | — | X | — | — | X | X |
| 10 | — | x | — | x | — | x |
| 11 | x | x | x | x | x | x |
| Total | 2 | 9 | 5 | 6 | 3 | 4 |
| Percent[a] | 180/0 | 820/o | 45% | 55% | 270/o | 360/o |

[a]Percent of the 11 manufacturers surveyed who market to each group

SOURCE D S Shepard Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

## MARKETING TOOLS

Of the 11 manufacturers surveyed, 10 said they introduced new products at trade shows, 7 depend on their sales force, 6 advertise in professional and trade journals, 5 advertise in user journals, and 2 rely heavily on word of mouth (table 13).

Ironically, although the most frequently used marketing device is trade shows, many of the manufacturers added that the shows were not very helpful in marketing their products. They serve to show what the competition is doing and to introduce new products, but not to make large sales. Actual sales take place outside of the trade shows, mostly through personal contact between sales representatives and dealers or institutions.

Advertising in professional and trade journals educates therapists and dealers on what is avail-

**Table 13.—Tools Used to Market a New Product**

| Manufacturer code | Word of mouth | Trade shows | Professional journals[a] | User journals[b] | Sales representatives |
|---|---|---|---|---|---|
| 1 | — | X | X | — | X |
| 2 | X | X | — | — | X |
| 3 | — | X | — | X | — |
| 4 | — | X | — | — | X |
| 5 | — | X | X | X | X |
| 6 | — | X | X | — | X |
| 7 | — | X | — | — | X |
| 8 | — | X | — | X | — |
| 9 | — | — | X | — | — |
| 10 | x | x | x | x | — |
| 11 | — | x | x | x | x |
| Total | 2 | 10 | 6 | 5 | 7 |
| Percent[c] | 180/0 | 91 % | 55% | 45% | 640/o |

[a]Professional journals include trade journals for therapists, hospital supply catalogs, etc
[b]User journals include magazines for persons with disabilities (e g., *Paraplegia News*), catalogs, and newsPaPers
[c]percent of 11 manufacturers surveyed who use each marketing device.

SOURCE D S Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

able and builds brand-name recognition. Advertising directly to the user is useful for small companies with products that fall outside of the usual range, e.g., three-wheel power alternatives and sports chairs. These products are not usually prescribed and not a regular part of a dealer's stock. Users may have to request that a dealer order them; but if enough orders are placed, the dealer may decide to stock the item. Word of mouth is also a useful advertising tool for these smaller, less traditional companies.

## OBSTACLES TO MARKETING

The largest single impediment to marketing a new product is its cost, according to *8* of the 11 manufacturers surveyed (table 14). "Cost" includes the cost of the R&D needed to develop the new product, the cost of setting up production for a new product, and, most significantly, the cost of the marketing process itself.

Three of the manufacturers also identified communication as a major obstacle to marketing a new product. The best communication is through personal contact with sales representatives who can demonstrate and educate. That is a very costly, limited process, given the dispersed locations of therapists, dealers, and users. Advertisements in professional, trade, and user journals are not as good because they reach not the entire market, but only those people with a special interest in wheelchairs. Not all users read user journals, and most first-time purchasers do not. One of the most widely read user journals, Paraplegia News, is read almost exclusively by veterans.

Three manufacturers said that the medical community is slow to accept new concepts and designs in wheelchair technology. Part of this reluctance hinges on safety issues. For instance, doctors and therapists may hesitate to prescribe a power wheelchair that runs at a higher speed than most, because they are at risk of malpractice suits if a person is injured while using a device. The manufacturers are aware of this but believe that doctors and therapists are unwilling to prescribe new devices even for people who want them and are capable of using them safely.

Brand-name identification was also mentioned as a marketing impediment for smaller companies. This is less of a problem for manufacturers of unique products than for those who make a more

**Table 14.— Factors That Are the Largest Impediments to Marketing a New Product**

| Manufacturer code | cost of product | Communication[a] | Medical acceptance | Brand identification[c] | Third-party payment[d] |
|---|---|---|---|---|---|
| 1 | — | x | — | — | — |
| 2 | x | x | x | — | x |
| 3 | x | — | — | — | — |
| 4 | x | — | — | x | — |
| 5 | x | — | — | x | — |
| 6 | x | — | — | — | — |
| 7 | x | — | — | — | — |
| 8 | — | x | — | — | — |
| 9 | x | — | — | — | x |
| 10 | x | — | x | — | — |
| 11 | — | — | x | — | x |
| Total | 8 | 3 | 3 | 2 | 3 |
| Percent[e] | 73 % | 270/o | 270/o | 180/0 | 270/o |

[a]Communication between manufacturer and others (dealers, therapists, doctors, users) is limited and difficult, hindering diffusion of innovations
[b]Products that vary greatly from the norm are slow to be accepted by the medical community and hence are not prescribed Diffusion is hindered
[c]Strong brand name identification makes it difficult to get people to try a product from a company with which they are not familiar
[d]Third-party reimbursement is difficult to get for new products It is also often slow in Corning making dealers hesitant to sell products for which they may nOt be reimbursed or that are more expensive than the reimbursement received Money is lost during the lag time between billing and receipt of reimbursement
[e]Percent of the 11 manufacturers surveyed who identified each item as an impediment to marketing

SOURCE D S Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app B)

standard product. Given two products that appear to be essentially the same in function and design, it is more likely that a therapist will prescribe and a dealer will stock brands that are familiar to users. Manufacturers also said that brand-name identification is more of a problem with first-time users than with people who are making a repeat purchase, Active users tend to be aware of the products around them and to compare features. On a second purchase, the user may have enough information to request a particular brand of wheelchair, whereas the first-time user depends almost entirely on the therapist and dealer to make that decision.

Third-party reimbursement policies are an obstacle to marketing as well. Products that do not fall into established categories may not be reimbursable at all or only at a rate below cost. Dealers are hesitant to sell products on which they do not make enough profit. Under Medicare, they may choose not to accept third-party assignment and to bill the user directly for the full cost. This practice is also not a guarantee of full payment, as the user may not be able to afford the price or may choose to go to a different dealer where third-party assignment is accepted. The lag time involved in obtaining third-party reimbursement for more expensive or less standard products may also discourage dealers from selling them. Long lag time may result from a claims review process that may approve all purchases of inexpensive, standard models as a matter of course but review all purchases of more expensive, more innovative wheelchairs very carefully.

Although most manufacturers carry product liability insurance, one manufacturer surveyed believed that the high cost of such insurance curtails innovation by keeping profits low. His company, therefore, focused on product improvement, rather than on development of entirely new products. Although such a focus will not lead to major breakthroughs, it usually produces results more quickly and at lower cost than development of new products.

## ROLE OF STANDARDS

Almost half of the manufacturers surveyed (5 of 11) said that they take existing or proposed standards of outside organizations into account when designing their products (table 15). Three of the five identified the VA standards as important. Of these three, an importer from Britain considers both VA and British standards; one takes proposed Rehabilitation Engineering Society of North America standards into account; and one considers only VA standards. Two indicated that

**Table 15.— Role of Voluntary Standards in Manufacturers' Design of a New Product**

| Manufacturer code | Yes | No | Don't know | Which ones? |
|---|---|---|---|---|
| 1 | — | X | — | — |
| 2 | — | X[a,b] | — | — |
| 3 | — | — | X | — |
| 4 | — | X[a] | — | — |
| 5 | X[a] | — | — | VA |
| 6 | X | — | — | VA, British standards |
| 7 | X[a] | — | — | — |
| 8 | X | — | — | RESNA |
| 9 | X | — | — | — |
| 10 | — | X | — | — |
| 11 | — | X | — | — |
| Total | 5 | 5 | 1 | |
| Percent[c] | 45% | 45% | 90/0 | |

[a] Products are manufactured to the company's own standards, which are said to be more stringent than any existing or Proposed standards.
[b] Standards change too often and are too difficult to understand for it to be financially feasible to use them.
[c] Percent of manufacturers surveyed who gave each response.

SOURCE D S Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B)

their internal standards were more stringent than existing or proposed standards.

Five of the companies stated that they do not take external standards into account, with one adding that existing standards are too confused and confusing to make them worth considering. One other manufacturer did not know what role standards played in the development of its products, since the wheelchair was designed by an outside firm.

VA standards were the most frequently mentioned, both by those who use them and those who do not, probably because they are the only currently written standards. Manufacturers hoping to obtain a VA contract obviously must consider VA standards.

Reactions to the idea of industry-wide standards were mixed. Some manufacturers disliked the idea because they felt the standards would be set too low; they are already manufacturing products to conform to more rigorous standards than they expect to see adopted. If low standards are adopted, they felt that products that meet the standards but are of lower quality and cost than their products would gain a competitive advantage. Other manufacturers, who also believed they are making a high-quality product, welcomed the idea of standards because they believed it would force the lower quality competitors to improve their products, thus benefiting the users. Standards would raise the cost of cheaper products, thereby decreasing the price differential and eliminating some of the current competitive advantage the lower quality manufacturers may have. Regardless of what effect manufacturers thought standards would have, most felt that they would be lower than current technology makes possible.

## EFFECTS OF OTHER FEDERAL POLICIES ON R&D

When asked about the effect of Government policies on R&D, three respondents said they were not influenced by any other Government policies, two of them were unsure, and four of them said that they were subject to other influences (table 16). For two of those last four, the relevant agency

**Table 16. –Presence of Government Policies That Affect R&D**

| Manufacturer code | Yes | No | Don't know | Which ones? |
|---|---|---|---|---|
| 1 | — | X | — | — |
| 2 | X | — | — | Government funding of R&D. The company cannot compete, has a disincentive to fund its own R&D. |
| 3 | — | | X | — |
| 4 | X | | — | FDA—good manufacturing practices, quality control, complaint monitoring. |
| 5 | X | — | — | Product liability laws. HCFA reimbursement and approval processes for new, innovative products. |
| 6 | — | | X | — |
| 7 | X | | — | FDA—good manufacturing practices. |
| 8 | — | X | — | — |
| 9. | X | | — | Standards have an indirect effect on product design. |
| 10. | — | X | — | — |
| 11 | X | — | — | VA specifications—the company hesitates to make anything that they cannot sell to the VA. |
| Total | 6 | 3 | 2 | |
| Percent[a] | 55% | 27% | 18% | |

[a]Percent of 11 manufacturers surveyed who gave each response

SOURCE D S Shepard Harvard School of Public Health, telephone survey of manufacturers 1983 (see app. B)

is the Food and Drug Administration (FDA). Although the FDA has not yet written any standards, companies are subject to "good manufacturing practice," which pertain mostly to recordkeeping procedures. In addition, the FDA investigates complaints that come through their office and may choose to monitor quality.

Interestingly, one small manufacturer (#2) felt that R&D by Government agencies was a disincentive for a small company to fund its own R&D. A small company cannot compete with the level of funding and amount of Government R&D and hesitates to invest large amounts of money and time into R&D only to have a Government agency come out with the same product sooner, according to this manufacturer.

## PARTICIPATION IN OBTAINING REIMBURSEMENT

Six of the eleven companies surveyed participate in getting their products approved for third-party payment (table 17). Five of these six focus their efforts on getting VA approval and contracts. One of them aids individual users in getting VA payment for their wheelchairs but does not have a VA contract. Two of them have participated in getting Health Care Financing Administration (HCFA) approval of their products. One has participated in getting approval from an agency other than HCFA or the VA. The remaining five manufacturers do not participate.

**Table 17.—Active Participation in Getting Product Approved for Third-Party Payment**

| Manufacturer code | Yes | No |
|---|---|---|
| 1 | — | X |
| 2 | X[a,b,c,d] | — |
| 3 | X[b] | — |
| 4 | X[a] | — |
| 5 | X[a,c] | — |
| 6 | X[a] | — |
| 7 | — | X |
| 8 | — | X |
| 9 | — | X |
| 10 | — | X |
| 11 | X[a] | — |
| Total | 6 | 5 |
| Percent[e] | 55 % | 45 % |

[a] Company participates in getting VA approval of their product
[b] Company may participate in getting VA payment for their product in individual cases
[c] Company has participated in getting HCFA approval of their product
[d] Company has participated in getting reimbursement from parties other than HCFA and the VA
[e] Percent of manufacturers surveyed who gave each response

SOURCE: D. S. Shepard, Harvard School of Public Health, telephone survey of manufacturers, 1983 (see app. B)

In general, it is not necessary to petition for HCFA approval of a product. As long as the product can be classified in an existing category of durable medical equipment, it is not necessary to get special approval. When the Amigo was first designed, it was not classified as a wheelchair. As discussed above, a congressional amendment was necessary to obtain coverage. Companies that have made similar products since then have been assured of HCFA coverage.

A company may wish to create a new coverage classification when its product can be covered under an existing category but is so much more costly than other items in that category that reimbursement to dealers would be minimal, An example might be a curb-climbing wheelchair. Although this device might be classified as a power wheelchair, its cost is so much greater than most other power chairs that the reimbursement rate would discourage dealers from selling it. For example, under Medicare, the product might have an allowable charge of $1,500. or $2,000, while its actual cost could be $10,000. If a special category could be created for it, then reimbursement would be based on its cost, and the disincentive to selling it would be removed, However, the cost and time involved in petitioning for the new classification may be substantial.