3.
Roles of the Federal Government

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Roles of the Federal Government

AS A MAKER OF NATIONAL POLICY

Accessibility to the Handicapped

Federal laws and regulations to protect wheelchair users are few in number, general in pm-pose, and weak in enforcement. Most policies have their legal basis in Section .504 of the Rehabilitation Act of 1973 (Public Law 93-112), intended to prevent the exclusion of physically or mentally handicapped people from any program or activity receiving Federal money. One part of this broad act requires that all publicly owned or federally assisted buildings, both residential and nonresidential, be accessible to people with physical disabilities. ' Buildings predating these laws need not be brought up to standards, unless they undergo alterations that affect accessibility. In that case, the alterations must make the building accessible.

The Urban Mass Transportation Administration (UMTA) has exhibited a continuing commitment, but ambiguous philosophy, toward assuring the mobility of disabled persons. The UMTA has not decided whether accessibility means access to all mass transit systems or access to public places via special transportation services. In May 1979, the UMTA ruled that half of all buses must be wheelchair-accessible by 1989. That ruling is currently being challenged by local transit authorities and some persons with disabilities who believe that special separate transportation services are more effective and cost efficient (24).

[1]Applicable Federal Government regulations are: "Policies and Procedures for the Enforcement of Standards and Requirements for Accessibility by the Physically Handicapped," 24 CFR 41; and "Standards for Design, Construction, and Alteration of Publicly Owned Residential Structures," 24 CFR 40. The standards of accessibility for residential structures are those written by the American National Standards Institute, "Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped, No. A117.1, 1980." The Secretary of Housing and Urban Development is responsible for designing plans to bring buildings into compliance when voluntary compliance is not possible. The Architectural and Transportation Barriers Compliance Board is responsible for any further necessary action.

Effects of Government Policies on Wheelchair Design

Federal standards for accessibility to the handicapped have influenced wheelchair design somewhat and apparently also have been shaped by it. Door width standards, for example, have been designed to accommodate the average-sized wheelchair. The Veterans Administration (VA) recommends a minimum door width of 36 inches, based on a typical wheelchair width of 27 to 29 inches from the outermost points of the wheels and handrims (20). The Architectural and Transportation Barriers Compliance Board recommends basing door widths on an average wheelchair width of 26 inches,

By making more services and facilities accessible to persons with physical disabilities, the Federal Government may be encouraging handicapped persons to be more active and involved in public, thereby stimulating the demand for lighter weight and more esthetically designed wheelchairs so they can be more active.

State and local policies also have had an effect on wheelchair design, for manufacturers must consider the relevant policies of all States and municipalities in which they sell their product. Fire codes are most important; they affect the fabric, foam, and glue used in wheelchair upholstery. California and Boston city fire codes tend to be the most stringent. No Federal fire codes exist, but the Food and Drug Administration (FDA) is expected to establish fire standards within the next few years (8). National standards will relieve the manufacturers' burden to be aware of and compliant with the policies of 50 different States,

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AS A PURCHASER

As mentioned above, Federal and State Government funds are involved in over half of all wheelchair purchases. The policies of the three main Federal purchasers, Medicare, Medicaid, and the VA, differ from one another, and among regions or States within each purchasing program.

Medicaid

Medicaid policies are determined by each State within Federal laws and regulations. At the Federal level, Medicaid policies are established by the Health Care Financing Administration (HCFA). Massachusetts, which has one of the more comprehensive Medicaid programs, is used as an illustration of State policies. In Massachusetts, Medicaid pays an "adjusted acquisition cost" for all wheelchairs determined to be medically necessary. This adjusted acquisition cost includes the dealer's cost (excluding associated costs such as shipping and handling) plus a percentage increase, typically 30 percent (12). As in most other States, this cost is divided almost equally between the State and Federal Governments.

To receive reimbursement, a dealer must file a Prior Authorization Form, completed by both the prescribing physician and the dealer, documenting the medical need for the wheelchair and the type of wheelchair recommended. The form is reviewed and reimbursement is approved, denied, deferred pending receipt of additional information, or approved with modifications. A decision must be made within 15 days of receipt of the Prior Authorization Form. In cases where a 15-day delay would jeopardize the user's health or delay discharge from a hospital, an immediate decision may be requested by telephone, with written documentation to follow. The more expensive the wheelchair and accessories recommended, the stricter the review.

Medicaid in Massachusetts will rent and repair wheelchairs for beneficiaries whose needs are temporary; it also covers repairs of purchased wheelchairs and provides a temporary replacement. If the rental period exceeds 3 months, or if the cost of the repair will exceed $35, the Prior Authorization Form must be filed. Authorization of repairs is rarely denied, so the dealer may feel safe in making the repair before formal authorization is received.

Federal policy dictates that if a Medicaid reimbursement is obtained, the dealer must accept it as payment-in-full. This is different from Medicare, in which the patient may pay coinsurance, a deductible, and possibly the excess over Medicare's allowed reimbursement. For users covered under both Medicare and Medicaid, Medicaid pays the coinsurance and deductible as defined by Medicare.

In fiscal year 1982, the Massachusetts Medicaid program bought 1,069 wheelchairs, of which 212 (20 percent) were electric, at a total cost (including some accessories) of $639,000. Separately purchased wheelchair accessories, such as legrests, desk tops, and armrests, cost $166,000. Medicaid's average cost to purchase, customize, and equip one wheelchair was $752. This is the sum of purchase costs plus accessory costs divided by the number of wheelchairs bought. Costs for manual and electric wheelchairs could not be separated.

There were an additional 1,069 months of wheelchair rentals (the numerical agreement with purchases is coincidental) at a total cost of $47,000. Medicaid paid for 8,492 repairs, at a total cost of $455,000. Repairs figure almost as prominently in these data as in the VA data reviewed earlier on the assumption that purchase and repair costs remained constant and the lifetime is 3.5 years. On the basis of the method described earlier, the average annualized cost per chair is $266 for capital and $122 for maintenance, or *$388* total. (Annual amounts were extrapolated from data for the months of January, March, July, and October [7].)

Extrapolating from Massachusetts data, national Medicaid expenditures for wheelchair purchases, rentals, and repairs were extrapolated at about *$50* million in *1982*.[2]

[2]This estimate was approximated from the Massachusetts figures on the assumption that other States' Medicaid programs purchase wheelchairs at a similar rate, relative to their 1980 census population, and at similar costs. This figure was computed using the Massachusetts Medicaid expenditures for wheelchairs, a State population of 5.737 million persons, and a national population of 227.7 million (32).

Data from California generate consistent extrapolations. Extrapolations from data for October through December 1982 indicate that California's Medi-Cal (Medicaid) program paid $190,000 over 1982 for rental of wheelchairs and accessories (an average of 612 items under rental each month) and $3.15 million for purchasing 7,192 wheelchairs and accessories over the same period (2). As the California population was about 24 million (32), the national Medicaid expenditure on purchase and rental (but not repair) of wheelchairs and accessories extrapolates to $32 million. If repairs were added, the total would probably be similar to that from Massachusetts. National extrapolations based on both of these States may be overestimates, however, since Massachusetts and California eligibility and reimbursement policies may be less restrictive than many other States.

A new product is approved for coverage in Massachusetts at the State level by Medicaid administrators on the advice of a consultant. The product rarely receives blanket approval for Medicaid payment; most frequently, a product is approved for payment only for a particular patient. The patient must petition for payment if the device is one that is not usually approved for payment, The decision often rests on the patient's persistence in pursuing payment (12). The addition of a product to the list of approved products comes only after many individuals have sought and received payment for it.

Medicaid places substantial responsibility on the wheelchair provider to limit costs. Its Durable Medical Equipment Manual (sec. 106 CMR 409.432) states:

> (A) The provider is responsible for making reasonably certain that the durable medical equipment or medical/surgical supplies furnished are the most cost effective . . . .
>
> (B) Before purchasing equipment or supplies, the provider must make a reasonable effort to purchase the item from the least-costly reliable source by comparing prices charged by different suppliers for comparable items.

Careful attention to the cost-effectiveness requirement would consider purchase costs, repair costs, and performance. Most providers would probably not be able to conduct cost-effectiveness studies, and would probably focus on part B of the regulation, seeking to furnish the wheelchair with the lowest purchase price.

Medicare

Medicare, like Medicaid, is a program of HCFA. Medicare is an insurance program for persons aged 65 and over who are eligible for Social Security or railroad workers' benefits and for disabled people. Unlike Medicaid, Medicare generally sets coverage policies at the national level. HCFA contracts with local intermediaries (insurance companies), which are responsible for processing and adjudicating claims based on medical necessity and reasonableness of cost. Medicare does not evaluate new equipment itself for coverage decisions but relies on the Office of Health Technology Assessment in the Public Health Service for coverage evaluations.

Medicare payments for wheelchairs are limited to 80 percent of the allowable charge,[3] which is determined yearly for each provider by the intermediary, and is the lowest figure among the actual charge for the item, its customary charge in the previous year, and the prevailing charge for that type of item the previous year. The actual charge is the billing for the particular item. The customary charge is the individual provider's most common charge for that item in the previous year. The prevailing charge, which measures the charges for a type of item for all providers in a geographic area, is set at the 75th percentile of charges submitted to Medicare for that type of item from the geographic area in the previous year. Providers whose charges are low and stable for their area thus receive almost 80 percent of their charge from Medicare. Providers that charge higher prices receive from Medicare a lower percentage of their billed charge. One dealer estimated that his allowable charge lagged behind his actual charge by 5 years, and he indicated that most accessories are not reimbursable (18). Power wheelchairs are paid for on an "individual consideration" basis.

[3] Medicare beneficiaries are responsible for the remainder of the price, but dealers may have difficulty collecting their total charges if the patients' share is high.

Dealers have two ways of receiving greater payment for products sold to Medicare recipients. First, they may bill the user instead of Medicare. In that case, the user must pay the full price, submit a claim to Medicare for 80 percent of the allowable charge, and pay the difference. Second, dealers can rent the wheelchair to the user on a long-term basis. Medicare places no time limit on the length of a rental and will pay for 80 percent of the rental fee up to the purchase price. This alternative imposes no added cost on the user. Reimbursement for rental chairs is approximately $35 per month for manual wheelchairs and $150 per month for electric wheelchairs (18).

Medicare has been trying to reduce rental costs by stringently reviewing all long-term rentals. So far, however, regulations have not been completed and promulgated, so they are not legally binding. Regulating long-term rentals will not necessarily reduce costs, since Medicare will be required to pay for rentals while a determination is made as to whether the wheelchair should be bought or rented.

All wheelchairs and accessories reimbursed by Medicare must be prescribed by a physician and must be medically necessary. Power wheelchairs must be prescribed by a specialist in physical medicine, orthopedic medicine, or neurology who has determined that "the patient is unable to operate a wheelchair manually" (Public Law 95-216). The need for a specially sized wheelchair, based on the patient's physical build or on the structural feature of the place of use, may be determined by the supplier and need not be included on the prescription.

Products that do not fit any existing category of reimbursable durable medical equipment may not be covered under Medicare, and creation of a new category requires a congressional amendment, Section 1861(s)(6) of the Social Security Act was amended in 1977 to allow coverage of "durable medical equipment including . . . . wheelchairs *(and devices designed to serve the same or similar purpose as that performed by a wheelchair . . . ")* (italicized parenthetical phrase was that added by the amendment). Representative Griffin, from the Michigan district in which Amigo Sales is located, sponsored the amendment. At that time, Amigo was the only manufacturer of a three-wheeled power alternative. Interestingly, the Amigo had been covered under Medicare prior to *1976,* at which time the decision was made to discontinue coverage, necessitating the amendment (6).

National data on costs to Medicare of wheelchair purchases, rentals, or repairs could not be obtained.

Veterans Administration

The VA is reportedly the largest Federal purchaser of wheelchairs, although the authors' calculations made for this case study suggest that Medicaid is larger when State and Federal shares are combined. In 1976, the VA accounted for 11 percent of all wheelchair purchases (in dollars) (17). The VA pays the full cost of two wheelchairs for those veterans who medically require them and who meet the VA's eligibility requirements. Eligibility depends primarily on the extent and service-connected status of the veteran's disability.

A physician must determine the need for a wheelchair; the rehabilitation therapist or the prosthetics technician determines the type of wheelchair needed based on environmental and physical factors. Provision of a power wheelchair requires approval by a committee at the VA facility. Veterans engaged in registered sports, such as wheelchair basketball, may have their sports chairs supplied by the VA. Once it supplies a wheelchair, the VA also makes or pays for needed repairs to an eligible veteran's chair and provides a substitute wheelchair for use while the veteran's own chair is being repaired, if necessary.

VA medical centers may purchase wheelchairs for their own and veterans' use from one of three categories. The first category is a low-priced manual chair used for transportation within hospitals and clinics. Called a "depot" chair, it is purchased in large quantities under competitive contract (currently with the Invacare Corp.) and stocked in regional depots. This method generally provides a wheelchair most quickly and least expensively.

Second, a wheelchair may be purchased from those listed on the Federal Supply Schedule compiled by the General Services Administration (GSA). Chairs listed must fit a "commercial item description" (CID)—a description of a wheelchair design based on the design of a currently available model. If an appropriate CID does not exist, a manufacturer may petition the VA or GSA to write a CID to fit its product. A description must be approved by the U.S. Department of Commerce and the GSA before it is finalized. Within each CID, wheelchairs are given priority based on price.

Finally, a VA facility may purchase a wheelchair for an individual veteran if it is not on the Federal supply purchasing list. A waiver from the VA Central Office in Washington, DC, is necessary if the cost exceeds $1,000.

The VA has long set design or performance standards for most wheelchairs it buys. Historically, the VA's standards have been written with a specific wheelchair in mind, usually an Everest & Jennings, Inc. (E&J) model (17). In 1977, performance standards were written that focused more directly on function rather than design specifics. Standards for power wheelchairs are currently under revision, based on the conclusions of the Wheelchair Workshop III, cosponsored by the VA *(26).* A child's wheelchair made by E&J Canadian has been identified that comes close to meeting these standards, and modifications to make a similar adult chair are underway. If the VA decides that the adult chair meets the standards, it will become the VA model. Manufacturers who will want to obtain VA contracts may have to make products similar to the E&J wheelchair.

Effects on Innovation

The policies of these three reimbursement programs may hinder innovation in wheelchair design and diversity. Medicaid pays in full, but only for the least costly chair needed. Medicare pays only part of the allowable charge, which may itself be less than the actual charge. A supplier who accepts Medicare payment on assignment receives 80 percent of Medicare's allowed charge directly from Medicare. The supplier must agree, however, not to demand in total more than Medicare's allowable charge. This policy creates an incentive to encourage the patient to buy the 'least costly model that satisfies his or her prescription. In addition, the large, established companies are the best able to compete on the basis of price. The problem, however, is that the patient's prescription may not fully describe his or her needs.

Prior to the promulgation of performance standards for manual chairs in 1977 and for powered chairs in 1981, the VA's procurement standards may have protected the user's safety, but they appeared to function mostly in the interest of the major manufacturers *(29,30).* When VA standards were written in accord with E&J specifications, products were often evaluated on the basis of how closely they conformed to E&J's model. Also, manufacturers interviewed for this case study indicated difficulty in learning the protocols that the VA would use to evaluate a new product. This uncertainty has made innovation risky, as manufacturers do not know whether their products will meet VA standards and, if they do not, whether those standards might be modified.

Federal payers currently focus their payment decisions on purchase price without considering maintenance and repair costs. Although small manufacturers tend to have a competitive disadvantage in purchase price, due to diseconomies of scale, they may be superior in quality, and hence less expensive over the product's useful life. No data are available, however. Decisions made on the basis of total annualized cost would appropriately reward more durable models. Such analyses might open the door to smaller manufacturers, making the market less oligopolistic and more competitive,

AS A REGULATOR

Classification of Wheelchairs

The Center for Devices and Radiological Health of the FDA is charged with classifying all medical devices according to their potential risk to users and the degree of regulation required. Class I, general controls, encompasses devices for which general controls are sufficient to provide reasonable assurance of safety and effectiveness. These general controls are required of all three classes. Class II, performance standards, contains devices for which general controls are considered insufficient to assure safety and effectiveness, and information exists to establish performance standards. Class III, premarket approval, applies to devices for which Class I general controls are insufficient, information does not exist to establish a performance standard, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury (35).

Manual wheelchairs intended for short-term, indoor use are Class I. All other manual wheelchairs, power wheelchairs, standup wheelchairs, and three-wheel motorized devices (power alternatives) are considered Class II. Stair-climbing wheelchairs are Class III devices *(31).* Ninety days premarket notification and good manufacturing practices are required for all medical devices including wheelchairs. Manufacturing practices regulate conditions in the factory and bookkeeping procedures, but do not affect the products. To date, no standards have been written for any Class II products.

Development of Standards

Naturally, dealers' incentives to maintain their reputation motivates them to sell only safe and effective products; however, without stringent established guidelines, safety and effectiveness can be determined only through experience. Only the alternatives to power wheelchairs have undergone extensive testing to earn qualification for third-party payments. A dealer may attempt to minimize the possibility of selling a hazardous product by purchasing only from established companies, but even this is no guarantee. For example, in 1971, E&J sold the "Remarkable Mark 20, " an electric wheelchair designed for outdoor use by people with minimum hand coordination. It caused several potentially serious accidents (17). To prevent such accidents, the industry would need performance standards for safety, testing to determine whether standards are met, and enforcement to assure that standards are followed.

The lack of standards may also bear on the repair rate of wheelchairs. A wheelchair's need for repairs causes not only inconvenience and expense, but also can be a source of accidents. Accidents due to crossbars' breaking, for example, may be attributed to metal fatigue brought on by extended hard use of the chair, or to defective materials or welding. User complaints registered with the FDA's Center for Devices and Radiological Health include wheelchairs catching fire and wheels falling off (17). Manufacturers and the FDA blame the need for repairs on improper use by the consumer (17), but standards might improve wheelchair durability.

Wheelchair performance standards are currently being written by a task force of the Rehabilitation Engineering Society of North America. This task force is an independent group composed of seven wheelchair researchers, three wheelchair manufacturer representatives, two consumers, one FDA representative, one VA representative, one occupational therapist experienced in wheelchair prescription, and one surgeon specializing in spinal cord injuries. Although the standards will not be officially available for several years, manufacturers who are participating in the writing of the standards have access to the proposals and can consider them in their product design *(27).*

When completed, the standards will be adopted by the American National Standards Institute, although they will be voluntary only. The strongest force for compliance may be the pressures of the international marketplace. Rehabilitation Engineering Society of North America, which is the U.S. representative to the International Standards Organization (ISO),[4] is designing its standards in

[4]The ISO, headquartered in Geneva, Switzerland, sets performance and safety standards for dozens of types of scientific and medical devices.

coordination with the ISO standards, also in preparation. To the extent that Western European and South American countries adopt ISO standards as law, those U.S. companies with large export businesses will have a strong incentive to comply with the standards of the Rehabilitation Engineering Society of North America (14).

Investigation and Resolution of Complaints

If a person believes a wheelchair is defective, he or she can register a complaint with the FDA Center for Devices and Radiological Health, Device Experience Branch, which conducts a search for prior complaints against the product and summarizes the product's history. Only complaints that have been registered with the FDA are included in that history; rarely is a privately handled complaint included. The complaint is assigned a priority rating based on the reason for it. Cases that resulted in death receive highest priority. Those cases where serious harm could have or did occur receive the next highest rating. Both of these types of cases must be resolved within 30 days. The least serious level of complaint, a routine investigation, has no time limit (15).

The suggested priority and the summarized product history are sent to the Center's Regulatory Guidance Branch, where they are evaluated and action is taken. Full investigations are conducted by the field manager responsible for the geographic area in which the manufacturer is located. The field manager inspects the manufacturing plant and product specifications to decide whether the plant is capable of manufacturing to specifications. Assembly and quality control are evaluated, as is the quality of the raw materials. If the complaint is of the lowest priority, the inspector may choose not to investigate until the required biennial inspection (15).

After completing the investigation, the field manager sends an evaluation and recommendation to the Regulatory Guidance Branch, which makes a final decision, FDA prefers voluntary corrective action by the manufacturer rather than direct government intervention. Depending on the nature of the problem, the manufacturer may correct it at its source or may issue a recall of the affected products. Compliance is monitored by followup inspections, typically 30 days for a correction of an in-house problem and 3 months for a product recall.

If the manufacturer refuses to take appropriate action voluntarily, several options are available to FDA. FDA can require the manufacturer to give public notice, repair or replace defective wheelchairs, or give a refund to the user if there exists an unreasonable risk of harm to public health. FDA may petition the court to order a recall of devices that it determines are "misbranded" or "adulterated, " In theory, devices that fail to meet applicable standards could be recalled on these grounds. Finally, "red tag" injunctions may be issued, prohibiting shipment of products from individual warehouses. In practice, these actions are rarely carried out, because they are slow and cumbersome for FDA, and certainly unpopular with the manufacturer.

The most powerful leverage actually at FDA's disposal is the threat of a public announcement that could accompany such legal actions alleging that a product is defective, misbranded, or adulterated. To avoid such harmful publicity, manufacturers usually voluntarily recall a product that FDA considers defective or comply with other requests for corrective action (22).

AS A SUPPORTER OF RESEARCH, DEVELOPMENT, AND EVALUATION

National Institute of Handicapped Research

The National Institute of Handicapped Research (NIHR), sponsors research of interest to people with disabilities. Its $36 million research budget for fiscal year 1983 included not only $750,000 exclusively for wheelchairs, but also other programs, such as work station modifications for disabled persons, that relate indirectly to wheelchair users (28). The NIHR Rehabilitation Engineering

Center at the University of Virginia is researching such areas as power systems, seating, and human factors in wheelchair use. It is also assisting the Rehabilitation Engineering Society of North America in developing standards of wheelchair performance and design (see section "As a Regulator"). It supports two regional institutes to evaluate innovations, disseminate new product ideas, and stimulate the manufacture of all types of devices for handicapped persons.

The National Aeronautics and Space Administration

Through its Langley Research Center, the National Aeronautics and Space Administration is currently devoting about *$50,000* annually in professional time and expenses to apply state-of-the-art engineering techniques to wheelchair design as part of its mandate to demonstrate terrestrial applications of technology *(42).*

Veterans Administration

The VA's Rehabilitation R&D program includes wheelchair research and development projects based on the VA-cosponsored Wheelchair III Workshop *(26),* as well as a collaborative effort with the National Aeronautics and Space Administration involving computer simulation. Goals include design improvements targeting the wheelchair base, power base, and stability. In fiscal year 1983, the VA provided $511,000 for rehabilitation R&D projects on the power wheelchair, seat cushions, anti-roll back design, and a feedback controller.

Over two decades, the VA Prosthetics Center encouraged innovation by demonstrating that new types of wheelchairs were technologically possible, safe, and, most importantly, that there was a significant market for them—the VA. For example, the VA Prosthetics Center's work with power wheelchairs in the early 1970s demonstrated that electric wheelchairs could be safely used at speeds greater than a slow walk, and that they could be designed to be used on rough terrain. This encouraged wheelchair manufacturers to make chairs with those capabilities. Efforts centered around lightweight sports wheelchairs had similar effects (13). These occurrences support the hypothesis that manufacturers will innovate if they feel secure that their products will be purchased by Government agencies and reimbursed by third-party payers. The VA Prosthetics Center in New York City is now responsible for evaluating wheelchairs and other rehabilitative products.

AS A JUDGE OF PRODUCT LIABILITY

Product liability is a risk to any manufacturer. If a wheelchair-related injury or death occurs, the victim or family may file a lawsuit for financial compensation in Federal or State court against the manufacturer and others involved. However, the lack of standards for the wheelchair industry clouds the issue of responsibility.

One manufacturer claimed that product liability suits have replaced medical malpractice suits as the most common and most profitable lawsuits filed today. Many manufacturers choose to settle out of court, rather than incur the costs of a court battle. Others will incur the court expenses, if they believe the incident was not the fault of their product, to uphold their principles and discourage frivolous suits. Regardless of how the manufacturer chooses to resolve complaints filed, the costs are high.

The fear of possible product liability suits is a major obstacle to innovation, according to several of the manufacturers surveyed. This fear is greatest for an entirely new product and less for the majority of innovations, which are modifications of existing products.

All wheelchairs, especially power and power alternative wheelchairs, require a certain level of coordination to operate safely. Manufacturers

specify which impairments complicate the safe operation of their product with the hope of protecting users and avoiding responsibility for accidents to users with those impairments. This process may, however, shift the responsibility for safety to the dealer who sold the wheelchair and to the doctor and therapist who ordered it. Because of this fear of a product liability suit, some doctors and therapists may hesitate to prescribe or recommend a new product whose safety has not been proven.