Technology Assessment of the U.S. Assistive Technology Industry

February 2003

U.S. Department of Commerce Bureau of Industry and Security Office of Strategic Industries and Economic Security Strategic Analysis Division

Acknowledgements

This report was prepared by Stephen Baker, Margaret Cahill, and Stephanie Teeple-Low of the Strategic Analysis Division. Special thanks to: Don Barrett of the U.S. Department of Education; Carol Cohen, David Keer and Bill Peterson of the National Institute on Disability and Rehabilitation Research; Dinah Cohen of the Office of Secretary of Defense; Adele Gorelick of the Administration on Developmental Disabilities; Sally Rood (formerly) of the Federal Laboratory Consortium on Technology Transfer (FLC); Larry Scadden of the National Science Foundation; Jenifer Simpson of the Federal Communications Commission; Tyrone Taylor (formerly) of the FLC; Jim Geletka, former Executive Director, Rehabilitation Engineering and Assistive Technology Society of North America (RESNA); Lois Thibault of the U.S. Architectural and Transportation Barriers Compliance Board; Carolyn Ward of Conwal Incorporated; and Joel Kaiser of the Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services for their many invaluable contributions.

The survey was prepared with the design assistance of the National Science Foundation, with substantial input from NIDRR and the RERCs. Several organizations provided survey mailing lists, including the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA); the Rehabilitation Engineering Research Center on Telecommunication Access located at Gallaudet University; the Center for Assistive Technology — University of Buffalo; the American Orthotic and Prosthetic Association; and Medtrade, Inc.

BIS relied on the expertise of various other government agencies as well as university, federal and private laboratories in designing supporting survey for the study and in writing this report. Contributing agencies included: U.S. Department of Education, National Institute on Disability and Rehabilitation Research; Federal Laboratory Consortium for Technology Transfer, Rehabilitation Engineering Research Centers; U.S. Department of Health and Human Services: National Institute of Child Health and Development, National Institute on Deafness & Other Communication Disorders, National Institute of Neurological Disorders and Stroke; National Science Foundation: Biomedical Engineering and Research to Aid Persons with Disabilities; General Services Administration, Center on IT Accommodation; U.S. Department of Defense, Computer/Electronic Accommodations Program; Federal Communications Commission, Disabilities Issues Task Force; National Aeronautics and Space Administration, Jet Propulsion Laboratory; U.S. Department of Veterans Affairs, Technology Transfer Section, Rehabilitation Research and Development; U.S. Department of Energy, Office of Laboratory Management.

Learn more about the Office of Strategic Industries and Economic Security at: <u>http://www.bis.doc.gov/osies</u>.

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Foreword

The U.S. Department of Commerce, Bureau of Industry and Security,¹ Office of Strategic Industries and Economic Security produced this assessment for the U.S. Department of Education's National Institute on Disability and Rehabilitation Research² (NIDRR) and the Federal Laboratory Consortium for Technology Transfer³ (FLC). The study was undertaken as a result of a February 1998 request from Katherine D. Seelman, Ph.D., then the director of NIDRR at the U.S. Department of Education and C. Dan Brand, then Chairman of the FLC.

The Assistive Technology (AT) industry designs, manufactures, and markets devices used to increase, maintain, or improve functional capabilities of individuals with disabilities. Products that are AT devices encompass a range of technologies and engineering disciplines. AT devices include simple tools such as canes, walkers, conventional wheelchairs and hearing aids.

Increasingly, however, AT devices are becoming more complex, requiring manufacturers to integrate a variety of engineering and manufacturing processes and components. Examples include: computer-controlled wheelchairs with multi-plane occupant positioning; voice recognition software; refreshable braille displays for computers; advanced hearing aids; functionally adaptive prosthetics (some using advanced materials); remotely controlled door-openers; speech synthesizers; direction finders; communications devices; and an array of other items. Some of these products have utilized technologies derived from defense research.

Relatively little detailed economic data exists on the assistive technology industry in the United States, an activity that cuts across dozens of manufacturing sectors. BIS, with the assistance of other agencies, designed a survey to better assess the scope and overall health of the U.S. AT industry; to identify challenges and obstacles confronting AT manufacturers; and to determine what opportunities exist for strengthening the domestic industry.

BIS developed a survey and mailing list of domestic businesses engaged in the design, test, research, development, manufacture and distribution of AT products. The purpose of the data collection effort was to gather sufficient information to begin to: (1) comprehend the composition of the industry; (2) gauge its strength and competitiveness in world markets; and (3)

¹ On April 18, 2002, the Bureau of Export Administration changed its name to the Bureau of Industry and Security.

² NIDRR's statutory charge is to support research to maximize the self-sufficiency of individuals with disabilities of all ages. The agency funds projects to reduce barriers that individuals with disabilities face in education, housing, transportation, employment, rehabilitation, and recreation. For more information about the research funded by NIDRR, see Appendix D.

³ The Federal Laboratory Consortium represents more than 700 U.S. Government research laboratories from 16 federal departments and agencies. The FLC helps American companies to become aware of -- and to utilize -- unique inventions, research facilities, and engineering capabilities residing in federal laboratories.

understand the technology needs of individual firms and identify federal institutions (defense and non-defense) and organizations that could assist U.S. companies.

Scope of this Report

For the purpose of this assessment, BIS defined the Assistive Technology industry to include manufacturing, assembly, research and development, sales, distribution, product testing and consulting. Businesses engaged only in distribution were excluded. The survey was mailed in March 1999.

The survey captured a range of business information including the identification of products and markets, trends in revenues, sources of funding (both public and private) and employment concerns. In addition, the survey asked AT companies for their views on how the industry has been affected by federal and state regulations governing AT products; and by federal and state practices allotting resources for needy people with disabilities to procure AT devices and services.

Methodology

The industry survey was the primary source of information for this study. Survey data were supplemented by limited literature searches as well as direct contacts and interviews with AT industry executives and other industry professionals. BIS also met with representatives of the Centers for Medicare and Medicaid Services, the agency within the Department of Health and Human Services responsible for managing Medicaid and Medicare. Finally, BIS participated in a number of industry trade shows.

BIS sent the survey to about 1,600 U.S. firms and initially received only 232 responses bearing useable data. Out-of-date or otherwise incorrect addresses accounted for a large number of non-respondents; other firms abandoned the market, or were exempt from completing the survey. BIS obtained a total of 359 responses after contacting additional businesses.

Survey participants did not always answer every question. In calculating statistical percentages and averages of aggregated industry data, BIS corrected for non-responses and questionable zero responses. Because there is little financial and statistical information on the AT industry with which to benchmark BIS' survey results, readers of this report should consider the findings to be indicators of performance and trends.

Executive Summary

Overview

Each year, thousands of people around the world are confronted with some form of disability as a consequence of an accident, aging, disease, or other causes—and they wonder how they will cope. For others, it may be just another day of living with a disability, which they may have had since they were young. Regardless of when people develop a disability, they have a common cause—to identify and use, whenever possible, devices that enable them to lead a normal life and to be more productive.

U.S. manufacturers of "assistive technologies" (AT) are doing much to meet the needs of people with disabilities, producing thousands of products to address many conditions. Assistive technology is defined as encompassing any kind of process, system, or equipment that maintains or improves the capabilities of people with disabilities of any kind – physical or cognitive. Examples of AT products include hearing aids, talking books, braille computer displays, orthotics/prosthetics, and wheelchairs. See Table 2 for a more inclusive list.

The 359 companies who responded to the BIS survey reported sales in 1999 of \$2.87 billion, with sales growing 21.8 percent from 1997 to 1999. The industry manufactures more than 17,000 products, and BIS survey respondents employed just over 20,000 workers in 1999 in a mix of small, medium, and large businesses. Sixty percent of responding firms have 10 employees or less. Eleven percent of the responding firms accounted for 69 percent of the revenue.

There are questions, however, about the future of U.S. AT companies, specifically their ability to continue to grow and innovate. To varying degrees, the industry is thwarted by the size of product markets, which can be very small, making it difficult for companies to generate revenues sufficient to attract investors and discouraging them from making their own investments in R&D and manufacturing capacity.

Also, some industry survey respondents expressed concerns about how cumbersome public and private insurance program participation procedures and outdated compensation methodologies may stifle innovation in AT product development, and distort industry market forces. Public and private insurance programs decide which AT devices they will reimburse end-users for, as well as the amount of the reimbursement. Because AT manufacturers are uncertain of when and under what reimbursement structure they will be permitted to sell their product, many product

ideas remain on the shelf, according to survey data collected by BIS from more than 359 companies.

Conversations with company executives, in addition to survey data and written comments from companies, suggest that some product qualification and repayment processes within federal and state agencies may be in need of revision. There are two purposes in such action: 1) to create a more positive climate for innovation and sales in the AT industry; and 2) to ensure that people with disabilities are not denied access to products that can make their lives better.

At the same time, the economic status of many people with disabilities prevents them from acquiring the AT products they need. Many have inadequate private insurance, or are dependent on budget-constrained state and federal health agencies to provide partial or full funding of assistive devices.

Approximately 50 million Americans have some kind of disability—17.5 percent of the 285 million people who reside in the United States. Almost half of the people in this group are considered to be coping with a severe disability.⁴ In sheer numbers, the population of people with disabilities in the United States is certain to grow dramatically as the population ages. In 2001, the U.S. Census estimates that there are 59.6 million people living in the United States who are 55 years of age or older. The figure is projected to skyrocket to 102.7 million by 2025.⁵

Industry and government must rethink the way they work independently and together in order to better serve the American public; maintain market share in the domestic market; to expand sales of American-made AT products in markets overseas; and to incorporate defense and other cutting-edge technologies into AT products. A key challenge for the U.S. assistive technology industry is to effectively penetrate the underserved and unserved market base of Americans with disabilities.

Achieving this goal requires multiple actions on the part of the industry: 1) improving manufacturing efficiency and technology insertion, and fielding new designs to lower production cost; and 2) increasing awareness among people with disabilities of the availability of AT products for specific disabilities. Industry noted in its responses to the BIS survey that state and federal health agencies, regulators, and legislators need to provide more flexibility in administering medical assistance programs that provide AT products to people with disabilities.

At the same time, the U.S. manufacturers of AT devices and interest groups representing people with disabilities need to work more closely with the state and federal governments. New

⁴ See: <u>www.infouse.com</u>

authority and direction may be required to bring about changes in procedures governing the certification of AT equipment; and to increase funds for AT equipment that people with disabilities cannot obtain because of insufficient income or insurance.

In addition, many AT manufacturers operating in the United States might leverage their capabilities and improve product quality by taking advantage of technical resources and intellectual property available at Department of Defense and civilian federal laboratories. Survey data show that a large number of AT companies, many with limited technical resources, have had little or no interaction U.S. Government research organizations.

Finally, federal and state agencies need to revise procedures and adopt policies to encourage greater innovation in the AT industry and to support the AT manufacturing and services industry in the United States. The aim should not only be to serve domestic needs, but to foster expansion of the U.S. AT industry and to boost exports of U.S. AT products and services.

⁵ See: <u>www.census.gov/ftp/pub/population/projections/nation/summary/np-t3-f.txt</u>

I. Introduction

Each year, thousands of people around the world discover that they have developed some form of disability as a consequence of an accident, aging, disease, or other causes—and they wonder how they will cope. For others, it may be just another day of living with a disability, which they have had since their youth. Regardless of when people develop disabilities they have a common cause—to identify and use whenever possible devices that enable them to lead a full life and to be more productive.

U.S. manufacturers of "assistive technologies" are doing much to meet the needs of people with disabilities, producing thousands of products to address many conditions. "Assistive technology" is defined broadly as encompassing any kind of process, system, or equipment that maintains or improves the capabilities of people affected by disabilities of any kind – physical or cognitive.

The AT industry serves several groups of customers: those with temporary needs for assistive devices, and those with chronic medical problems or permanent disabilities that require assistive aids over their lifetimes. The majority of the AT industry's sales is concentrated in serving people with long-term or permanent disabilities.

The 359 companies responding to the BIS survey reported sales in 1999 of \$2.87 billion, with sales growing 21.8 percent from 1997 to 1999. The industry manufactures more than 17,000 products, and, according to the survey data, employed just over 20,000 workers in 1999 in a mix of small, medium, and large businesses. Sixty percent of respondent firms have 10 employees or less. Eleven percent of these firms accounted for 69 percent of the revenue.

There are questions, however, about the future of U.S. assistive technology (AT) companies – specifically, their ability to continue to grow and to innovate. To varying degrees, the industry is constrained by the scale and size of specific product markets, which can be extremely small, making it difficult for companies to generate large revenues and discouraging them from making large investments in research and development (R&D) and manufacturing capacity.

Further complicating life for AT manufacturers are insurance industry rules, which can hinder product introduction and distribution. Similarly, there are regulations within state and federal health agencies that can retard product sales and stifle innovation in AT product development. Demand for AT products is highly dependent on reimbursement from public and private insurers; there are limited alternative markets for most of these products.

At the same time, the economic status of many people with disabilities prevents them from acquiring the AT products they need. Disabled persons often do not have adequate insurance, or are dependent on budget-constrained state and federal health agencies to provide partial or full funding of assistive devices.

Because AT manufacturers are at times uncertain of the dynamics of the target market—or when theywill obtain acceptance of products from regulatory agencies—many product ideas may remain on the shelf, according to survey data collected by the Bureau of Industry and Security (BIS) from 359 companies. The data and discussions with company executives suggest that some processes within federal and state agencies may be in need of revision. The goals of such reform should be to: 1) encourage more innovation and risk taking by companies; and 2) ensure that people with disabilities are not denied access to products that can make their lives better.

To better serve the American public, maintain marketshare in the domestic market, and to expand sales of U.S.-made AT products in overseas markets, both industry and government must change the way they do business. U.S. AT companies have to examine their current business practices with an eye to the future. Despite demographic trends that will increase the market size, those manufacturers that fail to plan for the future may not survive.

The challenge before AT manufacturers is to find ways to produce AT devices more efficiently, at lower cost, and with improved utility to meet rising market demand, increased competition (domestic and foreign), and shifting economics. U.S. companies also must improve their capabilities in many instances in order to create new products as well as to refine and enhance products required in world AT markets.

Approximately 50 million Americans have some kind of disability—17.5 percent of the 285 million people who reside in the United States. Almost half of this group⁶ is coping with a severe disability. The population of people with disabilities in the United States, many of them elderly, is certain to grow dramatically in the years ahead. As of 2001, the U.S. Census estimated there are 59.6 million people living in the United States who are 55 years of age or older—a figure that is expected to skyrocket to 102.7 million by 2025.⁷

A key challenge for the U.S. assistive technology industry is to increase the quality and quantity of products available at lower prices. This will assist federal and state policymakers and the insurance providers in meeting the needs of this aging population. This will also allow the industry to reach more effectively the underserved and un-served portion of Americans who have disabilities. Achieving this goal requires multiple actions on the part of the industry:

⁶ See InfoUse, <u>www.infouse.com</u>

- improving manufacturing efficiency and fielding new designs to lower product cost;
- incorporating new technology from commercial, university, and government sources into products, including defense and civilian technologies available at Department of Defense and other government laboratories;
- increasing awareness among people with disabilities of the availability of AT products for specific disabilities;
- taking cultural differences into account when designing AT products for the U.S. market and for foreign markets; and
- working with state and federal health agencies, regulators, and legislators to provide more flexibility for administering medical assistance programs that provide AT products to people with disabilities.

Finally, the industry and interest groups representing people with disabilities should work closely with state legislators and the Congress to set priorities and to identify the types of disabilities and those groups that may most benefit from the allocation of additional funding support for the acquisition of AT products and the development of new AT devices. At the same time, the budgetary limitations on the private and government resources that will be available in the future will almost certainly require greater thought in setting funding priorities for meeting the needs of people with disabilities.

Markets & Future Demand

Growth in the number of older people in the populations of countries in the United States, Europe, Asia, and elsewhere suggest that there will be a strong, steady increase in demand over the next several decades for a broad spectrum of AT devices from hearing aids and canes to advanced wheelchairs, specially equipped automobiles, and personal communications devices.

Global sales by companies producing AT products and services in the U.S., according to BIS data, totaled \$2.87 billion in 1999, up from \$2.35 billion in 1997 -- an increase of nearly 22 percent. In fact, demand for AT products produced in the United States increased from 1997 through 1999 in almost every major market around the world. These figures represent sales by U.S.-owned companies in the United States as well as revenues of the U.S. business units of foreign companies.

BIS's data understate total sales by AT companies operating in the United States because many firms did not participate⁸ in the AT industry study, or did not report sales information. An

⁷ See <u>www.census.gov/ftp/pub/population/projections/nation/summary/np-t3-f.txt</u>

⁸ The BIS survey was mailed to approximately 1,600 firms. The Interagency Committee on Disability Research in its December 2000 report, *Strategy for the Development and Transfer of Assistive Technology and Universal Design*, estimates that there may be as many as 2500 AT firms operating in the United States.

executive of one U.S. mobility equipment company, for example, estimates the domestic market for his type of products alone (excluding simple wheelchairs) at \$1 billion annually.

The earnings data gathered in BIS' survey⁹ nevertheless is revealing in gauging the size of the markets in the United States and rising rates of demand in some world markets. Sales within the United States grew 25 percent for the 1997-1999 period. AT manufacturers in the United States reported even larger growth in demand in Canada and Mexico, where sales, collectively, jumped from \$48.9 million in 1997 to \$71.5 million in 1999—an increase of 46 percent.

<i>Table 1</i> — AT Company Sales Revenues By World Market Region					
	1997	1998	% Change 1997-1998	1999 (est.)	% Change 1998-1999
TOTAL	\$2,354,358,592	\$2,659,477,215	12.96%	\$2,865,970,683	7.76%
United States	\$1,856,378,902	\$2,126,719,899	14.56%	\$2,320,180,830	9.10%
Canada/Mexico	\$68,728,724	\$86,541,477	25.92%	\$99,182,574	14.61%
Western Europe	\$278,316,610	\$285,911,535	2.73%	\$282,131,864	-1.32%
Eastern Europe	\$64,631,449	\$57,232,404	-11.45%	\$59,007,169	3.10%
South America	\$12,925,206	\$14,505,746	12.23%	\$7,257,539	-49.97%
Central America	\$923,344	\$1,770,760	91.78%	\$1,406,900	-20.55%
Middle East	\$1,774,154	\$2,362,504	33.16%	\$2,181,313	-7.67%
Asia/Pac.Rim	\$36,766,537	\$37,898,850	3.08%	\$43,981,226	16.05%
Africa	\$1,499,946	\$1,782,534	18.84%	\$1,967,204	10.36%
Australia	\$24,314,968	\$25,548,868	5.07%	\$25,120,800	-1.68%
Other	\$8,098,753	\$19,202,638	137.11%	\$23,553,264	22.66%

Source: U.S. Department of Commerce/BIS AT Survey

For now, the United States is by far the largest market for U.S.-based AT manufacturers and service providers. Domestic market demand accounted for 76.5 percent of the 1999 sales of U.S. companies that participated in the AT survey. But with large older populations in Western Europe and Asia, there are clearly major opportunities for U.S. AT companies to expand sales beyond the borders of the United States.

To understand the dramatic expansion that the assistive technology market will experience in the next few decades, consider this: the average age of the U.S. population is getting older and with increased age comes an increased likelihood that one will develop a disability of some kind.

⁹ To avoid over or under representation of the industry, respondents were asked to provide information only on their AT business activities. Some businesses, however, did not isolate information on their AT-related revenues, product lines, R&D investments, work force, business investments and other metrics attributable to the AT market. Many firms not solely engaged in the AT industry were unable to estimate their AT revenues or the proportion of their employees' work week attributable to AT product business activities.

U.S. Census data¹⁰ show that 10 percent of the U.S. population that is between 18 and 34 years of age has some kind of disability, a percentage figure that rises steadily thereafter. For Americans between 65 and 74 years of age, about 42 percent have a disability; and 64 percent of people 75 years or older cope with some sort of disability.

Another positive driver for industry growth is the appearance of new AT technologies—a trend that is projected to continue. Increases in computer power, improved software, and the availability of low-cost microelectronic components that have boosted other sectors of the economy are enabling AT manufacturers to integrate more technology into AT devices. With continued advances in microelectronics, including new sensors and micro electro-mechanical systems, there is every reason to expect not only major innovations in the capabilities of today's AT devices, but also the creation of many new products.

However, a number of factors will make it difficult for the industry as a whole to prosper, even with these positive market forces. These challenges include the prevalence of small firms in the AT industry; problems in hiring and retaining a trained workforce; difficulties in attracting venture capital and other forms of investment; the technology needs highlighted in the BIS survey; and the disconnect between the AT industry and the resources of the federal laboratory system.

¹⁰ See <u>http://www.census.gov/hhes/www/disability.html</u>

Table 2 – Assistive Technology Product Categories			
Product Category	Description		
Architectural Elements	Door opening/closing devices, door levers, lifts and elevators, ramps, safety equipment		
Communication Devices	Augmentative and alternative communication devices (AAC), speech synthesizers, communication boards, board overlays, talking books		
Telecommunications	Wireless and wireline telephones, text telephones (TTY), amplified telephones, talking pagers		
Sensory Aids	Non-computer based devices, such as hearing aids, assistive listening devices, tactile aids for the deaf/blind, alerting devices, braille notetakers		
Computers	Hardware, software, accessories including screen readers, large print products, optical character recognition tools, braille displays		
Environmental Controls	Remotely controlled door openers, telephones, lights, televisions		
Aids to Daily Living	Aids for hygiene, dressing and undressing, toileting, washing, bathing, showering, manicure and pedicure, hair care, dental care, facial care and skin care, housekeeping, handling and manipulating products, and orientation		
Mobility	Transportation safety, vehicle lifts and ramps, walking/standing aids, wheelchairs, seating systems, other types of wheeled mobility		
Orthotics and Prosthetics	Spinal orthotic systems, upper/lower limb orthotic systems, hybrid orthotics, upper limb prostheses, upper/lower limb prosthetic systems, non-limb prostheses, functional electrical stimulators		
Recreation, Leisure, and Sports	Accessible toys, indoor games, arts and crafts, photography, physical fitness, gardening, camping, hiking, fishing, hunting, shooting, sports equipment, musical instruments		
Modified Furniture and Furnishings	Tables, light fixtures, sitting furniture, beds and bedding, adjustable height furniture, work furniture		

Source: U.S. Department of Education/National Institute of Disability and Rehabilitation Research (NIDRR).

In an effort to classify the wide variety of AT products, NIDRR has established a table of product categories for AT devices. The categories shown in Table 2 were used in the survey to collect product information from respondents. To prevent the exclusion of any product, the survey also provided for listing items that did not easily fit any of the categories.

II. AT Industry Composition

Scope & Diversity of U.S. AT Industry

The AT industry is not cohesive or easily characterized. The industry encompasses hundreds of companies that sell more than 17,000 different products¹¹ to a broad spectrum of customers who can have radically different needs. The U.S. AT industry consists of large-, medium- and small-size businesses producing a wide range of products intended for a frequently limited, sometimes regulated, and often partially subsidized market.

AT companies include businesses that develop, manufacture, distribute and support products tailored – exclusively or in part – to the needs of persons with disabilities. Software, electronics, household items, medical supplies, furniture, enhancements to existing products, and specialized devices are just a few examples. To some extent, companies are aligned in industry subgroups, such as manufacturers that make devices for people with hearing disabilities, mobility devices such as wheelchairs, or AT products for people who are blind.

Sixty percent of all survey respondents have fewer than 10 employees, a finding that suggests that in many instances AT industry workers shoulder multiple responsibilities within their business organizations. And, survey data indicate that it is not unusual for AT manufacturers and suppliers to produce a variety of products that serve multiple sectors of the AT market.

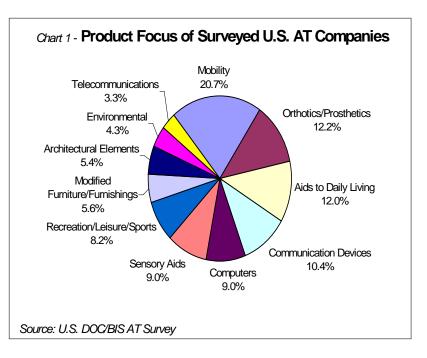
Most firms are primarily engaged in manufacturing, assembly and distribution activities. Of the 287 firms that reported manufacturing as a primary or secondary activity, 245 of them (*see Table 10*) stated that product distribution is also a primary or secondary function for their companies. Product assembly is a major, or secondary, role for 166 of the 359 survey participants. Some 141 firms disclosed that they count applied R&D activities as primary or secondary functions in their operations.

The AT product areas with the largest number of company participants (*as shown in Chart 1*) are: devices to aid mobility, 20.7 percent; orthotics/prosthetics, 12.2 percent; aids to daily living, 12 percent; and communications devices, 10.4 percent. Survey data show that significant numbers of companies also focus on computer related products (9 percent), sensory aids (9 percent) and recreation, leisure and sports products (8.2 percent).

¹¹ http://atto.buffalo.edu/registered/Resources/ATProductDatabases

Fewer companies said they made products for the following AT sectors: furniture/furnishings, 5.6 percent; architectural elements, 5.4 percent; environmental needs and systems, 4.3 percent; and telecommunications, 3.3 percent.

A host of support organizations, including consultants, independent product distribution companies, and private testing and research organizations play important roles in the U.S. AT industry. Of the 359 companies that provided BIS with data, 72



indicated that they are not engaged in manufacturing as either a primary or secondary activity meaning they perform other functions in the industry.

Product testing is one area where AT companies may rely heavily on outside firms. Only 89 of all reporting companies counted product testing as a primary or secondary activity for their firms. Similarly, just 62 companies stated that basic research is a primary or secondary activity. Nearly 70 firms reported that providing consulting services on AT industry-related issues is a primary or secondary activity for their enterprises.

The disparities between the number of companies that responded to the survey and those actually engaged in activities such as manufacturing, assembly, and distribution are partially explained by the use of contract manufacturers in addition to the contracted services mentioned above. Survey responses and conversations with owners of smaller AT businesses revealed that many firms use subcontractors (both domestic and offshore) to manufacture their products. Subcontracting can enable smaller companies to channel their often-scarce resources into new product development and/or marketing.

In addition, subcontracting can be a necessity in instances where product demand is too limited, or the nature of the AT device is so specialized that only a small production run is needed to produce a year's worth of units. Under these circumstances, retaining an in-house production staff and maintaining production equipment may not be cost-effective. Some AT companies determine that their capital is better spent on other AT business activities.

Frequently, companies become engaged in the AT industry by starting to design and manufacture AT devices in response to a personal injury or an illness of a loved one—not as a conscious, planned entrance into the market. There are other manufacturers that move into the industry by acquiring proven or emerging AT products developed by other individuals or companies.

Still other companies become engaged in the AT industry by accident because products or capabilities targeted for the general consumer market find application in the AT market, according to comments provided by study participants. Firms that develop software or manufacture aids to daily living, for example, have suddenly found themselves with an AT customer base because of subtle design provisions or options in a portion of their product line that turn out to be suited for persons with disabilities.

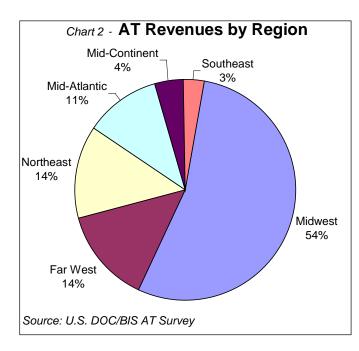
While there is a large and growing customer base for AT products, the business is not always highly lucrative for companies because of the specialized nature of the products, low production volumes, and other factors. A few firms participating in the survey acknowledged that their AT sales were "loss leaders." They stated that their AT products are used to complement more profitable ventures in the medical products and health care services markets.

Sales & Revenues

The bulk of the U.S. AT industry's revenues, survey data reveal, are concentrated among a handful of AT manufacturers. Of the 359 enterprises operating in the United States that responded to the survey, 11 firms accounted for nearly 69 percent (\$1.9 billion) of all 1999 U.S. AT industry revenues. Seven of these 11 firms are located in the Midwest (Indiana, Illinois, Michigan, Minnesota, Ohio and Wisconsin). Chart 2 illustrates the breakdown of AT company revenues by region.

Table 3 – States Hosting The Most AT Firms*			
State	Number of AT Firms	Revenues	
California	58	\$256,686,066	
Florida	28	\$48,963,000	
New York	24	\$37,350,267	
Michigan	22	\$35,331,922	
Minnesota	21	\$521,925,866	
Ohio	20	\$898,362,671	
Wisconsin	14	\$180,098,069	
Massachusetts	13	\$13,250,000	
Texas	13	\$19,549,620	
Pennsylvania	13	\$51,064,645	
Total	226	\$2,062,582,126	

Source: U.S. Department of Commerce/BIS AT Survey



Most of the 11 largest enterprises are engaged in manufacturing, assembly and distribution of a wide range of AT products.

In contrast, the next-largest 27 U.S. AT companies had 1999 revenues totaling only \$578 million—a little more than 20 percent of all industry revenues. The annual revenue of these firms ranged from \$10 million to \$70 million in 1999. The top three product categories represented by this group were mobility, orthotics/prosthetics, and aids to daily living.

In 1999, AT companies operating in the U.S. delivered \$2.87 billion in products and services worldwide, achieving solid growth relative to 1998 sales of \$2.66 billion and to 1997's level of \$2.35 billion. The U.S. AT industry posted gains in sales revenues of nearly 22 percent from 1997 through 1999.

Consumption of AT products by domestic customers accounts for most sales made by AT manufacturers in the United States. Domestic sales hit \$2.32 billion in 1999 compared to 1998's total of \$2.13 billion and \$1.78 billion in 1997. Revenues on domestic sales for AT companies operating in the United States grew by 19.6 percent for the 1997-1999 period.

AT Company Profitability

Businesses engaged in the manufacture of AT products operate in the market with different levels of experience, sophistication, and profitability. The economic returns captured by AT companies are affected by many variables, including basic operating modes. For instance, some companies manufacture or distribute AT products as a supporting activity of an overall marketing strategy for their core business—such as medical products. Other firms focus on AT products as their principle source of income.

The equation for determining profitability becomes more complicated when one considers that some AT firms enter the market with little awareness of the roles that regulatory and reimbursement agencies play in healthcare. These companies face a steeper learning curve than their established competitors. Still other enterprises operate on the fringes of the market, working in a development capacity supporting other AT product companies – and often doing so without a finely honed marketing strategy for their design concepts or products.

To gain a better understanding of the economic health of the industry, survey respondents were asked to provide net income data (*net profits after accounting for all expenses*) related to sales of AT goods and services. Nearly 50 percent of survey respondents — including small, medium and large firms — attribute 90 percent or more of their net income to AT business activities.

At a macro level, data show that overall profitability for the industry grew respectably over three years. Net income reported by survey participants rose from \$134.5 million in 1997 to \$162.2 million in 1999. Much of this growth, as measured in *sales revenue gains*, is concentrated in 10 percent of the AT companies – mostly large- and medium-size firms. Big losses posted by a few AT enterprises, however, limited growth in net income for large companies as a group.

Enterprise-level data indicate that net AT income as percent of sales revenue can vary significantly from company to company. Firms posting high net income can generate it on relatively lowvolume, high-price goods such as advanced wheelchairs – or on simpler products with low production costs and high profit margins. Similarly, when market

Table 4 Net Income For U.S. AT Industry by Size* [Millions of Dollars]			
	1997	1998	1999
Large Firms w/Sales	\$59.7	\$50.3	\$51.4
\$60 million and greater			
Medium Firms w/Sales \$10 to	\$33.7	\$35.6	\$60.1
\$60 million			
Small Firms w/Sales	\$41	\$51.1	\$50.7
under \$10 million			

*Note: Not all companies provided net income data. Aggregate data shown above should be considered only as a trend indicator. Net income growth increases for <u>Large</u> firms and <u>Medium</u> firms for 1998 and 1999 are overstated. This occurs because of the migration of a few companies into the <u>Medium</u> and <u>Large</u> categories.

Source: U.S. Department of Commerce/BIS AT Survey

demand supports volume production, earnings on low-profit AT products can make their manufacture attractive.

The levels of profitability achieved by AT companies vary across enterprise size as well as by the goods produced. Large companies, for example, are not necessarily the most profitable, survey data show. Medium-size companies, on average, are more profitable in terms of the percent of sales revenues retained as net income.

As a group, surveyed firms deriving 90 percent or more of net income from sales of assistive technology saw earnings grow approximately 30 percent between 1997 and 1999. This growth was largely concentrated in a group of slightly more than 200 companies. In 1999, global sales for these firms totaled \$2.626 billion compared to overall sales of \$2.87 billion for all AT companies operating in the United States that participated in the survey.

Table 5 – Profitability Profile of Companies Engaged in the AT Industry – 1999				
Net Income* as a Percent of Sales Revenue				
Percent of Revenue Attributable To AT Sales	90-100%	50-89%	Less than 50%	
1999 Sales Revenues	\$2,625,561,723	\$97,312,615	\$152,996,345	
Average Net Earnings as a % of Revenues*	5 %	17 %	13.6 %	
[Number of Companies]	[164]	[15]	[53]	

*Average net earnings were calculated on a smaller base of revenue and companies for each category because not all firms provided sufficient useful data in response to the survey question.

Source: U.S. Department of Commerce/BIS AT Survey

Seventeen companies that obtained 50 to 89 percent of their net income from sales of AT products and services had 1999 sales of \$97.3 million. Another 81 firms that collected less than 50 percent of net income from AT products posted sales of \$153 million.

At 17 percent, average net earnings as a percent of revenues was greatest in 1999 for companies that derived 50 to 89 percent of net income from AT product sales. Companies attributing 49 percent or less of their of net earnings to AT sales had average net income of 13.6 percent. Average net earnings on AT sales was smallest – five percent – for firms that generate 90 to 100 percent of net income from AT industry-related businesses.

Survey data provide no definitive explanation for why average net income is significantly lower (*on a percentage basis*) for companies that are heavily dependent on AT sales as their prime source of revenue. A number of factors may contribute to this situation.

In the case of smaller AT companies, their operating margins can be slimmer in some instances because of lower sales volume and revenue. In addition, those smaller companies that have a weak understanding of healthcare industry and regulatory pricing policies may have lower sales and could incur larger than necessary overhead costs.

Table 6 – AT Industry Income Growth 1997-1999							
Year 1997 1998 1999							
Aggregate Reported AT Net Income	\$134,473,288	\$136,996,145	\$162,222,609				
Growth in AT Net Income From 1997		+1.9%	+18%				
Number of Valid Responses	241	252	246				
Average Net Income Based on Valid Responses	\$393,655	\$543,635	\$659,441				

*Net income represents net profits after accounting for all expenses. "Valid responses" are data points provided by companies in response to the question as opposed to a blank response. Average net income was calculated on the following values: 1997 = \$94,873,288; 1998 = \$136,996,145; and 1999 = \$162,222,609. Source: U.S. Department of Commerce/BIS AT Survey

Looking at the AT industry from another vantage point, survey findings demonstrate that being bigger does not necessarily translate into higher profitability (*see Table 7*) as measured by net income on sales. In 1999, AT companies with sales revenues of \$60 million and higher posted sales revenues of \$1.975 billion. Of that amount, an estimated \$51.4 million¹² -- or about 2.8 percent – was captured as net income.

In contrast, medium- and small-size companies participating in BIS' survey, on average, appear to have significantly higher levels of net income as a percent of sales revenue. In the case of medium-size AT firms (those with 1999 sales revenues of \$10 million or more, but less than \$60 million), average net income was 13 percent on sales revenues of \$526.5 million. Small companies – those with sales revenue below \$10 million – achieved average net income of 13.1 percent on their operations. As a group, small firms generated \$374.4 million in sales revenue.

The data provided by survey participants do not explain why larger companies, which would presumably benefit from greater economies of scale in manufacturing and distribution, have lower net income (*on a percentage*

Table 7 Assistive Technology Company Net Income					
Firm Size	1999 Sales Revenue	% Net Income -			
	(Millions of dollars)	for 1999*			
Large	\$1,975	2.8%			
Medium	\$526.5	13%			
Small	\$374.4	13.1%			

*Net income was calculated on a smaller sales base because not all survey participants provided complete data. Source: U.S. Department of Commerce/BIS AT Survey

basis) than that achieved by small- and medium-size AT companies. One explanation for these differences in net income is that larger firms produce goods for which there are multiple suppliers and significant competition. In addition, some high-cost products, such as automated wheel chairs, may have low profit margins. Clearly, large losses reported by some firms depressed average earnings for this sector. Even after accounting for this, average net income for the group trailed that of medium- and small-size companies.

Small- and medium-size firms score high net profits on a percentage basis for a number of reasons. Some firms focus on producing special products for which they can earn a high profit margin. In addition, these firms may not incur the overhead charges that larger firms can incur as a consequence of their scale.

AT Industry Employment

As with many economic sectors in the United States, employment levels in the AT industry rise and fall with market demand. Overall, however, compelling demographics -- principally

¹² Percentage figures for net income cited above were calculated after accounting for non-responses and other data aberrations. Where necessary to avoid data skewing, extrapolation was employed to cover missing data points.

increases in aging populations in the United States, Europe, Asia, and other parts of the world -have helped keep the U.S. AT industry's employment base growing. On average, the number of employees per firm increased more than seven percent from 1997 through 1999.

For this same period, overall employment in AT companies participating in the survey climbed from 18,953 in 1997 to 20,315¹³ in 1999. Most of this growth (*see Table 8*) occurred in manufacturing, assembly and marketing/sales/administration. These three sectors account for more than 85 percent of total industry employment.

In contrast, engineers, scientists and technicians represent a small portion of the U.S. AT workforce, about 10 percent of the total AT workforce. But as a proportion of the AT workforce, between 1997 and 1999, this group increased its presence – by one percent overall – within the employment ranks of the AT companies participating in the survey.

Healthcare professionals are even a smaller component of the U.S. AT industry, accounting for less than 2.5 percent of the workforce in 1999. Total employment of healthcare professionals at AT companies participating in the survey grew from 442 in 1997 to 497 in 1999.

The greatest employment growth for 1997-99 among AT survey participants occurred in product assembly where 408 jobs were added, an increase of 10 percent. There was also substantial job growth – 359 positions—in marketing, sales, and administration during this time.

Employment levels in manufacturing were subject to mild swings over this three-year period. Survey participants reported a total manufacturing workforce of 7,392 for 1997, which represented 39 percent of the entire AT workforce at respondent companies. In 1998, that number fell to 7,178 before jumping to 7,643 in 1999 (37.7 percent of the AT workforce at respondent companies).

The changes seen in manufacturing employment in the AT industry appear to be driven by market factors and shifts in manufacturing practices. The shifts in employment levels might have been deeper were it not for management practices employed by some AT companies.

For many of the AT businesses surveyed, manufacturing and marketing-related responsibilities are distributed over a core group of personnel, with individual employees performing tasks in one or more of the job categories defined in the survey. This multi-tasking approach allows firms to retain key personnel in market downturns and to run their businesses with smaller staffs.

Other AT manufacturers, survey respondents indicate, use subcontractors for manufacturing and assembly activities. So-called 'job-shops' offer flexible and cost-effective alternatives for businesses that cannot justify maintaining their own manufacturing capability. It also enables some companies to handle market cycles more effectively while maintaining corporate focus on critical product development and marketing activities.

Table 8 — Composition of U.S. AT Company Workforce						
JOB CATEGORY	1997	% for year	1998	% for year	1999 (est.)	% for year
Scientists, Engineers, Technicians	1,713	9.1%	1,804	9.2%	2,056	10.1%
Healthcare Professionals	442	2.3%	504	2.6%	497	2.5%
Manufacturing	7,392	39.1%	7,178	36.6%	7,643	37.6%
Assembly	4,042	21.4%	4,409	22.5%	4,450	21.9%
Marketing/Sales/General & Administrative	4,864	25.7%	5,286	27.0%	5,223	25.7%
Other	447	2.4%	422	2.2%	433	2.1%
Totals	18,900		19,603		20,302	
Average number of employees/firm*	58.6		60	.6	62.	8

Source: U.S. Department of Commerce/BIS AT Survey

^{*} Averages calculated on base of 323 firms and employment figures of 18,953 for 1997, 19,577 for 1998, and 20,315 for 1999. The growth in average employment over the period was 7.2 percent.

¹³ Employment figures cited vary slightly from those cited in Table 9 because of irregularities in reporting by survey participants.

III. Market Strength & Reach of U.S. AT Firms

One measure of the strength and growth potential of AT companies operating in the United States is the extent of ownership of multiple production, research, service, distribution, and administrative facilities. Most of the AT product manufacturers and service companies that participated in the survey appear to be U.S.-based businesses.

The survey asked participants to identify all of the facilities they owned, domestic and foreign. In total, the 359 surveyed businesses reported 442 facilities worldwide. Eighty-three companies have at least two facilities -- and of this group, 26 enterprises operate three or more facilities.

Twenty-four of the	Table 9 — Facilities* Operated by AT Survey Participants						
•	No. of Facilities						
facilities operated by	Firm Operates	USA	Canada	Mexico	Europe	Australia	
survey participants are	One	359					
located in other countries:	Two	41	3	2	10	1	
16 in Europe, one in	Three – or more	18	2		6		
I '	Total AT facilities operated by survey participants = 442 worldwide						
Australia, five in Canada,	*Figures cited here are only those AT facilities operated by survey participants. The term						
and two in Mexico.	"facilities" includes corporate offices as well as production and distribution facilities. Source: US DOC/BIS AT Survey						

Forty-six of the 359 companies responding to the survey provided data on their ownership. Of these 46, one company is Canadian, 14 are based in Western Europe, and 31 are U.S. firms.

AT Technological Leadership, Research and Development

The strength of the larger U.S. companies operating in the AT market relative to small American players and foreign competitors may be influenced not just by marketing and distribution muscle, but also by their level of investment in research and development. As might be expected, the ten largest firms in 1999 spent the most per company on research and development—more than \$52.1 million, or an average of \$5.2 million per company.

In contrast, the second-tier group of companies spent \$15.9 million in total – an average of $695,238^{14}$ per company for the same period. Only seven of the 27 companies in this category spent more than \$1 million on R&D in 1999. The largest sum allocated to R&D by any single firm was \$3 million.

¹⁴ Average calculated on data provided by 23 second-tier firms.

R&D expenditures were dramatically lower at the third-tier level, where average spending for 319 companies in 1999 is estimated at about $$171,000^{15}$ (*See Section V for more on R&D investment*). Just 17 of these 319 companies had R&D expenditures exceeding \$500,000 in 1999 with the largest expenditure by a single company being \$5 million.

For many of the U.S. AT companies that provided survey data, investing in R&D is not a high priority. With respect to applied research, nearly 24 percent of companies report that it is a primary activity and another 16 percent state that R&D is a secondary activity. The responses provided by survey participants (see Table 10) imply that for nearly 60 percent of companies applied R&D is not a significant function of their operations.

Table 10 — Business Activity Characterization						
Activity	Primary Activity (# of firms)	Percentage of Respondents*	Secondary Activity (# of firms)	Percentage of Respondents*		
Basic Research	26	7.26%	36	10.06%		
Applied R&D	85	23.74%	56	15.64%		
Product Testing	40	11.17%	49	13.69%		
Manufacturing	250	69.55%	37	10.34%		
Assembly	134	37.43%	32	8.94%		
Distribution	193	53.91%	42	11.73%		
Consulting	19	5.31%	49	13.69%		
Basic research was defined as the pursuit of a planned search for new knowledge, whether or not the research refers to a specific application. Applied R&D was defined as the application of existing knowledge to problems involved in the creation of a new product or process, including work required to evaluate possible uses, or apply existing knowledge to problems involved in the improvement of a present product or process. Research and development (R&D) includes basic research and applied research in the sciences and in engineering, and design and development of prototype[s], products and processes. For the purposes of this survey, R&D includes activities carried on by persons trained, either formally or by experience, in the physical sciences including related engineering, and the biological sciences including medicine.						

Source: U.S. Department of Commerce/BIS AT Survey

*Companies were encouraged to select as many types of activities as necessary to fully describe their business operations. As a result, many respondents selected more than one primary or secondary business activity. The responses appear above.

An even lower priority for AT companies is basic research, which may not provide any nearterm payoff in the form of cash-generating product improvements or new products. Barely seven percent of the 359 participants in BIS' survey consider basic research a primary activity of their company; and only 10 percent count it as a secondary activity. In short, basic research is not an activity that 85 percent of survey respondents engage in to any significant extent.

¹⁵ Average R&D spending by 319 firms with 1999 annual sales revenue of less than \$10 million is estimated based on data from 195 companies. No information was provided by the remaining 124 firms.

Market Opportunities & Challenges

It appears that a significant portion of the people with disabilities in the United States is underserved in terms of access to AT devices simply because of their economic condition. An estimated 23 percent of those aged 21 to 64 with a *non-severe disability* are unemployed; and approximately 74 percent of people with *severe disabilities* are without jobs.¹⁶ This makes it difficult for many people with disabilities to afford the assistive technologies that are available.

Besides lacking personal financial resources to acquire AT products, people with disabilities at times are faced with difficulties in working with state and federal regulations, out-of-date product lists, and a lack of knowledge of the application and usefulness of devices, according to written comments submitted by survey participants. State and federal regulatory agencies, they noted, often fail to stay current on the latest medical innovations and application of AT devices—new and existing—to address disability issues.

This is not only a problem for people with disabilities. It also is an obstacle for manufacturers trying to bring new products to market. The challenge of establishing product recognition and acceptance does not end with the government; winning over private health insurance providers is also critical to launching new products and staying in business. In short, with many non-market variables to contend with, the AT market can be a high-risk business venture for manufacturers.

U.S. Exports & Foreign Competition

At this time, the U.S. AT manufacturing industry appears to be healthy and it competes in international markets. About 23 percent of survey respondents' 1999 sales of \$2.87 billion were derived from foreign markets. U.S. companies, however, face strong competition from Asian and European manufacturers.

The four largest export markets for the United States are Western Europe, Canada/Mexico, Eastern Europe and the Asia/Pacific Rim region. The foreign market regions with the strongest growth in purchases of U.S. AT products from 1997 through 1999 were: Canada/Mexico, rising 44 percent; and Asia/Pacific Rim, up 20 percent.

While these figures are respectable, U.S. manufacturers cannot be certain of retaining this marketshare in the future. Sales of AT products to foreign customers by U.S. manufacturers, in fact, declined noticeably in 1999 in some markets. Customers in Western Europe cut back

¹⁶ See <u>http://www.census.gov/hhes/www/disability.html</u>

purchases slightly. South America and Central America posted steep reductions of 50 and 21 percent, respectively. Sales to Australia and the Middle East also declined.

Trying to expand, or at least retain, domestic and foreign customer bases may prove to be a challenge for U.S. AT manufacturers. The United States does not dominate all facets of the global AT industry by any means. For example, Germany's Siemens AG is a market leader in hearing aids, and Sweden-based Permobil is a technological leader in high-performance, computer-controlled wheelchairs.

Western Europe is the largest export market for AT products manufactured in the United States, but at \$282 million for 1999, U.S. firms' presence in the Western European market is hardly exceptional. U.S. AT sales to Western Europe represent just 12.2 percent of the \$2.32 billion in sales rung up by U.S. AT manufacturers in the domestic U.S. market.

According to Association for the Advancement of Assistive Technology in Europe¹⁷(AAATE), more than 20,000 AT products are sold in Europe and annual market sales are estimated at about 30 billion Euros (approximately \$28.2 billion). This figure differs significantly from the

estimates of the size of the U.S. AT industry in this report, which are based on survey data provided by companies. AAATE based its calculations on European industrial sector data that covers a much broader pool of manufacturing activities than the production of products for the disabled.¹⁸ Consequently, it appears that the reported level of AT product sales by European companies is greatly overstated.

Nevertheless, Europe is the "largest potential market for AT product in the industrialized world," according to some

Table 11 — Top Competing Nations*					
Competitor Country	Number of mentions	Number of firms citing a nation ten or more times			
Germany	57	18			
Canada	27	17			
Denmark	23	7			
United Kingdom	22	18			
Sweden	16	7			
Switzerland	11	2			

Note: The AT companies referenced in the table above either produce in one location and distribute through firms in many countries; or manufacture and distribute products in multiple locations worldwide. *Some foreign competitors were listed by more than one respondent; each instance was included in the tally for the country, which is given in the second column. Each of the top six competitor countries was cited more than 10 times by survey participants

Source: U.S. Department of Commerce/BIS AT Survey

British analysts. They note that in 1995, there were an estimated 26 million potential consumers of AT products in Europe – a figure that is projected to increase 25 percent by 2020.¹⁹

¹⁷ See <u>http://www.fernuni-hagen.de/FTB/aaate.htm#resources</u>

¹⁸ BIS conferred with Christian Bühler at AAATE concerning the basis for its estimate of AT business activity in Europe.

¹⁹ See <u>The Role of Assistive Technology in Alternative Models of Care for Older People – Appendix 4, p. 336</u>, Donna Cowan, Alan Turner-Smith, Centre of Rehabilitation Engineering, King's College, London, England, <u>www.archive.official-</u>documents.co.uk

In marketing products in Europe, U.S. AT companies may encounter many of the same problems they experience in the United States. Across Europe there are national social systems with varying regulations for reimbursements to people with disabilities for purchases of AT products, according to AAATE.

Understanding the full dynamics of AT product manufacturing and trade around the world is difficult because there is limited data -- and what information is available often is fragmented. BIS' survey data covers only the global activities of respondent companies operating in the United States.

To gauge the extent of U.S. AT company awareness of competitors, survey participants were asked to identify their five major worldwide competitors.²⁰ Interestingly, only about nine percent of AT survey participants cited foreign-owned firms as competitors. Even so, responses to survey data indicate that U.S. AT companies are concerned about foreign competition.

At the same time, survey results suggest that many U.S. firms that manufacture and distribute AT products are not fully aware of their competition and what's going on in the world AT market. When asked for an estimate of their company's share of the world market, 80 of the 359 companies surveyed (about 22 percent) provided no answer; another 109 reported that their market share was zero. For the remaining 170 companies, responses ranged from less than one percent to 100 percent – the average global marketshare being 13.1 percent.

The wide spectrum of responses for these two questions may be attributable to the significant disparities in the sophistication and analytical capabilities of U.S. AT companies, which include a handful of very large enterprises and much greater numbers of very small operations. Some respondents acknowledge in written comments and conversations that they simply found it too difficult to estimate their share of the AT market or to stay abreast of the activities of foreign competitors. It was also stated that the U.S. Government does not have sufficient data to properly assess the AT market.

AT firms also were asked if they thought foreign producers of assistive technology devices have any advantages over their firms--advantages *not related* to the quality or features of their products. In response, 60 percent of survey participants answered "*No*" to the question.

²⁰ In all, 294 of the 359 survey respondents listed at least one competitor, for a total of 1,218 responses. Eight companies responded with regional responses (Asia, Europe, etc.) or said they knew of no competitors who filled the same market need.

But, 105 companies (29 percent) stated that their foreign competitors have advantages unrelated to quality or product features (*see table 12*). Another 37 firms had no response.

AT companies then were asked whether foreign competitors are able to manufacture AT products less expensively. Twenty-one percent of survey participants gave no response. The

Table 12 – Do foreign competitors have advantages unrelated to product quality and features?						
Response Number of Percentage of Responses Responses						
Yes	105	29.2 %				
No	217	60.4 %				
No response	37	10.3%				

Source: U.S. Department of Commerce/BIS AT Survey

companies that chose to respond were almost equally divided on the answer, although more AT firms thought that foreign manufacturers were more efficient.

There is a degree of contradiction in the responses to the questions posed in *Tables 12* and *13*. Sixty percent of U.S. AT companies declared that their competitors have no edge that is unrelated to product quality and features. Yet when asked if foreign manufacturers are more efficient producers – an apparent advantage – only 38 percent of participating companies

Table 13 — Can foreign competitors manufacture less expensively?						
Response	nse Number of Percentage of Responses Responses					
Yes	146	40.7 %				
No	137	38.2 %				
No response	76	21.1 %				

Source: U.S. Department of Commerce/BIS AT Survey

asserted that foreign companies cannot manufacture at lower costs than U.S. AT companies.

The difficulty that some companies have in assessing their competitive positions in the global marketplace is reflected in the number of non-responses in *Tables 12* and *13*. While just 10 percent of participants did not respond to a question related to competitive advantage (*Table 12*), the number of non-responses jumped to 21 percent for the question about manufacturing cost competitiveness (*Table 13*).

With respect to whether foreign companies can manufacture less expensively, U.S. AT firms' responses varied considerably by product category. Most of the respondents (70 to 74 percent) that manufacture communications devices and computer controls *do not* believe their foreign competitors can produce their products less expensively.²¹ In contrast, about 60 percent of respondents that manufacture aids to daily living, mobility products, and furniture and furnishings *believe* that foreign competitors manufacture products less expensively.

²¹ Whether U.S. manufacturers today would still be so confident about their ability to manufacture AT-related communications devices and computer controls as cost effectively as foreign companies is unclear. Since the survey data were collected, a large portion of the U.S. electronics manufacturing supply base that AT companies might rely on has been moved to other countries or shut down.

In written comments accompanying their "*Yes*" or "*No*" responses, companies expressed considerable concern about a range of economic and regulatory advantages held by foreign competitors. In some instances, survey participants noted that labor and material costs were so low in other regions of the world that foreign competitors can sell products below the material costs of U.S. firms.

Table 14 — Technology Breakout: Can foreign AT firms manufacture less expensively?							
Product Category	Number of Firms	"Yes"	% of Firms	"No"	% of Firms	No Response	% of Firms
Architectural Elements	31	12	38.71%	11	35.48%	8	25.81%
Communication Devices	61	14	22.95%	35	58.33%	12	18.33%
Telecommunications	19	8	42.11%	9	47.37%	2	10.53%
Sensory Aids	52	22	42.31%	21	40.38%	9	17.31%
Computers	52	9	17.31%	31	59.62%	12	23.08%
Environmental Controls	26	9	34.62%	12	46.15%	5	19.23%
Aids to Daily Living	70	32	45.71%	23	32.85%	15	21.43%
Mobility	119	54	45.38%	41	34.45%	24	20.17%
Orthotics/Prosthetics	70	28	40.00%	29	41.43%	13	18.57%
Recreation/Leisure/ Sports	48	28	58.33%	13	27.66%	7	14.89%
Modified Furniture	32	15	46.88%	11	34.38%	6	18.75%

Source: U.S. Department of Commerce/BIS AT Survey

More responsive product review and approval procedures for medical products in many foreign countries were cited as providing an edge for competitors in launching products in their home markets. In addition, some companies asserted that European nations were more supportive of their AT industry, enabling rapid introduction of many technological advancements in the industry while slowing imports by not providing adequate guidance regarding their market's product certification requirements.

Not unlike companies in other segments of American industry, U.S. AT companies complain that their inventions and product designs are effectively being stolen at times as a result of patent and copyright infringement. Companies have identified exact copies of U.S.-patented AT products that were produced in China without license—and then sold in the United States.

U.S. AT Industry's Future

While U.S. companies face significant competitive pressure in some markets and product lines, survey data show that companies are largely positive on their prospects for competing effectively in the years ahead.

U.S. AT executives were asked to predict how their overall competitive prospects would change in the next five years. More than 72 percent of the companies responding to the question anticipated that their businesses would grow to some degree—with 34.8 percent expecting conditions to "improve greatly" and another 37.5 percent expecting their prospects to "improve somewhat."

Another 27 percent of surveyed firms said business would be flat or shrink. Specifically, 21 percent of companies forecast that business prospects would "stay the same." Another 5 percent projected business to "decline somewhat"—and less than one percent of respondents stated that business would "decline greatly."

Unfortunately, it is not clear which if any market forces are driving this apparent optimism for the future. The business confidence expressed by most respondents may have been generated in part by the economic boom occurring at the time the survey was conducted.

Table 15 - Self-Reported Business Prospects						
Competitive Prospects Will	Number of Responses	Percentage of Responses				
Improve Greatly	117	34.82 %				
Improve Somewhat	126	37.50 %				
Stay the Same	71	21.13 %				
Decline Somewhat	18	5.36 %				
Decline Greatly	3	0.89 %				

Source: U.S. Department of Commerce/BIS AT Survey

Is the bright market outlook held by survey participants skewed? While it may be difficult to predict the future, AT firms are keenly aware of demographic trends—the aging of large populations of people in Asia, Europe, North America, and other parts of the world.

In addition, U.S. AT companies recognize that there is growing public awareness of both the need for and utility of AT products—and a proliferation of product types as well. All these factors point to surging demand for AT products over the next several decades. As a consequence, many companies are optimistic about the future.

IV. Positioning U.S. AT Firms for Growth

Although many U.S. AT companies have a positive outlook about their future business prospects, managers recognize that to retain and expand their market positions they must reduce delays in the development, introduction and marketing of new products. With the likelihood of increased foreign competition in the years ahead, the time-to-market equation will become increasingly critical to establishing market position.

For many U.S. AT companies, a change of operating culture may be required. Some firms, for example, may need to strengthen product design and manufacturing capabilities. Several survey respondents described their manufacturing processes and marketing methods as inadequate and out-of-date when compared to other, more technologically advanced and competitive industries. In some instances entirely new technologies will have to be mastered and employed by AT manufacturers operating in the United States if they are to remain competitive with offshore companies.

In parallel, AT firms must continue to work with state and federal regulatory agencies streamline processes for setting reimbursement levels for AT products used by people with disabilities. The U.S. AT industry should work with private insurers to more quickly post new products on their schedules of eligible AT equipment for people with disabilities. In concert with these steps, U.S. trade agencies must intensify their efforts to assist U.S. companies in penetrating foreign AT product markets.

The Regulatory Environment

Generating product recognition and acceptance is critical to sales, especially for AT manufacturers that make products for low-demand niche markets where operating margins and profits can be thin. Compounding the challenge to AT manufacturers is the fact that the AT market currently is relatively small—and that in portions of the AT market customer base nearly 75 percent of consumers are unemployed. This means that the customers for AT products often times have little or no surplus income with which to make purchases.

Companies face additional downward price pressure given that most of the customers with disabilities are dependent on public and private health insurance programs to underwrite much of the cost of AT equipment. These institutions and state agencies place price limits on

reimbursements for AT products—and they determine what products are eligible for reimbursement payments.

Among the challenges facing the AT companies operating in the United States, according to industry executives, are to: 1) get state and federal health agencies to accelerate the acceptance process for new AT products; and 2) to expand the range of AT products eligible to be covered under public and private health programs.

Rapid approval of new products is particularly crucial to small companies launching new products, both to achieve sufficient volume to operate economically and to establish a strong market presence. Where the application of state and federal regulations or private insurance policies produce unnecessarily long delays in product introduction, the effect can be to reduce cash flow, damage companies, and to delay or even suppress development of new products.

Federal agencies and programs identified by some survey respondents as having policies that adversely affect the ability of AT companies to develop and market products include: the Centers for Medicare and Medicaid Services (CMS – formerly the Health Care Finance Administration [HFCA]), the National Institute on Safety and Health (NIOSH) and the Food and Drug Administration (FDA). In one instance, a company charged that "HCFA Medicare dictates…purchases of cheap imported goods" over domestic products that may cost more without giving adequate consideration to product performance and quality.

According the reported data, the problems that AT companies encounter and the perceived level of difficulty can vary widely depending on company size and kinds of AT products involved. While 30 percent of respondent companies described the product approval process as having an average to high level of difficulty, about 70 percent of responding firms cited no significant problems with FDA. For these companies, the approval process may run smoothly – or their products may not be subject to FDA approval.

A number of survey participants also stated that their desire to pursue the development and manufacture of AT products is tempered by fears of inadequate protection for their business against product liability claims. Larger firms participating in the survey rated product liability as a moderate problem. The concerns of larger firms focused on the potential for misuse of a product as well as product performance and quality matters. Interestingly, smaller firms, as a whole, did not rate product liability and other legal issues to be a major deterrent. It is also worth noting that AT companies of all sizes expressed concern about on-the-job injury claims brought by their own employees.

Beyond issues of domestic regulation, participants in the AT industry want greater assistance in overcoming regulatory and other legal issues related to exports, trade and foreign standards. Survey data do not show U.S. AT companies to be burdened with trade obstacles of "crisis-like" proportions. Nevertheless, a large number of companies say they face serious trade problems. When asked to rank how tariffs and trade barriers affected their ability to work in foreign markets, 152 of 343 companies responding to the question stated that such practices are difficult to extremely difficult to overcome. A few companies stated that some problems were insurmountable.

In written comments, survey participants asserted that trade opportunities are seriously diminished by a range of market distorting practices. Specifically, U.S. AT companies cited special financing packages, tax incentives, tax reductions, product R&D subsidies to companies, and other subsidies for AT product commercialization and manufacturing provided by the governments of some European (United Kingdom, France, Germany, Sweden) and Asian (China, Taiwan) nations. In some countries, U.S. AT manufacturers claim they are hurt by import duties levied on U.S. AT goods, and damaged by AT product certification rules.

The portfolio of government assistance, incentives and subsidies available to foreign competitors of U.S. AT companies in some Asian and European countries is viewed as providing an unfair advantage. Direct U.S. federal government assistance available to U.S. AT companies is largely limited to competitively awarded Small Business Innovation Research (SBIR), National Science Foundation grants, and other Department of Education funding.

The comments submitted by respondents with respect to the foreign market conditions and trade practices suggest that some actions by the Office of the U.S. Trade Representative and other federal trade agencies may be required. Specifically, companies indicated that what is needed is an intensified effort to get foreign governments to remove trade barriers and roll back market-distorting subsidies that unfairly hinder U.S. AT companies attempting to do business in foreign markets.

It is also apparent in written comments that some AT companies have little or no experience in selling in foreign markets and limited knowledge of regulatory and trade policies. These factors, to some extent, may have shaped complaints about difficulties in marketing overseas. It appears that U.S. AT firms, in some instances, need to expend more effort to learn how to conduct business and sell in international markets.

Strengthening U.S. AT Technological Capabilities

To compete effectively in future years, U.S. AT companies must improve their performance on many fronts, including manufacturing, utilization of technology (commercial and defense), and the development and fielding of new products. In the face of rising competition and high labor and material costs, U.S. manufacturers have no choice but to learn to produce more efficiently to retain markets and remain profitable.

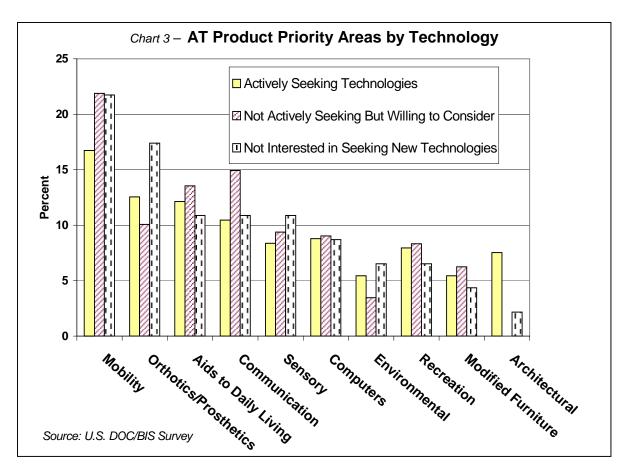
On a positive note, most of the 352 companies responding to a question on fielding new products, indicated that they were: 1) actively developing products themselves, 2) actively seeking to acquire new products, 3) or willing to evaluate new products. Only 20 percent of firms responding to the question stated that they were not willing to review new products—or were not developing or seeking new products.

The picture, however, becomes a bit more worrisome when comparing corporate attitudes against actual practices. Many U.S. AT manufacturers, data suggest, do not utilize modern manufacturing processes and technology in product development and production as effectively as they might.

Responses by AT survey participants indicate that many companies are not aggressive enough about seeking out new technologies that would enable them to create new products – or to maintain advantage in the marketplace for existing products. Failure to implement advances in manufacturing and marketing processes used by competitors only serves to thwart growth, and limits the ability to quickly respond to emerging trends in world markets.

Asked to describe their approach to deploying new technology, 62 percent of firms indicated that they are passive in their pursuit of new ideas -- or not interested at all. Some 183 AT companies (52.6 percent) said they *were not actively* seeking technologies but were willing to consider new technologies as they become available. Another 34 firms (9.7 percent) said they *were not interested* in seeking new technologies. Fewer than 40 percent of the 348 companies responding said they were "actively seeking technologies from outside sources." An examination of industry responses on AT product priorities by technology (*see Chart 3*) shows that interest in developing new technologies varies across AT product categories. Companies were generally most interested in pursuing or acquiring new technology that would support product development in the areas of mobility, orthotics and prosthetics, aids to daily living, and communications.

There appear to be clear opportunities for the AT industry to pursue the application of technology to enhance their product development and manufacturing capabilities significantly. Survey responses suggest, however, that much of the industry is not utilizing the resources available to it. U.S. Government laboratories, for example, have a wealth of defense-related and civilian technologies available for transfer to private industry. These laboratories also offer extensive



expertise and consulting services. Relatively few AT companies have used the capabilities of U.S. federal government laboratories to augment their own R&D and engineering capabilities. When asked whether they knew how to tap the expertise resident at federal R&D and technology centers, only 25 of 359 companies (less than 7 percent) said they have such experience and capability.

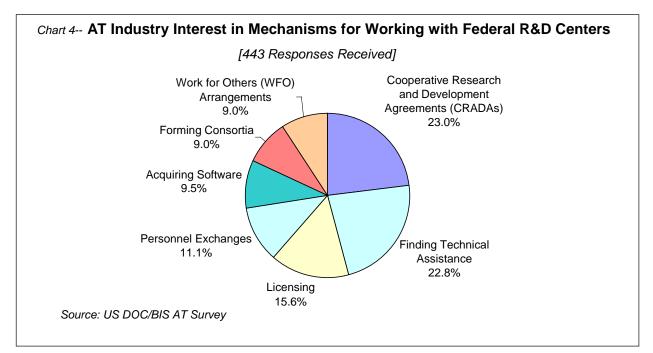
In response to a separate question on whether they had previously worked with private industry, universities, and government laboratories, or other outside institutions to develop AT products or related technologies, 46 of 338 companies said they had done so on one or more occasions. These 46 companies reported 98 such collaborations, 47 percent of which were with universities; 21 percent were with industry organizations; 18 percent with unidentified organizations; and 14 percent with government laboratories.

Even though only a small number of U.S. AT companies have sought to leverage the resources of federal R&D centers, there is an indication that firms might become more interested in utilizing federal capabilities where it makes sense. No less than 58 percent of 338 respondents to a survey question stated that they would be interested in working with federal R&D institutions.

These companies, in fact, want to pursue a range of relationships with federal research centers. Specifically, companies are looking for assistance in designing and developing products, and in refining manufacturing processes. AT manufacturers also expressed interest in acquiring intellectual property of all kinds through technology licenses. Access to federal laboratory software was a key priority for 9.5 percent of firms.

Survey participants showed a strong interest in various forms of research collaborations with federal laboratories. Their prime motivation is to tap into the defense and civilian technologies developed by the labs and to access the know-how of professionals employed there. In 23 percent of the responses received companies stated a desire to work with the labs through cooperative research and development agreements (CRADAs).

A number of AT companies also want to use federal facilities on a "work-for-others" basis, which can enable them to leverage unique government R&D capabilities for proprietary work. In these arrangements, a company typically pays all costs associated with conducting the research and retains all rights to the intellectual property and expertise developed in the research project. AT manufacturers also are interested in collaborations involving industry consortiums; and these firms want to pursue personnel exchanges that place their people at government laboratories for extended periods.



The inexperience that U.S. AT manufacturers have in working with federal research centers suggests several things. First, many companies, because of the nature of their products, may not really require, or benefit from, the involvement of federal labs. Second, the data indicate that significant numbers of companies simply are not aware of the resources that reside within the federal laboratory system—and the data show that relatively few AT firms have experience accessing these capabilities.

Why this is the case is hard to know. Survey data do not provide sufficient information to determine the cause of a seemingly low awareness of federal research centers. The findings, however, raise questions about how in touch AT companies are with respect to technologies and intellectual property available to them in commercial and university circles as well as that resident in federal defense and civilian laboratories.

Institutional change may be required in some U.S. AT companies to enable them to more effectively leverage thin R&D budgets so they may develop and field new products faster. As a part of any such effort, U.S. AT companies must develop a greater awareness of the public R&D resources available to them—and the R&D capabilities that are resident in private contract-research institutions as well.

It also may be appropriate for federal manufacturing assistance programs in DOD and civilian agencies and federal laboratories to undertake outreach programs to help familiarize AT manufacturers with their research, engineering, and technological capabilities. Activities might include on-site programs at laboratories that are focused on U.S. AT vendors; and participation by federal labs at any major meetings held by AT industry and related organizations.

Such an outreach program should include educating AT companies on the limitations that federal laboratories have in providing assistance to companies. Typically, research centers can only extend assistance in cases where the work would be consistent with the institutions' R&D missions – and in instances where such assistance is not readily available from private contractors.

Manufacturing & Design

Access to and the application of technology is not only critical to developing new products and to enhancing the performance of existing products, but it is also essential to efficient, cost-effective manufacturing. U.S. AT manufacturers, according to survey data, want to enhance

their access to both new production methods and to organizations with special defense and civilian technological capabilities to help them improve their manufacturing processes.

The AT manufacturer's aim is twofold: 1) to maximize output and lower costs on existing product lines; and 2) to employ production technology to enable the introduction of new materials enhances product quality, performance, and manufacturing output. Unfortunately, the application of new manufacturing processes or automation in the AT industry often is constrained by low volume and small production runs.

Interestingly, 74 percent of companies who responded to a question about whether a lack of automation was a major hindrance stated that it was only a minor obstacle. This finding, however, does not necessarily lessen the need for many AT companies to improve processes wherever it is possible.

The technical sophistication of U.S. AT companies varies greatly. AT companies are in search of both relatively simple forms of assistance as well as advanced technical services and manufacturing know-how. About half of the industry, data indicate, may not feel that assistance from outside organizations is needed.

Only 176 (49 percent) of 359 companies chose to respond to a question asking them whether they want assistance in one or more of five areas: metrology, ISO 9000²² quality control, process verification, equipment demonstration, or European "CE" mark²³ safety standard requirements.

At least a few AT companies may suffer from corporate culture barriers, such as the "notinvented here" syndrome found in other parts of U.S. industry, that hinder the adoption of new technology by some segments of the AT industry. Alternatively, companies already may be utilizing solutions that are to be found at federal labs or do not feel that they apply. In one instance, an AT manufacturer advised BIS that it viewed the provision of assistance to private companies, some of which might be current or potential competitors, as damaging to the competitive position of the firm.

Generally speaking, the data show that it is mostly smaller companies that are most interested in outside technical assistance to improve manufacturing. Very large AT manufacturers, however,

 $^{^{22}}$ ISO 9000 is a quality standard established by the International Standards Organization. It is recognized around the world and can be applied to companies of all sizes in any industry.

²³ The CE mark is the official marking required by the European Community for all electric and electronic equipment that will be sold, or put into service for the first time, anywhere in the European Community. It proves to the buyer -or user- that a product fulfills all essential safety and environmental requirements as defined in the European Directives. Manufacturers also must include operating instructions and safety notices in the language of the country in which the product is sold.

also expressed a desire to tap outside expertise to help them optimize manufacturing capabilities. As might be expected, industry needs vary considerably.

In the case of metrology, only eight companies wanted help with precision measurement in manufacturing. Six of these firms had annual sales of \$2 million or less.

Table 16— Relevance of Technologies/ Interest in Federal Lab Assistance						
Technology Description	1	2	3	4	5	Number of Firms Interested in Federal Lab Assistance
Electronic Components & Systems	149	5	23	30	116	61
Board-level Electronics	126	7	14	14	150	47
Lasers/Optics	30	8	10	25	224	32
Integrated Circuits	118	6	16	19	150	46
Software Programs	118	21	15	29	135	56
Mechanical Components	178	12	21	32	81	58
Fastening, Joining & Assembly		19	17	17	69	56
Ferrous and Nonferrous Metals 134		8	12	11	135	42
Composite Materials 107		13	37	26	122	56
Plastics and Non-Metals	198	10	31	19	56	75
Sensors/Transducers	84	6	32	25	156	51
Test/Measurement Instruments	97	24	19	25	135	48
Motion Control Equipment	50	14	33	20	182	42
Fluid Power & Handling Devices	22	8	12	14	234	23
Energy Cells 46		8	27	21	182	38
Legend			<u>w</u>	would improve your products if incorporated.		
1are <u>currently incorporated</u> into your products.			<u>would be important</u> additions to your products in the next 5-10 years.			additions to your products
2 <u>would improve</u> your firm's productivity if incorporated.			<u>cannot be applied</u> to your product line			

Source: U.S. Department of Commerce/BIS AT Survey

Of 176 companies responding to this survey section, 37 companies expressed interest in getting outside help in manufacturing process verification. Only two of these firms had sales exceeding \$10 million annually. Again, small companies showed the greatest demand for these services— some 30 firms, each with 1999 annual revenues of less than \$10 million. The other seven companies were larger AT firms, each with revenues of \$11 million to \$140 million.

There is strong company interest in equipment demonstration, which would allow AT manufacturers to get a better appreciation of how the application of new systems, controls,

processes, etc., might enhance product quality and operational efficiency. Fifty-eight firms in all cited a need for such demonstrations—mostly smaller enterprises; six companies with annual revenues ranging from \$12 million to \$110 million also showed interest in these technology demonstrations.

The form of manufacturing assistance generating the greatest demand, however, has to do with mastering administrative and manufacturing procedures to attain international standards compliance certifications. Fifty-five companies said they need assistance with ISO 9000 certification—seven of the firms having 1999 revenues of \$13 to \$100 million. Smaller companies with revenues of less than \$10 million – 47 in all – have the greatest need for help with ISO 9000 standards.

The same is true in the case of the CE mark that appears on products that meet European Union safety standards. Some classes of U.S. AT products – and other goods – cannot be sold in the European Union because they lack this certification. Smaller AT companies, 77 with revenues below \$10 million in 1999, expressed interest in receiving assistance in producing products to conform with CE standards. Another seven larger firms with revenues of \$12 million to \$100 million said they need help as well.

U.S. AT manufacturers also stated that their manufacturing enterprises could benefit from closer linkages with U.S. standards organizations such as the Underwriters Laboratory, American National Standards Institute, Federal Communications Commission, and the National Institute of Standards and Technology at the U.S. Department of Commerce.

Universal Design

The success of U.S. AT companies in the future will depend as much on product design as their ability to employ cost-effective and efficient manufacturing processes. The challenge before many AT companies is to design products, where practical, that are needed by people with disabilities – and to some extent by the larger, general population.

Companies that are able to interest the general public in their products benefit from higher sales volume. Not only do they receive greater revenue, but per-unit profit increases as manufacturing costs drop with enhanced economies of scale. Higher profitability can make it easier for companies to justify producing more specialized, low-profit-margin goods for people with disabilities. And, improved cash flow also enables AT companies, most of which are small firms, to bring new AT products to market faster.

Designing products that can be used both by those with disabilities as well as the general public is known as *universal design*. It manifests itself in many ways, including: ease of use, tolerance for error, and minimizing the physical effort required to manipulate the product. *Universal design* is the process of designing products and environments (including assistive technologies) to be usable by people with the widest range of abilities possible, without the need for adaptation.²⁴

Economics and market forces are, in fact, causing many U.S. AT companies to look more closely at the way they design products – and to better understand how they may serve both people with disabilities and the broader markets. Without question there are significant market opportunities for AT manufacturers outside of their traditional markets. Those companies that can make products that serve multiple sets of customers often have greater opportunities to grow and profit than AT companies fielding narrowly focused goods. For this reason, universal design is a key strategy in the development of AT products going forward.

The trend in universal design to some degree is spurred indirectly in the United States by laws and regulations that provide assistance and accommodations to persons with disabilities to enable them to function more effectively in society (*See Appendix A*). The Rehabilitation Act of 1973 and subsequent amendments (1986, 1998), the Telecommunications Act of 1996, and the Assistive Technology Act of 1998, are a few examples of legislation that has mandated that people with disabilities have equal access to key services and technologies. These laws have driven manufacturers and designers of commercial products, housing, and buildings to give much greater consideration to the needs of persons with disabilities as well as to the requirements of the general public.

At the same time, AT manufacturers are challenged continually to field products comparable to, or better than, those offered by competitors. This task is not always easy. Success in AT manufacturing is determined not just by engineering features, but by capturing sufficient volume to enable a company to justify production and turn a profit. By employing universal design features in their goods where practical, manufacturers can position their product to reach a broader customer base.

Just how in tune are U.S. AT manufacturers and service providers with market demographics? Are they considering larger market opportunities, when practical, in designing AT products for their customers with disabilities?

²⁴ *See* the website for The Center for Universal Design, North Carolina State University, at <u>http://www.design.ncsu.edu/cud/</u>.

Table 17— Universal Design Questions and Responses						
Questions	Answer " Yes "		Answer " No"		No Answer	
QUESIIONS	Firms	%	Firms	%	Firms	%
Consider those aging with disabilities?	280	77.9%	65	18.2%	14	3.9%
Consider those with multiple disabilities?	240	66.8%	89	24.9%	30	8.4%
Explore applications for those without disabilities?	209	58.4%	138	38.3%	12	3.4%
Interested in learning more about universal design?	224	62.3%	107	29.9%	28	7.8%

Source: U.S. Department of Commerce/BIS AT Survey

Of 359 firms that responded to this question, 58 percent said they actively took into consideration the needs of people without disabilities when designing products for people with disabilities. But, survey data also show that a large percentage of respondents – 38 percent – does not yet embrace this practice. It remains to be seen whether this behavior will result in significant numbers of U.S. AT manufacturers finding themselves at a competitive disadvantage in the future because they fail to maximize the utility of their products through the use of universal design principles.

The transition to universal design principles for manufacturers appears to be something that most U.S. AT companies readily can achieve. And, there are signs that more U.S. AT manufacturers are aware of the importance of universal design. Sixty-two percent of companies responding to the survey said they wanted to learn more about the universal design process.

According to survey data, a majority of respondent AT companies exhibits a high level of sensitivity to the design requirements of their customers. Almost 78 percent of companies participating in the survey report that they consider the needs of people who are aging with disabilities in designing AT products for people with disabilities. Similarly, nearly 67 percent of respondent companies stated that they consider the needs of individuals with multiple disabilities (to assure that such people can actually use a device) when developing products.

While not yet employing universal design as a general practice, a number of manufacturers said they make products that could be used by the general population, but that they have not attempted to actively market to a broader customer market. In other instances, companies said that their products were too specialized for use by the general population.

It is clear that the sophistication of companies' design, engineering, and market research practices can vary considerably. This is evident in data on AT companies' employment of user groups in product development. Often times, useful but overlooked design ideas only can be

obtained through feedback from the end user – and it is the information about subtle differences that can distinguish a good product from a great one.

Almost 62 percent of survey participants have focus groups or similar mechanisms to gather user information for product design. Many AT firms work with health care professionals, hospitals, educators, dealers, and endusers to develop and improve products. Large numbers of small companies as well as medium- and large-size manufacturers, survey data show, regularly use customer input mechanisms to gather information to optimize product design. Ten companies, each with 1999 sales of \$60 million or more, indicated they used such tools. Another 20 firms with sales ranging from \$10 to \$60 million also use these methods – as do more than 150 smaller companies with sales under \$10 million.

Still, a large portion of the respondent AT companies -38 percent^{25} – does not gather user input to support the quality of their design efforts. Foregoing this phase of product development can prove to be detrimental in terms of product exposure, assured product performance in extreme environments, corporate goodwill, and lost opportunities to develop a more useful product.

Small companies were less likely to use focus groups or other customer input mechanisms. Indeed, only one company with annual sales greater than \$60 million replied "No" to the question on whether their firm uses customer input mechanisms. Seven companies answering "No" had 1999 sales of \$10 to \$60 million; and another 112 firms in the "No" category had annual sales below \$10 million.

Companies offered few explanations; respondents were not directed to indicate anything other than a "Yes" or "No" response to the survey question. Several firms, however, submitted comments stating they believed there was no need to improve their devices. For smaller companies, carrying out design and market research may be more difficult because of insufficient resources and more pressing internal demands.

Attracting & Retaining Skilled Personnel

The ability of U.S. AT manufacturers to compete effectively both in domestic and foreign markets is determined in part by whether they can attract and retain skilled professionals and manufacturing personnel. Some survey data suggest that the AT industry could encounter

²⁵ Percentages were calculated on a base of 294 respondents. Companies responding "yes" or "no" to the question were not counted in the percentage calculation if they did not provide financial data for the survey. A total of 351 companies responded to the question on the use of focus groups.

problems in the future – and indicate that U.S. AT companies may have to be more proactive in recruiting people into the industry.

It is not clear whether the market conditions that existed in the late 1990s are valid indicators of the employment problems AT companies could face in the future. The robust economic conditions and the tight employment environment that existed then and its effect on the AT employment environment may be instructive for future planning.

Not only did the AT industry experience solid job growth in the late 1990s, but a significant number of companies also found it difficult to employ skilled people across a wide range of fields. Of the 357 companies that participated in this portion of the AT survey, 84 (25 percent) reported problems in hiring people. The number is sufficiently large to suggest that AT industry leaders may want to consider their future labor requirements – and options.

The key concern for U.S. AT companies is whether they can recruit the necessary workforce and control wage expense to maintain their competitive positions in domestic and world markets. It's not clear whether the pool of workers available to the AT industry will grow slowly in the future — and whether firms will have to offer significantly higher wages to fill positions. Greater management attention may be needed to understand the potential benefits of using more automation as an economical and practical option for coping with staffing difficulties and controlling production costs.

The labor shortages reported by companies crossed 23 separate skill areas and affected very large companies as well as small manufacturers. Sixteen companies with annual sales of \$10 to \$315 million reported difficulties in filling positions. Most of the companies that cited employment problems, however, were smaller firms with annual sales of less than \$10 million.

The staffing difficulties identified by survey participants included professional positions, skilled occupations, and administrative functions. New product engineers, software developers, and biomedical device designers are some of the professional positions (see Table 18) companies have had trouble filling.

Likewise, on the manufacturing floor, companies reported difficulty in finding qualified people for assembly work that required hand dexterity, such as soldering. Also in short supply are craftsmen in areas such as shoemaking and textile production. The manufacture of AT products is frequently dependent on the use of older, less automated production tools and processes. But, companies also stated that it is increasingly difficult to find machine operators and production managers with skills suited to these manufacturing operations. The reasons for these shortages are varied. Many of these skilled workers are in high demand elsewhere in the job market. AT firms must compete for talented personnel against other industries. As a result, AT businesses in need of key people are often unable to find them, and finding qualified persons with experience in the AT industry is even more difficult.

While many of the skills the AT industry requires can be somewhat generic, serving the smaller and more complex market of the AT industry adds a new degree of difficulty to recruitment efforts. For example, an effective billing/collection agent in the AT industry requires specialized knowledge of insurance programs and their relationships to federal and state-level medical reimbursement programs. Similarly, AT product representatives must be knowledgeable of the variations in reimbursement levels of 50 state governments to determine a product's actual cost to the end user.

Table 18 — Reported AT Industry Skills Shortages*					
Scientists, Engineers & Techs	Manufacturing & Assembly	Healthcare Professionals			
Biomedical Engineers/Designers	Machinists	Certified Rehabilitation Techs			
Computer Programmers	CNC Machine Operators	Occupational Therapists with			
Digital Signal Processing (DSP)	Metal Fabricators	design/manufacturing skills			
New Product Design Engineers	Mold Makers				
Electrical Engineers	Welders	Marketing/Sales/General &			
Electronics Designers and Techs	Shoemakers	Administrative			
Fluid Engineers	Sewing Machine Operators	Accountants			
Mechanical Engineers	Shop floor skills	Billing/Collection skills			
Process Engineers		Product Representatives			
Software Developers/Engineers					

Source: U.S. Department of Commerce/BIS AT Survey

* Based on comments from 89 of 357 survey participants.

In most industries, excessive turnover in staff generally is considered detrimental to achieving high productivity; this is the case in AT product manufacturing. While this does not appear to be a major problem for the industry as a whole at this time, at least 10 percent of AT industry survey participants are affected.

Large and small companies alike cited excessive turnover as a concern, but smaller firms appear to be affected most. About 25 percent of the 38 companies reporting employee-retention problems had 1999 sales of \$10 million or greater; the balance are smaller companies. The retention problem is driven by several factors, including competition for workers, the quality of the workforce available to companies, and in some instances the very nature of the work.

Small firms often compete for – and frequently lose – skilled personnel to larger companies. Low unemployment in some regions has led to a shortage of skilled employees, which has

produced greater competition among businesses for workers. The retention issue encompasses both production workers and professionals. Companies reported difficulty in hiring and retaining marketing, computer programming, and electrical and mechanical engineering personnel.

The quality of the available workforce, in some instances, adds another dimension of difficulty to the retention problem. Several companies reported that a majority of new hires 1) have little or no manufacturing expertise; and 2) require extensive training before they are adequately productive. But once trained, many workers lose interest in manufacturing and assembly work, and quit. One firm stated that it typically retains one new hire for every six trained.

V. Financing & Investment

Capital Expenditures

The lifeblood of any industry is investment capital, a resource that is vital to building manufacturing facilities, creating and commercializing new products, and underwriting research and development. Access to capital is essential for starting new firms as well as for sustaining existing operations. In the U.S. AT industry, there are great disparities in the availability of capital -- with smaller firms typically having fewer resources to work with than larger firms.

The largest company participating in the survey had sales of about \$800 million in 1999 and capital expenditures²⁶ of \$32.2 million. For most larger²⁷ firms in the U.S. AT industry, however, capital expenditures were significantly lower – ranging from \$1.2 million to \$6 million for 1999. Across medium-size companies (*annual sales of \$10 million to \$60 million*) capital expenditures ranged from \$25,000 to \$2.1 million.

The largest single capital expenditure by a small AT company responding to the survey (*annual sales of less than \$10 million*) in 1999 was \$732,000 on sales of \$3 million. Spending the equivalent of 24.4 percent of gross sales on capital expenditures in a given year is far beyond the norm for U.S. manufacturers. But for small companies, many of which may be bringing new production facilities online for the first time, higher than average capital investment is not unusual. In some instances, AT firms' capital expenditures far exceeded sales revenues. One firm, for example, reported sales revenues of \$250,000, but capital expenditures of \$600,000.²⁸

U.S. AT companies participating in the survey reported sales revenue in 1999 of \$2.87 billion and had capital spending of \$85 million²⁹ (3 percent). This compares to capital spending of \$82.1 million (3.1 percent) in 1998 on sales revenues of \$2.66 billion and \$88.7 (3.8 percent) million in 1997 on sales revenues of \$2.35 billion.

²⁶ For the purpose of this study, capital expenditures were defined as costs associated with the purchase of assistive technology-related capital plant and equipment. Respondents were asked to provide the dollar amounts for the expenditures their firms *incurred* (whether paid in the year or in a subsequent year) in dollars for 1997 through 1999, indicating the source (internal or external) of the capital funding.
²⁷ Large assistive technology firms are defined as having sales of \$60 million or more; medium-size AT companies of \$10

²⁷ Large assistive technology firms are defined as having sales of \$60 million or more; medium-size AT companies of \$10 million to less than \$60 million; and small firms have sales under \$10 million.

 $^{^{28}}$ The data were obtained with a telephone call to the company.

²⁹ These figures are approximations. Not all companies provided both sales revenue and capital spending data. Sales revenues and capital spending figures cited in this report understate actual sales revenue and capital spending by survey participants. Capital spending expressed as a percentage of sales revenues are estimates based on incomplete data as described above.

Capital expenditures for the AT industry as a percentage of sales in 1999, 1998, and 1997 trailed the U.S. average³⁰ for manufacturing. As a percentage of sales, capital investment by the manufacturing sector as a whole is estimated at 3.7 percent in 1999, 3.9 percent in 1998, and nearly 4 percent in 1997. Although the largest U.S. AT manufacturers have substantial

revenues, their capital expenditures as a percentage of sales generally were below the national average for U.S. manufacturers – and less than that of medium- and small-size AT companies.

Table 19 — AT Industry Sales & Capital Outlays*					
(Millions of dollars)					
Sales	Capital Percent of Year				
Revenue	Expenditures	Sales			
\$2,354	\$88.7	3.8%	1997		
\$2,659	\$82.1	3.1 %	1998		
\$2,876	\$85.0	3 %	1999		

Source: US DOC/BIS Survey. *See footnote No. 30

Eleven large AT companies, each having sales in excess of \$60 million, accounted for \$1.97 billion of the \$2.87 billion in 1999 revenue reported by U.S. AT manufacturers participating in the survey. Capital expenditures by these AT firms amounted to about 3.1 percent of sales. Ten companies qualified as "large" firms in 1998 – and collectively their sales totaled \$1.81 billion. Capital expenditures were about 3.1 percent. In 1997, seven large companies logged sales of \$1.43 billion and allocated \$57.7 million – 4 percent – to capital expenditures.

Medium-size AT companies responding to the survey on average had capital expenditure rates that were below that of their larger counterparts and under the national average for the entire U.S. manufacturing sector for the 1997-99 period. Twenty-five companies reported 1999 sales revenue of \$526.6 million. After correcting for statistical aberrations, data indicate this group of companies invested about 2.6 percent of sales revenue into capital expenditures, which exceeded \$12.2 million.

Spending on capital investment by this group of companies dropped significantly in 1999 – both in actual dollars and on a percentage basis – relative to 1997 and 1998. A part of this decline is attributed to the movement of one company into the "large company" category, but this does not fully explain the decline of investment in the face of sharply higher revenues.

In 1998, 23 mid-size companies participating in BIS' survey posted sales revenues of \$466.8 million; capital expenditures were at least \$14.2 million – or about 3.6 percent of sales revenue. For 1997, 24 companies with sales of \$10 million to \$59 million generated total revenues of \$569.2 million. This group of companies invested about 3.7 percent of sales revenue into capital expenditures, which exceeded \$17.3 million.

³⁰ See Annual Survey of Manufactures, U.S. Census Bureau, May 30, 2001.

Most respondent AT companies operating in the United States are enterprises with revenues under \$10 million. Approximately 324 small firms participated in BIS' survey and many of these firms did not provide useable revenue and capital expenditure data. Total revenues for

small companies that did provide useable data exceeded \$374.4 million in 1999 and capital expenditures were at least \$12.9 million. This segment of the industry experienced slow growth between 1997 and 1999 with revenues climbing 5.8 percent over the period. In contrast, revenues for the largecompany segment grew by a

Table 20 — AT Firm Capital Outlays – Percent of Sales*								
(Millions of dollars)								
Company Size	Sector Sales % of Sales Year							
Large	\$1,431	4%	1997					
	\$1,814	3.1%	1998					
	\$1,974	3.1%	1999					
Medium	\$569	3.7%	1997					
	\$467	3.6%	1998					
	\$527	2.6%	1999					
Small	\$354	4.5%	1997					
	\$378	4.3%	1998					
	\$374	4.2%	1999					

Source: US DOC/BIS Survey *Sales figures are rounded

strong 38 percent over these three years.

Medium-size companies, as a group, showed a decline in sales from \$569 million in 1997 to \$526.6 million in 1999. This slide appears to be partly driven by the movement of one AT manufacturer into the large-company category. Overall capital expenditures by medium-size companies, as a percent of sales, also showed some decline, especially in 1999.

After correcting for statistical aberrations, data indicate that small AT firms responding to the survey put the equivalent of 4.2 percent of sales revenues of \$374 million into capital expenditures in 1999. The higher rate of investment relative to the 3.7 percent rate for large companies and 2.6 percent level for medium-size firms may be explained by several factors. First, smaller firms, as mentioned earlier, often spend a larger percentage of revenues on capital investment in their start-up phase. Also, it is not unusual for small firms to allocate more of their revenues to capital expenditures simply because of their small scale.

Small companies participating in the survey reported revenues of \$378 million for 1998 with capital expenditures in excess of \$13 million. Capital expenditures are estimated at 4.3 percent of sales revenues, after statistical corrections. For 1997, capital expenditures came to \$13.6 million, or about 4.5 percent of sales revenues of \$354 million.

Trends in R&D Expenditures & Funding

In 1999, AT companies participating in BIS' survey spent at least \$100 million on research and development -- about 3.5 percent of sales of \$2.87 billion. Overall, the percentage of investment in R&D to sales appears roughly comparable to overall levels for the U.S. manufacturing sector³¹ as a whole.

Given the diversity of technologies employed in AT products, however, this level of investment may not be adequate for all segments of the AT industry. AT equipment that utilizes electronics, control technologies, or advanced materials might require higher levels of investment while companies producing simple products from commodity materials may have less demanding and less costly R&D needs.

Also, data show that smaller companies often devote a greater percentage of sales revenue to R&D than do bigger companies. Eleven large companies with collective annual sales revenue of \$1.98 billion spent the equivalent, on average, of about 2.8 percent of sales revenue on R&D. The R&D expenditures by large companies exceeded \$50 million and accounted for nearly half of R&D spending by all

Table 21 — R&D As A Percent of Sales Revenue*							
(Millions of dollars)							
Company Size	Sales Revenue	% R&D	Year				
Large	\$1,341	3%	1997				
\$1,814		2.6%	1998				
\$1,975 2.8% 1999							
Medium	\$569	3.2%	1997				
	\$467		1998				
	3.7%	1999					
Small	\$354	8.5%	1997				
	\$378	8%	1998				
	\$374	9.6%	1999				

Source: US DOC/BIS Survey *Sales revenues are rounded. Some percentages calculated on an adjusted base.

classes of AT companies participating in the survey.

In comparison, R&D spending by 27 mid-size companies amounted to about \$16 million (3 percent of sales revenues of \$526.5 million), or 16 percent of total respondent AT industry R&D expenditures. Small companies allocated in excess of \$33 million to R&D, or 9.6 percent of sales revenues (after statistical correction) of about \$374.4 million.

Consistent with the nature of many new small companies, R&D expenditures often are well above the three-percent range that is common for medium- and large-size firms. While the norm may be about 10 percent of sales revenues, R&D spending rates in excess of 150 percent are not uncommon. In one instance, a company reported an R&D investment rate of 4,500 percent—a figure achieved because revenues for the firm were virtually non-existent relative to \$450,000 in R&D investment.

³¹ See National Science Foundation, Science And Engineering Indicators 2000, Volume 2, Appendix Table 2-57.

R&D spending patterns for 1998 and 1997 are not very different from those found in 1999. Large AT companies had sales of \$1.81 billion and spent at least \$42 million on R&D—about 2.6 percent of sales revenue.³² The slightly higher level of R&D expenditures as a percentage of sales in 1999 (2.8 percent) may be explained by the \$100 million boost in revenues attained by large firms in 1999. This gain may have allowed companies to increase R&D spending to meet needs while relaxing spending as a percent of revenues.³³

Mid-size companies in 1998 appear to have allotted slightly more funding to R&D, as measured as a percentage of sales revenue (4.1 percent³⁴ versus 3.7 percent) than in 1999. However, actual spending in dollars for R&D still climbed year after year – from \$13.4 million in 1998 to \$15.9 million in 1999. Overall revenues for the group for these years were \$467 million and \$527 million, respectively.

Flat sales for small companies did not reduce investment in R&D. As a percentage of sales, smaller companies as a group in 1999 increased R&D spending to about 9.6 percent on average from 8 percent in 1998. Sales revenues for the group in 1999 were \$374 million compared to year-earlier sales of \$378 million in 1998.

In 1997, small firms as a group contributed on average the equivalent of about 8.5 percent of sales revenue to R&D; overall sales revenue was \$354 million. Large companies in 1997 had sales revenues of \$1.34 billion, a sum equal to about 3 percent of that was invested in R&D. Mid-size companies appear to have allocated slightly more than three percent to R&D in 1997 on sales revenue of \$569 million.

Utilization of External Funding

Most AT companies participating in the survey obtained funds for research and development from internal resources as opposed to outside entities such as banks, venture capitalists, or state and federal government grant programs. Developing a product for a very small market with the inherent cost premiums of small production runs – and selling it to a segment of the population with limited financial means – can make it difficult to attract venture capital.

Nevertheless, it appears from survey data that many U.S. AT companies are able to attract substantial outside capital to fund R&D when they have the right product idea. These

³² R&D percentage calculated on a sales base of \$1.64 billion because some companies supplied sales data but no R&D spending information.

³³ The 1999 sales gain cited excludes additional revenue for the group that results from the addition of a new company with sales in excess of \$60 million.

³⁴ Percentage calculated on a sales base of \$330.3 million because not all firms provided R&D spending data.

manufacturers are mostly small firms and represent a minority of this segment of the AT industry. The use of outside funding by mid-size companies is tiny – and nonexistent in the case of large AT firms.

For the 1997-1999 period, no large company that participated in BIS' survey reported using external funding sources to support R&D programs. Total R&D expenditures reported by this group were flat in 1997 and 1998 at \$41.3 million and \$41.9 million, respectively; R&D spending in 1999 exceeded \$50 million.³⁵ In these three years, the largest firms showed increasing ability to support R&D with internal funds.

Fewer than 10 percent of mid- and small-size companies responding to survey questions reported using external funding in the 1997-1999 period. Of the \$12.8 million in R&D expenditures reported by mid-size companies for 1997, just \$574,000 came from external sources.

In 1998, only two of 23 mid-size firms (8.7 percent of companies) reported obtaining outside funding for R&D - \$350,000. This was just 2.6 percent of the \$13.4 million spent on R&D by mid-size companies that year. For 1999, use of external funds by mid-size AT companies for R&D fell to \$245,000 as overall R&D spending for the group increased to \$15.9 million.

In terms of utilization of external funding sources to drive R&D programs, it seems that small companies lead. And in many instances, these small companies sought large leverages on limited internal R&D funds. In 1998, one company spent \$19,000 of internal funds, but obtained about \$555,000 in outside funding; the firm's revenues for that year totaled \$800,000.

Sixteen small companies reported raising \$3.5 million in 1999 to support their R&D operations, a figure that represents 10.5 percent of the \$33.3 million spent overall on R&D by small AT companies. In 1998, 15 small firms reported obtaining \$2.6 million in funding for R&D, which was about 7.6 percent of total small-company R&D expenditures (\$34.2 million) reported by survey participants. Similarly, in 1997, 13 small AT companies raised \$2.5 million from external sources to support R&D – about 7.1 percent of the \$35 million R&D outlays reported for 1997 by survey participants.

Just why AT companies, both large and small, don't make greater use of outside funding resources cannot be explained by the data obtained in the BIS survey. Based on written comments on financing issues provided by survey participants, it appears there is both a desire and a need by many AT companies to access outside capital sources. Many smaller companies,

³⁵ Total R&D expenditures cited for large, medium, and small companies understate actual reported industry expenditures for R&D. Not all companies that participated in BIS's survey provided data on their R&D expenditures.

however, may not be aware of the full extent of the portfolio of private sector funding opportunities that exists – or know how to go about obtaining that funding.

Beyond securing direct funding from financial houses, there also is some evidence that AT companies are not fully cognizant of ongoing federal and state grant and partnership activities that might directly, or indirectly, support their R&D efforts. These include consulting services, partnering opportunities, and grant programs at the Departments of Defense and Energy, National Science Foundation, National Aeronautics and Space Administration, National Institute of Standards and Technology, and the Small Business

Administration.

The use of the Small Business Innovation Research (SBIR) grants by U.S. AT companies is a case in point. This competitive award program may be the largest single source of federal government funds available to U.S. AT companies. Some smaller initiatives, such as National Institute on Disability and Rehabilitation Research's (NIDRR) Field Initiated Projects program,³⁶ are also sources of assistance.

Table 22 - SBIR Grants For AT R&D*				
Year	Phase I	Phase II		
1996	\$1,656,814	\$4,706,173		
1997	\$1,866,976	\$7,077,403		
1998	\$1,946,141	\$6,732,453		
Total	\$5,469,931	\$18,516,029		

Source: U.S. Department of Commerce/BIS AT Survey

*Figures represent a partial total of SBIR grants to AT firms.

All for-profit U.S. businesses employing fewer than 500 persons are eligible to compete for SBIR grants of up to \$250,000; funding can span several years through SBIR Phase I and Phase II grants.³⁷ Only 14 percent of all survey respondents (52 companies), however, applied for SBIR funding for years 1997-1999.

SBIR rules restricting applications to companies with less than 500 employees do not appear to be a significant barrier in this industry. No more than 10 companies participating in the BIS survey appear to have been affected by the SBIR employment base ceiling.

³⁶ Field-initiated (FI) projects must further one or both of the following purposes: (a) develop methods, procedures and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities; or (b) improve the effectiveness of services authorized under the Act. FI projects carry out either research activities or development activities. [For more information on NIDRR research, see *http://www.ed.gov/offices/OSERS/NIDRR/Programs/res_program.html*]

³⁷ Under SBIR's Phase I program companies must establish "proof of concept" to demonstrate the merits of the work; Phase II funding is awarded only after Phase I work is judged to be successful. The SBIR program was established in 1982 under the Small Business Innovation Development Act to stimulate technological innovation; encourage disadvantaged and minority persons engaged in technological innovation; and increase commercialization of inventions derived from federal research and development programs.

The low participation rate by U.S. AT manufacturers cannot be attributed to a lack of success in winning SBIR grants. For the three-year period, survey participants reported submitting 181 grant applications – and winning 80 separate grants under a competitive process. This is a higher-than-normal success rate (44 percent) for companies competing for SBIR grants.

The SBIR grants covered a range of AT-related fields, including: hearing, sight, mobility, environmental controls, communication software solutions, sensory aids, orthotics/prosthetics, and aids to daily living. Agencies awarding grants for AT product-related R&D were the Departments of Agriculture, Defense, Education, Health and Human Services (HHS), and Transportation (DOT); and the National Science Foundation (NSF).

HHS was the largest single dispenser of SBIR grants to respondent AT companies with 92 awards, followed by Education, 28; NSF, 26; Agriculture, 15; DOD, 5; and DOT, 5. Incredibly, no AT company participating in the survey reported applying for SBIR grants from either of two federal science and technology giants – the Department of Energy (DOE) and the National Aeronautics and Space Administration (NASA). Although there are many activities resident at federal laboratories and engineering and technology centers that are applicable to AT companies, it may be that: 1) much of the industry is unaware of these institutions' vast capabilities; or 2) the SBIR opportunities available at DOE and NASA are of little practical value to AT companies.

Table 23 — Summary of Respondents' SBIR Proposals				
Category	Summary of Proposals			
Software, Computers	Research proposals were funded for improvements to computer design and control, hardware and software integration for braille embossers and displays, multi-media			
	training, alternative input and control devices, and telemedicine.			
Acoustics	Research on the integration of acoustic detection technology into a vehicle's			
	operator interface.			
Mobility	Research for improved wheelchair transmissions and the development of integrated			
	transport restraint systems.			
Electronics	Research with digital signal processors, telecommunication interfaces, wireless			
	communications, monitoring.			
Manufacturing	Research in the application of laser micromachining.			
Material Science	Research on composites in the construction of prosthetic feet and ankles.			

Source: U.S. Department of Commerce/BIS AT Survey

Specific feedback from a handful of surveys does not offer clear clues as to why more AT firms do not pursue grants. One company was very positive about the program, stating that it enabled research and development on several products incorporating the latest in technology. Another company, however, was critical of SBIR proposal reviewers, suggesting they were more inclined to approve and partner with entities having strong academic affiliation rather than businesses prepared to develop products adaptable to the medical reimbursement environment.

A related program that U.S. AT companies rarely take advantage of is the Small Business Technology Transfer Program (STTR).³⁸ Just two companies reported receiving awards in the 1997-99 period, Phase I grants totaling \$100,000 and Phase II grants of \$284,000. The STTR program may not be as attractive to AT companies because it requires collaboration with outside organizations. This can involve greater effort and may raise concerns about protecting intellectual property. Survey data do not provide any explanation for the low level of use of STTR by AT companies.

Several AT companies participating in the survey suggested that federal and state governments increase both the number of grants that are awarded and the total amount of funds available for R&D grants in programs that would support the development of AT technologies. In addition, companies stated that increased availability of low-interest loans to finance R&D would be helpful.

³⁸ A program through which federal agencies fund cooperative R&D projects involving a small business and a university; an approved, contractor-operated, federally funded research and development center; or a nonprofit research institution.

VI. Government, Industry and the Future

Public assistance at the federal and state levels has enabled many people with disabilities to buy AT products they otherwise could not afford. The importance of these subsidies to those with disabilities becomes especially clear when examining the segment of the population with severe disabilities.

Nearly 74 percent of all persons with severe disabilities between the ages of 21 and 64 are unemployed, according to Bureau of Census data.³⁹ For the most part, these people rely on federal and state assistance programs for help in acquiring AT products.

Today, most of the support for people with disabilities comes in the form of payments from the Medicare and Medicaid programs⁴⁰ administered by the Centers for Medicare and Medicaid Services (CMS). Other public support for those with disabilities is delivered through health services-driven programs at the Department of Health and Human Services, and the Department of Veterans Affairs.

In addition, federal agencies provide limited, focused funding for research on AT devices for people with disabilities. This activity is centered largely at the National Center for Medical Rehabilitation Research (NCMRR) at the National Institutes of Health; the National Institute on Disability and Rehabilitation Research (NIDRR) at the Department of Education; the Department of Veterans Affairs; and the National Science Foundation.

Federal and state support to help people with disabilities obtain assistive technology has evolved over many decades (*see summary history in Appendix B*). Although public demand for the creation of a healthcare system was an issue government agencies were pressed to address in the early 1900s, the enactment of Social Security in the 1930s built the broad foundation for expanded delivery of health benefits by public agencies and by private insurers.

World War II spurred increased federal investment in health care and research on rehabilitation engineering. Congress further expanded access to medical care for the needy in 1950. And in the 1960s, government medical assistance programs were expanded further by Congress with the

³⁹ See <u>http://www.census.gov/hhes/www/disability.html</u>

⁴⁰ **Medicare** provides health insurance to people who are at least 65 years of age, people with disabilities, and people with permanent kidney failure. The scope of coverage includes hospital care, medical equipment, supplies, and related services and materials. **Medicaid** is a health insurance program for low-income people and people with disabilities. This program is supported with federal and state funds and administered by the states, which individually determine eligibility standards and the scope of benefits and services to be provided (*See http://cms.hhs.gov*). CMS was formerly known as the Health Care Financing Administration (HCFA).

passage of medical programs for the aged and needy, including the creation of Medicare and Medicaid.

Government assistance for people with disabilities has been a major driver to the AT industry, helping foster a market environment that encourages companies to create new, innovative AT products. U.S. AT manufacturers have had more stable markets and greater predictably in sales than could be expected without this market stimulus. The demand created by federal and state funding has enabled the production of numerous AT products that might otherwise be too costly to produce and sell because of insufficient economies of scale.

The symbiotic relationship between state and federal government agencies and AT products and services companies extends beyond the commerce generated by support payments. AT companies also benefit from federal R&D programs in at least two ways: 1) they produce intellectual property that companies can transform into products; and 2) they are a source of limited R&D grants.

R&D data on federal spending on assistive technology is not systematically collected across agencies and collated annually; thus attempting to discuss funding history in a comprehensive way is not possible at present. But federal spending on AT-related R&D and technologies has been increasing over time, driven in part by congressional direction and legislation.

At the National Institutes of Health, for example, expenditures for AT R&D have climbed significantly. Total funding⁴¹ hit \$116 million in fiscal year 2000, up from \$100.4 million in

1999 and \$79.3 million in 1998 – a 46 percent increase for the two-year period. The National Science Foundation (NSF) allocated \$8.6 million to a range of disability research projects, many of which are supportive of assistive technology; \$900,000 of the NSF funds went to AT-specific R&D.

Table 24 — NIH Assistive Technology R&D Spending (Millions)						
FY 1998 FY 1999 FY 2000 Change						
Total w/SBIR*	\$79.3	\$100.4	\$116.0	46%		
Non SBIR	\$59.8	\$79.3	\$94.8	58.5%		
SBIR Only	\$19.5	\$21.1	\$21.2	8%		

*Small Business Innovation Research grant program.

Source: Strategy for the Development and Transfer of Assistive Technology and Universal Design, Interagency Committee on Disability Research, December 2000.

The Department of Education through the National Institute on Disability and Rehabilitation Research (NIDRR) allocated about \$15.7 million to R&D in FY 2000; and the Department of Veterans Affairs R&D budget for assistive technology was \$5.6 million.⁴²

⁴¹ See Strategy for the Development and Transfer of Assistive Technology and Universal Design, Report of the Interagency Committee on Disability Research In Response to the Presidential Executive Memorandum of July 25, 2000.

Despite the benefits the U.S. companies obtain from public spending for people with disabilities, the AT industry's relationship with federal and state agencies is less than optimal, according to survey participants. Numerous companies expressed frustration with the way federal and state government agencies conduct business. Some AT product manufacturers complained that often they must traverse a regulatory maze – one in which federal and state agencies are effectively the "market maker" for products.

At issue are processing delays for product classification, inconsistencies among states' reimbursement amounts for the same product, and differences in reimbursement policies. The designation of AT devices into product classifications is an area of contention and misconception.

Companies that develop new, innovative products strive to obtain a new product classification code because this can result in higher state and federal reimbursement levels. When a new product, however, is not found to be unique and can be classified under an existing product code, then earnings on subsidized sales of the affected AT device to people with disabilities might be lower. This occurs because a different formula is used for AT product codes created before 1987. Regulatory agencies use a baseline allowance plus inflation factors to determine reimbursement or compensation allowances on AT products sold to people with disabilities who seek assistance.

In written comments, AT companies called on the federal and state governments to consider taking a number of actions to improve the ability of those with disabilities to obtain AT products—and to strengthen the business climate for AT manufacturers in the United States. Such comments included the following recommendations:

- Normalize federal and state qualification and reimbursement policies to the maximum extent possible. Companies reported that product reimbursement amounts varied considerably depending on what state their customer lived in, despite the fact that their manufacturing costs were fixed or increasing over time
- Stabilize allowed payment levels for AT products.
- Establish low-cost financing or other forms of financial assistance for people with disabilities to acquire AT equipment.
- Expand AT reimbursement schedules to include a broader range of AT services and allow greater access to special treatments and devices not covered by Medicare.
- Revise the Medicare definition of "durable medical equipment" to encompass fixtures, furniture, and aids to daily living.

⁴² Agencies supplied R&D figures at the request of BIS. For more information on research efforts at the Department of Veterans Affairs, see Appendix F.

• Allow reimbursement for higher-cost AT devices when they have proven to perform more effectively than comparable lower-cost devices.

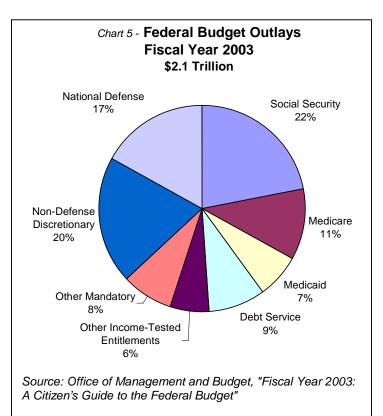
Potential Future Funding Bottlenecks

Can an upward spiral of federal and state funding support for health care funding (including subsidies for people with disabilities to acquire AT devices) be sustained? There is no certain answer to this question at this time. What is clear is that the shift in the demographic makeup of the U.S. population towards a much older society virtually ensures that demand for AT devices and services will grow substantially. This is likely to place unprecedented demands on state and federal public assistance programs.

The U.S. Government's ability to support major increases in funding for health care programs, including subsidies for AT products and services, likely will be strained as federal agencies compete for budget authority. At this time, 55 percent of the federal budget is obligated to entitlement programs – with Medicare and Medicaid now accounting for 19 percent of all federal expenditures (*see chart below*). Annual payments on the national debt account for another 9 percent of the federal budget today, a figure that rises with interest rate hikes and/or increases in national indebtedness.

Mandatory program spending is projected to grow at twice the rate of discretionary accounts between 2002 and 2006. While discretionary account budgets are projected to grow 11.3 percent during this period, mandatory spending on programs such as Social Security, Medicare, Medicaid and others will jump 22.7 percent, excluding interest payments on the national debt, according to the Office of Management and Budget.

Thus, any real growth (as a percent of the U.S. budget) in federal healthcare programs to increase support for assistive technology for people with disabilities may be difficult in the future. Funding would likely have to come from defense



or non-defense discretionary accounts, which have sustained significant reductions as a percent of the federal budget over the last decade.

What does this mean for the U.S. AT industry? There is no doubt that overall federal outlays for Medicare, Medicaid, and other programs will increase—as will overall subsidies for AT products. But any expectations for expanding the scope of AT goods that qualify for AT subsidies – or increasing the level of subsidies allowed for classes of AT products – may have to be tempered.

In the face of a major rise in reimbursement claims in the years ahead, the challenge for federal and state agencies and private insurers will be to set priorities in meeting the needs of people with disabilities and to strike a balance on reimbursement payments. Indeed, it may be necessary in the future to reduce payment levels on some AT devices – or remove some affordable AT products from government and private insurance reimbursement schedules – to keep both public assistance programs and private insurance coverage for AT services viable and solvent.

VII. Recommendations

Overview

Never before has there loomed such a huge market for AT products. In addition to the large bubble of aged parents of the baby boom generation, there are the baby boomers themselves. Together, these groups represent just the first large waves of growing demand for AT products in the United States and by aging consumers in other parts of the world.

Advances in the medical field have greatly affected the quality and length of life for people worldwide. As a result, people are living longer, and their need for AT products is likely to grow as they age. Moreover, society generally recognizes that AT products make living independently less difficult and more meaningful. Strong demand for AT products is assured for decades to come.

AT manufacturers in the United States stand to benefit greatly from the demographic shifts that are occurring in United States, Europe, Asia and elsewhere—but only if they can operate efficiently, field superior products ahead of competitors, and overcome corporate, institutional and market barriers. AT manufacturers in the United States face strong competition from abroad in many AT product classes, both in international markets and at home.

The AT industry in United States, as noted earlier in this report, is highly fragmented and may include as many as 2,700 companies, most of them small, having annual sales of less than \$10 million annually. The AT industry survey data demonstrate that the technical and business management sophistication of AT companies in the U.S. varies greatly. The survey also shows that many AT companies, large and small, are having to negotiate various kinds of obstacles – including regulatory and trade practices – that hinder their efforts to market and sell AT products in the U.S. and abroad.

Another challenge before many AT industry executives is to learn how to more effectively leverage private and public financial and technology resources in developing products and in manufacturing. In other instances, it appears that some AT companies must invest more effort learning how to market in foreign countries — and how to traverse regulatory processes at home and overseas.

At the same time, based on comments submitted by survey respondents, it appears that there may be opportunities for federal and state agencies and private insurers to streamline AT product regulatory processes; and to achieve greater standardization in reimbursement policies on various classes of AT products. Federal agencies and the AT industry also should identify nations' discriminatory trade policies that impair or restrict trade of U.S.-origin AT products and services.

In addition, the AT industry would benefit from greater interaction with federal R&D organizations in developing and designing products, resolving technical issues, and in optimizing manufacturing processes. It is apparent from survey responses that a large portion of the AT industry is not fully cognizant of the breadth and depth of the engineering, manufacturing, and research capabilities of federal agencies such as the Departments of Commerce, Defense and Energy, and the National Aeronautics and Space Administration.

Recommendations

AT Industry Data

- *Foreign competitors*: Assessments of the competitive status of U.S. AT manufacturers and providers of AT services should be prepared periodically by industry. Information gathering should encompass: market share data on major product classifications; reimbursement policies on AT products for people with disabilities in other nations; and subsidies by national governments for R&D and manufacturing of AT products.
- *Market position:* The AT industry should commit to collecting comprehensive information on the assistive technology market in the United States and overseas. The industry should use this data to prepare detailed reports on sales revenues, market trends, and related issues on an annual or biannual basis. The assessments should include projections of future market performance when possible.

Regulation & Trade

- *Education:* The AT industry and federal agencies should hold periodic forums to educate AT manufacturers on foreign engineering, performance, safety, and environmental standards that can affect product acceptance and certification in overseas markets.
- *Trade assistance*: The Departments of Commerce and State and other government agencies should consider assembling a reference guide of contacts for understanding the performance, safety, and environmental standards and other regulations that can affect the industry's ability to sell in foreign markets. This document should be posted on

appropriate web sites and linked to business, engineering, and research organizations that AT companies utilize.

- *Barriers:* The AT industry should identify countries with discriminatory trade policies and catalog punitive practices regarding the importation, distribution, sale and delivery of U.S. AT products and services. The industry should itemize the nature of such practices (e.g. tariffs, unreasonable certification requirements, etc.) and actively consult the Department of Commerce's International Trade Administration, the Office of the U.S. Trade Representative, and the Department of State on these issues.
- *Enforcement:* Where infringement and theft of intellectual property can be demonstrated, the AT industry should request that U.S. Government agencies intensify enforcement of U.S. and international patent laws. AT firms participating in the BIS survey identified exact copies of U.S. patented AT products produced in China and sold in the United States. AT companies should consult the Department of Commerce's International Trade Administration and U.S. Trade Representative, Department of State on appropriate courses of action, including imposition of tariffs and other punitive actions if infractions warrant them.

Manufacturing

- *Technical forums:* AT manufacturers and U.S. trade associations such as the Assistive Technology Industry Association (ATIA -- <u>www.atia.org</u>) and the Accessibility Equipment Manufacturers Association (AEMA -- <u>www.aema.com</u>) should organize forums to improve the management, technical, and quality control capabilities of AT companies in the United States, which are largely small enterprises.
- Production & management: AT industry organizations should assemble a central reference source for AT companies operating in the United States to: obtain assistance with manufacturing problems, get support on training issues, learn of new processes, and identify consultants and other resources. Survey results suggest that many AT companies are unaware of organizations such as the National Center for Manufacturing Sciences, DOD's Manufacturing Technology Program, the U.S. Navy's Best Manufacturing Practices Program, the National Institute of Standards and Technology, and other manufacturing support organizations.

Research & Development

• *Technology Transfer*: AT industry organizations and federal agencies should work together to assemble a catalog of private and U.S. Government organizations that generate and license, or otherwise transfer, technology to industry. Survey data suggest that many AT companies are not aware of organizations such as the Federal Laboratory Consortium (<u>www.federallabs.org</u>), the National Technology Transfer Center (<u>www.nttc.edu</u>), and many other public and private research organizations that are sources of technical assistance, product ideas, and patented inventions.

Engineering and research organizations at the Departments of Commerce, Defense, and Energy – as well as those at NASA, the National Science Foundation and elsewhere – should on a biannual basis conduct joint information forums to highlight inventions and other intellectual property that might have application in assistive devices for people with disabilities. Many AT companies are too small to spare the time or money to try to personally visit dozens of federal R&D and engineering organizations. Survey data show that fewer than seven percent of survey participants said they had the experience or capability to tap the expertise at federal R&D facilities.

• *Research priorities:* AT companies in the United States should establish an industry panel on R&D priorities to: 1) help companies plan their R&D investments; and 2) aid federal R&D program managers in determining where best to allocate their AT R&D funds; and to avoid duplication of industry and government R&D expenditures.

In addition, consideration should be given to the establishment within the federal government of an interagency advisory committee for assistive technology R&D. Its charge would be to: 1) help identify promising technologies that may be applied to address the needs of specific groups of people with disabilities; 2) advise federal agencies on research priorities; and 3) make recommendations on AT-specific R&D programs that should be reduced in scope or eliminated. The group should issue public reports every three years to Congress and executive branch agencies. Membership would include: DOC (NIST), DOE, DOD, Education, HHS (NIH), NASA, NSF and VA.

• *Federal Data:* Federal research and development expenditures focused on assistive technology and people with disabilities should be collected and assembled annually. The effort should be directed by the Department of Education or HHS.

• *Financing:* Federal R&D agencies, in conjunction with AT industry organizations, should conduct an outreach program to make more AT manufacturers operating in the U.S. aware of the Small Business Innovation Research and the Small Business Technology Transfer programs. Survey data show that only 14 percent of survey participants applied for such grants.

VIII. Appendices

Appendix A Laws Impacting the Assistive Technology Industry

REHABILITATION ACT OF 1973, AS AMENDED

The Rehabilitation Act of 1973 was the first "rights" legislation to prohibit discrimination against people with disabilities. This law targets those specific programs and activities conducted by federal agencies (those receiving federal funds) such as colleges participating in federal student loan programs, federal employment, and employment practices of businesses with federal contracts. It states that no qualified individual with a disability in the United States, shall, solely by reason of her or his disability, be excluded under any program or activity receiving federal financial assistance, or under any program conducted by any executive agency, including the United States Postal Service.

The standards for determining employment discrimination under the Rehabilitation Act are the same as those used in Title I of the Americans with Disabilities Act (ADA). Sections 504 (included in the 1973 Act) and 508 (part of the Act Amendments of 1998) are the two most commonly invoked sections that prohibit discrimination based on a disability and mandate that all federally funded agencies provide equal access to technology and information for all people.

SECTION 504 OF THE REHABILITATION ACT OF 1973, AS AMENDED (29 U.S.C. § 794)

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against an individual with a disability, working or participating in federally funded programs or activities. It compensates otherwise qualified individuals who have been discriminated against because of a disability. In cases of intentional discrimination, Section 504 has been invoked to elicit punitive damages (in addition to remedial compensation) from a defendant, in an effort to deter other possible offenders.

To succeed under a Section 504 claim, the individual must show that his or her disability was the sole reason for adverse action. Any programs or services receiving federal funds are subject to Section 504. For example, termination of a federal employee for the sole reason that the employee is infected with Auto Immune Deficiency Syndrome (AIDS), yet was able to perform all other job functions, would be basis for action under Section 504.

Where other factors are involved in a decision to terminate, a Section 504 action will not succeed. For example, in a 1995 Minnesota case, an ex-housing authority executive director

attempted to sue the Housing Authority Board under Section 504 on the basis that she was discriminated against due to her disability. The employment record showed poor job performance evaluations, and an admission by the ex-employee that the job relationship was generally not working out. These additional factors involved in the dismissal showed that her disability was not the *sole* factor (if a factor at all) in her dismissal. *Demming v. Housing and Redevelopment Authority of Duluth, Minnesota*, 63 F.3d 950 (8th Cir. 1995). Thus, her claim did not succeed.

The act is narrower than ADA in that it prohibits discrimination by groups that receive any amount of federal funding. Under the ADA, even a private entity that receives no federal funding is expected to comply with all accessibility regulations if it is regularly accessed by the public. On the other hand, the definition of disability under Section 504 is broader than the definition used in the Individuals with Disabilities Education Act (IDEA). Although IDEA applies only to students receiving a free appropriate education until graduation at high school level, the class of individuals is smaller than is covered under Section 504. Section 504 covers students with communicable diseases (e.g. hepatitis), alcohol or drug addiction, those with temporary disabilities, and students with allergies or asthma. Section 504 also provides for reasonable accommodations for parents with disabilities at school functions, such as PTA meetings.

HEARING AID COMPATIBILITY ACT OF 1988 (PUB. L. 100-394)

Hearing aid compatible telephones incorporate an electromagnetic coil in the telephone receiver that emits a magnetic field. The electromagnetic emission is detectable as sound by some hearing aids. The Hearing Aid Compatibility Act requires that telephones (except cellular phones) manufactured or imported after 1989 contain this coil. The rule requires that phones in workplace, confined settings, emergency locations and hotels also feature this coil. Additionally, the Act requires the phones to have volume control capability.

It is not always clear without testing to know if a telephone is hearing aid compatible. And while no retrofitting of existing phones is required by law, a deadline for replacement of old telephones has now been set. The deadline was set beyond the normal life of a telephone, and varies by the age of the telephone. Most phones in the workplace must have been replaced by January 1, 2000; however, phones purchased between 1985 and 1989 are given until 2005. The act allows for employers to assume their phone is compatible, if purchased after 1989.

If a phone is incompatible, an employee or guest can request a compatible telephone. The law requires the employer to comply with the request. To reduce confusion regarding compatibility,

phones manufactured after April 1, 1997 must be marked "HAC" if they are hearing aid compatible and meet the standards of the Act.

THE AMERICANS WITH DISABILITIES ACT (42 U.S.C. § 41705)

Congress enacted the Americans with Disabilities Act (ADA) in 1990 to protect persons with disabilities from discrimination based on their disability. Until that point, individuals with disabilities had no legal remedy by which to fight unequal treatment by employers and landlords; unequal access to public buildings, recreational facilities and public transportation; and substandard education and health services. Comparable to laws which prohibit discrimination based on race, color, sex, age and religion, the ADA gave individuals equal opportunity to enjoy the same public services the rest of the population enjoy.

In order to seek protection under the ADA, a person must meet the statutory requirements defining "disabled." To be considered disabled, he or she must posses a physical or mental impairment that substantially limits one or more of his or her major life activities; have a record of such impairment or be regarded as having such an impairment. The impairment must be long-term or permanent. Pregnancy, for example, can substantially limit certain life activities but is a temporary situation. Thus a pregnant person is not considered disabled. Further, Supreme Court decisions have excluded persons with conditions that are readily corrected with medication or devices, such as diabetes or imperfect vision.

The ADA is divided into five main titles. The first addresses employment issues. Discrimination in the work place continues to disadvantage individuals socially, economically and educationally. Both private and government employers are now required to focus on an individual's level of job performance, as opposed to an individual's disability. Where a reasonable accommodation can be made to facilitate the individual, an employer must comply. The ADA does not require an employer to give preferential treatment to a disabled person; the employee is still required to meet performance standards and possess skills necessary to meet the essential requirements of a particular job. If a reasonable accommodation can be made that puts the employee on the same or better skill level than others, the employer must comply. Case law illustrates that something as simple as rearranging a work schedule or providing special software or furniture is a reasonable accommodation, and can increase individual productivity, as well as provide for valuable input to the company as a whole.

The second title of the ADA addresses public services, which include state and local government instrumentalities. Any service provided by a government entity that is accessible to a nondisabled person must also be accessible to a disabled person. For example, public hearings or meetings must provide a written transcript, a sign language interpreter or a sound amplification system to accommodate deaf individuals. Public transit systems, such as buses and railroads, must be accessible to individuals with disabilities. Court decisions have further explained that the public entity, not the individual, can choose among various alternatives of accommodation. It need not choose the most modern or expensive method, as long as the result is effective communication.

Title three requires that any places, publicly or privately owned, that are accessible to the general population, must also be accessible to the disabled. New structures must be built pursuant to specific dimensional standards. Existing facilities must remove barriers to accessibility, if readily achievable. A *reasonable effort at accommodation* must be made. This includes posting raised-letter or Braille signs for the visually impaired, or installing a wheelchair ramp near an entrance. Where it is impractical or impossible to build a wheelchair ramp, a door bell may be installed to notify someone that help is necessary. Courts have held that a reasonable accommodation does not have to be the most expensive alternative, but an efficient method by which to meet the need of the individual.

The ADA, under Title IV, also requires telecommunications companies that offer telephone service to the general public to have a telephone relay service available to individuals who use telecommunication devices for the deaf (TTYs). The Federal Communications Commission has issued rules that implement this requirement. The FCC oversees use of standard operating systems, confidentiality of calls, and prohibition from intentionally altering a relayed conversation

Title V of the Act forbids threatening or retaliating against individuals with disabilities, or those attempting to aid people with disabilities, in asserting their rights. This protects people, such as the parents of a disabled child, who are not disabled themselves, but have a strong relationship to the child and advocate on his behalf.

TELEVISION DECODER CIRCUITRY ACT OF 1990 (PUB. LAW 101-431)

In an effort to provide equal access to television medium by the deaf and hearing-impaired, the act was passed to require new televisions to have built-in decoder circuitry. Closed-captioned television transmissions have made it possible for people with hearing disabilities to gain access to television, and serves to improve the quality of their life. The act helps not only those born with a hearing disability, but people who experience loss of hearing throughout their lives. Furthermore, closed captioning improves reading skills in children and literacy in adults, and helps immigrants who are learning English as a second language.

In the past, if consumers wanted to take advantage of closed captioning, they had to buy a separate decoder and connect it to the television. The act recognized that as of 1990, technology was available that enabled the closed caption decoding to be built into television sets during the manufacturing process. The availability of decoder-equipped televisions has greatly increased the audience, and the increased size of the market now provides a larger consumer base for advertisers.

The law requires that all televisions, 13 inches or greater in size that are manufactured or imported into the United States comply with the internal decoding circuitry. The law also envisioned that closed captioning would continue to be made available on new televisions as technology progressed. As a result, in July 2000, the Federal Communications Commission amended its rules to require closed captioning display capability in digital television receivers.⁴³

The ADA mandates captioning for all government-funded public service announcements. In addition, Presidential and Vice-Presidential candidates will not receive federal campaign money unless they caption their commercials. A candidate for either office must certify that any television commercial prepared or distributed will be accompanied by closed captioning of the oral content of the material.

TELECOMMUNICATIONS ACT OF 1996 (47 U.S.C. §§ 255,251(a)(2))

The Federal Communications Commission (FCC) proclaims the implementation of Section 255 of the Telecommunications Act of 1996 "the most significant opportunity for people with disabilities since the passage of the Americans with Disabilities Act in 1990." When signed into law in 1996, Section 255 updated the Communications Act of 1934, which was consequentially renamed as the Telecommunications Act of 1996. The Access Board and the FCC were given 18 months to develop accessibility guidelines for telecommunications equipment. Section 255 mandates that, if readily achievable, telecommunication service and equipment be accessible to and useable by persons with disabilities. When determining if an alteration is "readily achievable," the FCC will look at such factors as technical feasibility of implementing the design, expense of design or development, additional time required to design equipment, and defining fundamental characteristics of a product.

"Now, just as persons with disabilities can navigate our public streets because of the ADA's requirements for curb cuts, all our citizens can navigate the information superhighway without confronting barriers that stop them cold," declared FCC Chairman William Kennard in his

statement dated July 14, 1999. Dialing numbers on a telephone, checking messages from voicemail, or doing business via an automated response system, is an essential and efficient part of every day life. For persons with disabilities, these activities may be impossible. Section 255 seeks to resolve this discrepancy in accessibility.

The Act adopted the same definition of disability as the ADA, thus affecting the same group of people, and allowing incorporation of legal precedent into defining the legal parameters of the term.

INDIVIDUALS WITH DISABILITIES EDUCATION ACT (20 U.S.C. §§1400 et seq.)

The Individuals with Disabilities Education Act was amended in 1997 to significantly improve educational opportunities for children with disabilities. The Act provides all children equal access to a common curriculum, rather than separating or excluding those with disabilities. A team consisting of educators, parents and doctors assesses each child with a disability. Based on those results, students are then mainstreamed into classrooms, given the appropriate supplementary aids and services.

The success of the program relies on the mandatory, individualized assessment of the child's current educational level, accessory needs, expected performance levels and regular checks of progress. Based on the idea that a child with a disability will thrive and advance more rapidly when placed in classrooms, and allowed to participate in activities with nondisabled students, Individualized Education Programs (IEP) are developed, monitored and updated regularly. The IEP program requires involvement from parents, students and teachers. Regular meetings are required to discuss academic progress, short-term objectives and long-term goals of the student, so that he or she may be prepared for post-graduation employment and other activities.

Through these individualized meetings, specific augmentative needs for the child are also assessed. The team of educators and parents determine whether the child needs special aids, services, or accommodations. Based on reports prepared at these meetings, the public agency must ensure that all service requirements set forth in the IEP are provided, at no cost to the parents. However, a parent may not insist on any accommodations until after an IEP is established. (In special cases an interim, or temporary IEP may be developed). A school may be required to provide computer equipment, make modifications to school grounds or vehicles, or provide additional staff to meet the needs of the child. The aim of the program is to develop the least restrictive environment, monitor progress regularly, and educate a child with a disability to the same high academic and performance standards given to children without disabilities.

⁴³ See http://www.fcc.gov/Bureaus/Mass_Media/News_Releases/2000/nrmm0031.html

A child with a disability, just as a child without a disability, is also subject to disciplinary guidelines. A school may remove a child for up to ten school days at a time for any violation of school rules. Suspension or expulsion of the child, however, cannot be based on behavior that is a manifestation of his or her disability. Intentional acts such as possession of dangerous weapons or controlled substances, are subject to the school's regular disciplinary procedure, and may require long-term removal or expulsion. At this point, the school may request a hearing officer to determine appropriate measures. During any long-term removal for behavior that is not a manifestation of disability, schools are still required to provide services, to the extent deemed necessary, to enable the child to appropriately progress through the IEP. A student may not be removed for more than 10 days if disruptive behavior is a manifestation of the disability.

A student's right to a free appropriate public education terminates upon graduation with a regular high school diploma. IDEA, therefore, is effective only for the duration of education through a secondary education.

ASSISTIVE TECHNOLOGY ACT OF 1998 (PUB. LAW 105-394)

The Assistive Technology Act (the AT Act) was a renewal and expansion of the Technology-Related Assistance for Individuals with Disabilities Act of 1988. It provides federal support to states for researching and promoting assistive technology for individuals with disabilities. The 1988 law first defined assistive technology as a combination of devices and services. An AT device is any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain or improve functional capabilities of individuals with disabilities. "Devices" include the full range of technology from day-to-day living tools to prosthetics, medical equipment, wheelchairs, all the way up to the most complex computer communications systems. An AT service includes any service that directly assists an individual with a disability in the selection, acquisition, or use of an assistive technology device.

The AT Act affirms that assistive technology is a valuable tool to improve the lives of people with disabilities, and provides the framework by which federal government will promote access to AT devices and services. Under the plan, all 50 states plus the District of Columbia, Puerto Rico and outlying areas are eligible to receive support. Funding is provided initially for 10 years, and may be increased by 3-year increments if further eligibility is demonstrated.

To receive funding under Title I of the Act, states are required to support public awareness programs, promote interagency coordination that improves access to assistive technology

devices, provide technical assistance and training, and provide outreach support to statewide organizations that provide AT devices and services. For 1999 \$30 million was appropriated.

Title II of the Act relates to coordinating federal efforts pertaining to assistive technology and universal design research. It includes grants for small business research, unique individual AT needs, and technical training for people who develop AT devices. Title III allows the Secretary of Education to award grants to pay for specified costs, or provide alternative (low interest) financing to purchase assistive technology components for people with disabilities.

Assistive technology is now seen as a valuable tool that can be tailored to address the unique strengths and weaknesses of each individual with a disability. Devices can be customized to fit the appropriate setting in which that individual works or lives, in doing so focusing on specific tasks the individual performs. Advances in technology make tools more portable and accessible.

As the area of AT progresses, more and more products developed to assist individuals with disabilities are crossing over into mainstream or "universal design" areas. Legislation requiring closed-captioned circuitry in televisions has proven useful for hearing customers attempting to watch TV in a crowded bar. Voice recognition software is being used at work, at home and in the military. Private and government laboratories alike have found new purpose in developing this technology.

SECTION 508 OF THE REHABILITATION ACT (29 U.S.C. § 794 (d))

Section 508 of the Rehabilitation Act of 1973, as amended in 1998, requires Federal departments and agencies to comply with accessibility requirements when they procure, develop, use or maintain electronic and information technology (E&IT), unless it is an undue burden (defined as "significant difficulty or expense"). As directed by law, these requirements include standards developed by the U.S. Access Board. The standards are based on recommendations from an advisory committee the Board established for this purpose.

The intent of Section 508 is to ensure that federal employees and members of the public with disabilities have access to and use of E&IT comparable to that of the employees and members of the public without disabilities.

E&IT includes products that store, process, transmit, convert, duplicate, or receive electronic information, copiers, computers, fax machines, information kiosks, software, operating systems,

websites and telecommunications equipment and services. The Section 508 standards provide technical and performance criteria that spell out what makes E&IT accessible to people with vision, hearing, speech, and mobility disabilities.

The Section 508 standards were published in the *Federal Register* on December 21, 2000 (65 FR 80500). Later, they were fully incorporated into the FAR (Federal Acquisition Regulations) and became enforceable on June 25, 2001 (48 CFR Parts 2, 7, 10, 11, 12, and 39). Only procured E&IT is subject to enforcement. The Section 508 standard provides (in Subpart A) a list of exceptions that agencies may claim as reasons for procuring a non-conforming product, such as lack of commercial availability.

The law includes an administrative complaint process. When an employee or member of the public files a complaint claiming an agency's procurement is not in compliance, the process for handling that complaint will follow already established procedures that exist under Section 504 of the Rehabilitation Act. Individuals may also file a civil action against an agency to seek injunctive relief and attorney's fees (but not compensatory or punitive damages).

The scope of Section 508 and the Board's standards is limited to the Federal sector. Section 508 is not a requirement for the industry. However, since the federal government spends billions of dollars on E&IT, it is in the interest of the industry to develop products that conform to the Section 508 standard, so that the federal government will be inclined to procure them. Since one method of conformance with the standards is compatibility of E&IT with assistive technology, the Section 508 standard supports the AT industry. Therefore, it is important for the AT and E&IT industries to work closely together to ensure interoperability between E&IT and AT.

The Access Board and the General Services Administration (GSA) are directed to provide technical assistance to individuals and federal agencies concerning the requirements of Section 508. Their websites, respectively, are <u>www.access-board.gov</u> and <u>www.section508.gov</u>.

Appendix B

Evolving Health Programs: A Key Driver In The U.S. AT Industry

The U.S. Government's work in helping to create a healthcare system to address the needs of the disadvantaged and people with disabilities has steadily escalated since 1915, when public concern for disadvantaged Americans became an important issue.

Social Security provisions of the 1930s sought to support state activities relating to public health care services for mothers and children. By the late 1930s, many Americans were clamoring for some form of health insurance to provide protection against unpredictable and potentially catastrophic medical costs. A central issue of discussion was whether this service should be privately or publicly financed. In the end, private group insurance financed through employers prevailed for most of the population.

Private health insurance grew rapidly through the 1940s, as employee fringe benefits expanded because of limits placed on wages during World War II. At the same time, numerous bills were introduced in Congress proposing national health insurance financed through payroll taxes, but these measures were never brought to vote. In 1950, Congress sought to improve access to medical care for needy people who were receiving public assistance. This was the beginning of federal participation in financing state-government payments made to providers of medical care to recipients of public assistance.

In 1960, Congress introduced limited legislation, including the "Medical Assistance to the Aged Act," which provided medical assistance to individuals who were less poor, yet still needing assistance with medical expenses. Congress established the Medicare and Medicaid programs as Title XVIII and Title XIX, respectively, under the Social Security Act in 1965. Coverage for people with disabilities and certain types of kidney disease was added to Medicare in 1973.

The Social Security Administration managed the Medicare system, and the Social and Rehabilitation Service managed Medicaid until 1977. These duties were then transferred to the newly established Health Care Financing Administration, under the U.S. Department of Health and Human Services, formerly known as the Department of Health, Education and Welfare.

The laws supporting access for persons with disabilities help drive demand for the AT industry. These laws have resulted in modifications to existing facilities and products and the creation of entirely new families of AT devices. For example, the requirements of the Americans with Disabilities Act generated demand for architectural elements such as ramps and lifts. The Television Decoder Circuitry Act increased sales of decoder circuitry and generated demand for closed-captioned programming. The Telecommunications Act of 1996 and related laws drove the development of new telecommunication devices and modifications to existing devices for people with disabilities.

Since then, the Congress has enacted at least three more pieces of legislation that will benefit persons with disabilities —and spur further development of AT products: The Individuals With Disabilities Education Act of 1997 (20 U.S.C. §§1400 et seq.); the Assistive Technology Act of 1998 (Pub. Law 105-394); and Section 508 of the Rehabilitation Act as amended in 1998 (29 U.S.C. §794d).

Appendix C

Centers for Medicare & Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), located within the U.S. Department of Health and Human Services, runs the Medicare and Medicaid programs — two national health care programs that benefit about 75 million Americans. CMS and the Health Resources and Services Administration run the Children's Health Insurance Program, a program that provides medical coverage for uninsured children in the United States.

CMS also regulates all laboratory testing (except research) performed on humans in the United States. In addition, CMS partners with the Departments of Labor and Treasury to help U.S. citizens and small companies obtain and retain health insurance coverage; these departments work to eliminate discrimination based on health status for people buying health insurance.

PROGRAM ADMINISTRATION

CMS spends more than \$360 billion a year buying health care services for beneficiaries of Medicare, Medicaid and the Children's Health Insurance Program. CMS has oversight responsibility for these programs, establishing policies that pay health care providers, and conducting research on the effectiveness of various methods of health care management, treatment, and financing. CMS also assesses the quality of health care facilities and services and takes enforcement actions as appropriate.

CMS has 4,000 employees working in its Baltimore, Maryland headquarters and 10 regional offices nationwide. The headquarters staff is responsible for national program direction. The regional office staffs provide CMS with the local presence necessary for customer service and oversight.

A brief outline of the three major CMS programs follows:

MEDICARE

Medicare is the nation's largest health insurance program, covering more than 38 million Americans at a cost of nearly \$200 billion. Medicare provides health insurance to people who are at least 65 years old, people with disabilities, and people with permanent kidney failure. Benefits fall into two major categories: Hospital Insurance (Part A) and Medical Insurance (Part B). Medicare Part A helps pay for inpatient hospital services, skilled nursing facility services, home health services, and hospice care. Medicare Part B helps pay for doctor services, outpatient hospital services, medical equipment and supplies, and other health services and supplies.

Medicare beneficiaries enrolled in managed care plans such as Health Maintenance Organizations (HMOs) can get both Part A and Part B benefits in most managed care plans and Preferred Provider Organizations. In 1999, the program expanded to provide services for members of HMOs with or without point-of-service options, provider sponsored organizations (closed networks operated by providers) and private fee-for-service plans. Medical savings accounts were also introduced.

MEDICAID

Medicaid is a health insurance program for qualifying low-income people and those with disabilities, and is funded and administered through a state-federal partnership. Although there are broad federal requirements for Medicaid, states have a wide degree of flexibility in the design of their programs. States have authority to establish eligibility standards, determine what benefits and services to cover, and set payment rates. About 33 million people are eligible for Medicaid, including certain low-income families with children; aged, blind or disabled people on Supplemental Security Income; certain low-income pregnant women and children; and people who have very high medical bills.

Because states have flexibility in structuring their Medicaid programs, there are variations from state to state. All states, however, must cover these basic services: inpatient and outpatient hospital services; laboratory and X-ray services, skilled nursing and home health services, doctors' services; family planning; and periodic health checkups, diagnosis and treatment for children.

CHILDREN'S HEALTH INSURANCE PROGRAM

CMS, along with the Health Resources and Services Administration, runs the Children's Health Insurance Program. Program benefits became available October 1, 1997, and provided \$24 billion in federal matching funds over five years to help states expand health care coverage to nearly five million of the nation's uninsured children. States set eligibility and coverage, following broad federal guidelines, and have flexibility in the way they provide services. Recipients in all states must have low incomes, be otherwise ineligible for Medicaid, and be uninsured. State programs differ, but all states must cover at least these services: inpatient and outpatient hospital services, doctors' surgical and medical services, laboratory and X-ray services, and well baby/child care, including immunizations. Some states may provide additional benefits. Benefits are not yet available in all States.

Appendix D

Small Business Innovation Research Program

The Small Business Innovation Research Program is a highly-competitive program designed to encourage small businesses to explore their technological potential and provide incentives to profit from technology commercialization. The program is based on the belief that including small businesses in the nation's research and development arena will stimulate high-technology innovation and entrepreneurship, as the United States meets its research and development needs.

SBIR targets entrepreneurial firms because innovation and innovators seem to thrive in these organizations. The risk and expense of conducting serious R&D efforts, however, are often beyond the means of small businesses. By reserving a specific percentage of federal R&D funds for small business, SBIR protects the small business and enables it to compete on the same level as larger businesses. SBIR funds the critical startup and development stages; and it encourages the commercialization of the technology, products, or service.

Since its enactment in 1982, as part of the Small Businesses Innovation Development Act, SBIR has helped thousands of small businesses compete for federal R&D awards. Their contributions have enhanced the nation's defense, protected our environment, advanced health care, and improved our ability to manage information and manipulate data.

Small businesses must meet certain eligibility criteria to participate in the SBIR program:

- American-owned and independently operated
- For-profit
- Principal researcher must be employed by the business
- Company size is limited to 500 employees

Each year, ten federal departments and agencies are required to reserve a portion of their R&D funds for award to small businesses through the SBIR program:

- U.S. Department of Agriculture
- U.S. Department of Commerce
- U.S. Department of Defense
- U.S. Department of Education
- U.S. Department of Energy
- U.S. Department of Health and Human Services
- U.S. Department of Transportation
- Environmental Protection Agency

- National Aeronautics and Space Administration
- National Science Foundation

These agencies designate R&D topics and accept proposals.

Three-Phase Program

Following submission of proposals, agencies make SBIR awards based on small business qualification, degree of innovation, technical merit, and future market potential. Small businesses that receive awards or grants then begin a three-phase program:

- Phase I is the startup phase. Awards of up to \$100,000 for approximately 6 months support exploration of the technical merit or feasibility of an idea or technology.
- Phase II awards expand Phase I results, with awards of up to \$750,000. During this time, the R&D work is performed and the developer evaluates the commercialization potential of the technology. Only Phase I award winners are considered for Phase II.
- During Phase III, Phase II innovation moves from the laboratory to the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR federal agency funding.

The U.S. Small Business Administration (SBA) directs the 10 agencies' implementation of the SBIR, reviews their progress, and reports annually to Congress on its operation. SBA also is responsible for collecting solicitation information from all participating agencies and publishing a quarterly Pre-Solicitation Announcement, outlining the topics and anticipated release and closing dates for each agency's solicitations.

For more information, visit <u>www.sba.gov/SBIR</u>.

Appendix E

Rehabilitation Engineering Research Centers (RERC)

The National Institute on Disability and Rehabilitation Research (NIDRR) funds the Rehabilitation Engineering Research Center (RERC) Program under authority of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 762(b)(3)). RERCs conduct programs of advanced research of an engineering or technical nature designed to apply advanced technology, scientific achievement, and psychological and social knowledge to solve rehabilitation problems and remove environmental barriers.

Each center is affiliated with one or more institutions of higher education or nonprofit organizations. RERCs work at the individual level focusing on technology to benefit those affected by sensory loss, mobility impairment, or communication difficulties. They also work at the systems level to eliminate barriers such as those found in telecommunications and the built environment.

In addition, each center is affiliated with a rehabilitation setting, which provides an environment for cooperative research and the transfer of rehabilitation technologies into rehabilitation practice. RERCs also develop systems for the exchange of technical and engineering information worldwide and improve the distribution of technological devices and equipment to individuals with disabilities.

Each RERC focuses on a specific area of disability-related research. For example, currentlyfunded RERCs are conducting research on hearing enhancement; technologies for children with orthopedic disabilities; tele-rehabilitation; prosthetics and orthotics; improved technology access for land mine survivors; ergonomic solutions for employment; assistive technology for older persons with disabilities; technology transfer; universal design and the built environment; communication enhancement; wheeled mobility; information technology access; and telecommunications access.⁴⁴

Further information on the RERCs is available on the following website:

www.ncddr.org/rpp/techaf/techdfdw/rerc/index.html

⁴⁴ For more information about the individual RERCs and other NIDRR-funded research, see <u>http://www.naric.com/search/pd/indextype.html</u>

Appendix F

Department of Veterans Affairs Research and Development

The Department of Veterans Affairs'(VA) Rehabilitation Research and Development Service (Rehab R&D) supports research relevant to the rehabilitative needs of veterans, including prosthetics, orthotics, mobility, orthopedics, neurology, physical medicine, spinal cord injury, communication disorders, sensory and cognitive aids.

Today, rehabilitation assumes a role of importance as a scientific discipline. As the population of veterans with chronic disease expands, due in part to improved survival following catastrophic events, the need for rehabilitation research increases. Since rehabilitation's fundamental clinical goal is to maximize functional recovery, this often means teaching compensatory techniques and providing adaptive equipment. The long-term effects on outcomes of many traditional approaches remain unproven, and as rehabilitation moves forward, VA Rehabilitation researchers must examine efficacy to allow its medical practice to be truly evidence based.

A crucial issue is whether external experience influences general health, quality of life and genuine recovery. VA Rehab R&D is committed to advancing and expanding the field of rehabilitation and to creating increased research capacity within the VA.

The following table lists the locations and functional specialty of each VA Rehab R&D Center.

West Haven, CT	Restoration of Function in SCI and Multiple Sclerosis
Pittsburgh, PA	Wheelchair and Related Technology
Gainesville, FL	Cognitive and Motor Impairment Rehabilitation
Atlanta, GA	Geriatric Rehabilitation
Portland, OR	Aural Rehabilitation
Seattle, WA	Prosthetics and Consequences of Amputation
Palo Alto, CA	Mobility
Houston, TX	Aging with a Disability
Cleveland, OH	Center for Functional Electrical Stimulation

Appendix G

Assistive Technology Industry Survey

U.S. Department of Commerce Bureau of Export Administration

TECHNOLOGY ASSESSMENT: ASSISTIVE TECHNOLOGY

THE PURPOSE OF THIS ASSESSMENT

The U.S. Department of Commerce/Bureau of Export Administration is working with the U.S. Department of Education/National Institute on Disability and Rehabilitation Research and the Federal Laboratory Consortium on a critical technology assessment of the U.S. assistive technology industry. The goals of this joint assessment are to:

- analyze the long-term health and competitiveness of the industry;
- determine the growth trends and emerging markets in this field; and
- develop a framework for more consistent transfer of technologies from U.S. defense and civilian government laboratories into the assistive technology industry.

Your firm's response to the attached survey will provide us with the information that we need to accomplish these goals.

PROTECTING YOUR INFORMATION FROM DISCLOSURE

Any information submitted in response to this questionnaire will be deemed **BUSINESS CONFIDENTIAL** and treated in accordance with section 705 of the Defense Production Act of 1950, as amended (DPA). Information submitted will not be shared with any non-government entity, other than in aggregate form, and the Department will assert the applicable Freedom of Information Act (FOIA) exemption if it is the subject of a FOIA request. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

GENERAL INSTRUCTIONS

- 1. Please complete this questionnaire in its entirety as it applies to the assistive technology operations of your organization or firm. This questionnaire applies to all of the assistive technology-related business for your firm; see page iv for a definition of assistive technology device.
- 2. The questionnaire has 2 sections as follows:

Section A. ORGANIZATION IDENTIFICATION Section B. I. COMPETITIVENESS II. FINANCIAL STATUS

- 3. It is not our desire to impose an unreasonable burden on any respondent. IF INFORMATION IS NOT READILY AVAILABLE FROM YOUR RECORDS IN EXACTLY THE FORM REQUESTED, FURNISH ESTIMATES AND DESIGNATE BY THE LETTER "E".
- 4. Questions related to the questionnaire should be directed to Margaret Cahill, Trade and Industry Analyst at (202) 482-8226 (e-mail: mcahill@bxa.doc.gov) or Steve Baker, Trade and Industry Analyst, at (202) 482-2017 (e-mail: sbaker@bxa.doc.gov). You may also fax your questions to (202) 482-5650.
- 5. Before returning your completed questionnaire, be sure to sign the certification on the next page and identify the person and phone number to be contacted at your firm if we have questions about your response. Return questionnaire by **May 19, 2000** to :

Brad Botwin, Director Strategic Analysis Division Room 3876, BXA re: AT U.S. Department of Commerce Washington, DC 20230

EXEMPTION

For this report, **assistive technology device** will be defined as any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain or improve functional capabilities of individuals with disabilities. If your organization has not conducted any manufacturing or non-manufacturing activity related to assistive technology devices in the United States since January 1, 1996, you are not required to complete this form. If this is the case, please provide the information requested below and return this page to the address above.

Name of Organization

Address (City, State)

Signature of Authorized Official

Name of Official-Please Print

Phone

Date

CERTIFICATION

The undersigned certifies that the information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. The U.S. Code, Title 18 (Crimes and Criminal Procedure), Section 1001, makes it a criminal offense to willfully make a false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

Company Name:

Signature of Authorized Official:

Title:

Phone Number (with area code):

Fax Number (with area code):

E-Mail address:

Date:

In the event that we have questions regarding your response, please provide below a point of contact with telephone and fax numbers and e-mail address, if different than above.

Title:

Point of contact:
Phone Number (with area code):
Fax Number (with area code):
E-Mail address:

DEFINITIONS

ASSISTIVE TECHNOLOGY DEVICE - any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA) - a written agreement between a private company and a government agency to work together on a project. In 1986 and 1989, legislation was enacted as part of the Stevenson-Wydler Technology Innovation Act to enable federal laboratories to enter into CRADAs with private businesses and other entities. CRADAs provide the means to leverage R&D efforts and to create teams for solving technological and industrial problems. Through CRADAs, companies or groups of companies can work with one or more federal laboratories to pool resources and share risks in developing technologies.

FACILITY - A site where assistive technology devices or equipment are manufactured and/or related research and development is conducted.

FIRM - An individual proprietorship, partnership, joint venture, association, corporation (including any subsidiary corporation in which more than 50 percent of the outstanding voting stock is owned), business trust, cooperative, trustees in bankruptcy, or receivers under decree of any court, owning or controlling one or more establishments as defined above.

RESEARCH AND DEVELOPMENT (**R&D**)- includes basic research and applied research in the sciences and in engineering, and design and development of prototype[s], products and processes.

For the purposes of this questionnaire, R&D includes activities carried on by persons trained, either formally or by experience, in the physical sciences including related engineering, and the biological sciences including medicine but excluding psychology, if the purpose of such activity is to do either or both of the following:

Basic Research Pursue a planned search for new knowledge, whether or not the search has reference to a specific application.

Applied Research Apply existing knowledge to problems involved in the creation of a new product or process, including work required to evaluate possible uses, or apply existing knowledge to problems involved in the improvement of a present product or process.

Research and development includes the activities described above whether assigned to separate R&D organizational units of the company or carried out by company laboratories and technical groups not part of an R&D organization. Reporting the R&D activities of such latter groups may require the use of estimates for some of the questions.

SMALL BUSINESS INNOVATION RESEARCH PROGRAM (SBIR) - a program through which federal agencies fund research and development efforts of a high risk nature that may have excellent commercial potential. The research is carried out by a small business and may not necessarily involve outside collaboration.

SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM (STTR) - a program through which

federal agencies fund cooperative R&D projects involving a small business and a university; an approved, contractor-operated, federally funded research and development center; or a nonprofit research institution.

TECHNOLOGY TRANSFER - a process for implementing a new application for an existing technology.⁴⁵

UNIVERSAL DESIGN - The process of designing products and environments (including assistive technologies) to be usable by people with the widest range of abilities possible, without the need for adaptation or specialized design. Seven Principles of Universal Design have been developed.⁴⁶ They include:

1. Equitable Use. The design is useful and marketable to people with diverse abilities;

2. Flexibility in Use. The design accommodates a wide range of individual preferences and abilities;

3. Simple and Intuitive Use. Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level;

4. Perceptible Information. The design communicates necessary information to the user, regardless of ambient conditions or the user's sensory abilities;

5. Tolerance for Error. The design minimizes hazards and the adverse consequences of accidental or unintended actions;

6. Low Physical Effort. The design can be used efficiently and comfortably and with a minimum of fatigue; and

7. Size and Space for Approach and Use. Appropriate size and space is provided for approach, reach, manipulation, and use regardless of user's body size, posture, or mobility.

UNITED STATES - Includes the fifty States, Puerto Rico, the District of Columbia, the Virgin Islands, American Samoa, and the Trust Territories of the Pacific Islands.

WORK FOR OTHERS (WFO) - research conducted or technical assistance provided by a federal laboratory for either a different federal entity or a private organization. Work is fully funded by the recipient agency or organization.

⁴⁵A. Reisman, "Technology Transfer: A Taxonomic View." Journal of Technology Transfer, Summer-Fall 1989, pp. 31-36.

⁴⁶Advocates of Universal Design. Copyright 1997, NC State University. For a fuller discussion, see http://www.design.ncsu.edu/cud/pubs/udprinciples.html

SECTION A Organization Identification

A1. Organization Address: Provide the name and address of your organization.

A2. Additional Facilities: If your organization has additional facilities also involved in any manufacturing or other activities related to assistive technology, please list them below.

Facility Name	City, State, Country

A3. **Parent Firm/Joint Ventures:** If your organization is wholly or partly owned by another firm, indicate the name and address of the parent firm and extent of ownership. Indicate whether the relationship is a joint venture.

Firm Name: ______ City, State, Zip: _____

% ownership____%

A4. Organization Activities: Please indicate the nature of your assistive technology business by checking the appropriate box(es):

	Primary Business	Secondary Business
Basic Research		
Applied Research & Development		
Product Testing		
Manufacturing		
Assembly		
Distribution		
Consulting		

A5. Product Categories

Below is a list of product categories for assistive technology devices derived from a list of major classifications developed by the National Institute on Disability and Rehabilitation Research (NIDRR). Indicate (\checkmark) what type(s) of assistive technology equipment/devices you manufacture, assemble, perform research in connection with, develop, or design. Item lists under the categories are not all inclusive; select the closest category.

Product Category	✓
A. Architectural Elements (e.g., door opening/closing devices, door levers, lifts and elevators, ramps, safety equipment)	
B. Communication Devices (including both high and low technology devices, such as augmentative and alternative communication devices (AAC), speech synthesizers, communication boards and board overlays, conversation books)	
C. Telecommunications (e.g., wireless and wireline telephones, text telephones (TTY), amplified telephones, talking pagers)	
D. Sensory Aids (non-computer based devices, such as hearing aids, assistive listening devices, tactile aids for the deaf/blind, alerting devices, braille notetakers)	
E. Computers (e.g., hardware, software, accessories, including screen readers, large print software, optical character recognition equipment, refreshable braille displays)	
F. Environmental Controls (e.g., remotely controlled door openers, telephones, lights, televisions)	
G. Aids to Daily Living (e.g., aids for hygiene, dressing and undressing, toiletting, washing, bathing, showering, manicure and pedicure, hair care, dental care, facial care and skin care, housekeeping, handling and manipulating products, and orientation)	
H. Mobility (e.g., transportation safety, vehicle lifts and ramps, walking/standing aids, wheelchairs, seating systems, other types of wheeled mobility)	
I. Orthotics/Prosthetics (e.g., spinal orthotic systems, upper/lower limb orthotic systems, hybrid orthotic systems, upper limb prostheses, upper/lower limb prosthetic systems, non-limb prostheses, functional electrical stimulators)	
J. Recreation/Leisure/Sports (e.g., accessible toys, indoor games, arts and crafts, photography, physical fitness, gardening, camping, hiking, fishing, hunting, shooting, sports equipment, musical instruments)	
K. Modified Furniture/Furnishings (e.g., tables, light fixtures, sitting furniture, beds and bedding, adjustable height furniture, work furniture)	
L. Other (Please Specify:)	

SECTION B I. Competitiveness

B I.1 Competitors and Competitive Prospects

Competitors: Who are your 5 major competitors, domestic or foreign?

Company Name & Country	
1.	
2.	
3.	
4.	
5.	

Your Market Share: What is your company's estimated share of the U.S. and world markets for your assistive technology products?

U.S. _____% World _____%

Competitive Prospects: Please rate how you expect your overall competitive prospects to change over the next 5 years:

Improve greatly	
Improve somewhat	
Stay the same	
Decline somewhat	
Decline greatly	

BI.2 Foreign Competition:

Do foreign producers of assistive technology devices have any advantages over your firm that are unrelated to the quality or features of your products?

	🗖 Yes	🗖 No
Are your foreign competitors able to mar	ufacture their	r products less expensively?
	□ Yes	□No
Comments:		

BI.3 Universal Design

BI.3a Who do you consider to be the target market for your products, and what type(s) of disability(ies) do they have?

BI.3b Do your product developers consider individuals who are aging with the accommodated disability(ies)?

	🗆 Yes	🗖 No	
If yes, please comment.			
BI.3c Do your product developers evindividuals with more than one disabi		their design processes	consideration for
	□ Yes	🗖 No	
If yes, please comment.			
BI.3d Has your company explored po			— ts for individuals w

BI.3d Has your company explored potential applications of your products for individuals who have no disability?

□ Yes □ No

If yes, please comment	П	yes, i	please	comment
------------------------	---	--------	--------	---------

BI.3e Would you be interested in learning more about these possibilities, which are part of the universal design process?

□ Yes	🗖 No
-------	------

BI.4 Customer Input. Does your company use focus groups or any other mechanisms to gather ergonomic, human factor, and other relevant user information for incorporation into the design of your products?

 \Box Yes \Box No

If yes, please discuss these mechanisms.

BI.5 Partnering **BI.5a.** Private Assistance

Within the last 3 years, has your firm submitted a proposal for research funding related to assistive technology to any private foundations or firms?

 \Box Yes \Box No

If yes, provide this information for each proposal. Attach an additional page if needed.

Name of Foundation or Fin	rm:			
Brief Description of Projec	et:			_
Did you receive funding?	□ Yes □ No			
How much funding?	1996:	1997:	1998:	
Name of Foundation or Fin	rm:			
Brief Description of Projec	et:			
1 5				-
Did you receive funding?	□ Yes □ No			
How much funding?	1996:	1997:	1998:	

BI.5b. SBIR Application

In the last 3 years, has your firm submitted a research proposal related to assistive technology under the Small Business Innovation Research (SBIR) program?

□ Yes	🗖 No
-------	------

If yes, please indicate which agency(ies) offered the SBIR.

D Environmental Protection Agency
□ Natl. Aeronautics & Space Admin.
National Science Foundation
Nuclear Regulatory Commission
□ Other:

Please briefly summarize your proposal(s):

What product(s) or technology(ies) were involved?

Has your firm applied for Phase I funding ? D Yes		No
Did your firm receive funding for Phase I?		No
If yes, how much funding? 1996 1997	1998	
Has your firm applied for Phase II funding ? D Yes		No
Did your firm receive funding for Phase II?		No
If yes, how much funding? 1996 1997	1998	

BI.5c. Cooperation with Laboratories

Has your firm ever worked with either private or government laboratories in the development of assistive technology products or related technologies?

\Box Yes \Box No

If yes, please provide the following information about your cooperative efforts:

Year(s)	Name of Laboratory	<u>Type of Lab:</u> I=Industry G=Govt. U=University O=Other	Products or Related Technologies Developed

Would you be interested in working with government laboratories on new or additional product and/or technology development projects?

\Box Yes \Box	N o
-------------------	------------

BI.5c. Cooperation with Laboratories (continued): If yes, listed below are some of the mechanisms available for working with federal laboratories. Please indicate with a \checkmark which one(s) would be of interest to you.

Mechanisms	1
Personnel Exchanges	
Cooperative Research and Development Agreements (CRADAs)	
Finding Technical Assistance	
Forming Consortia	
Acquiring Software	
Licensing	
Work For Others (WFO) Arrangements	

Do you know how to access the expertise and resources of the federal laboratories?

🗆 Yes 🛛 🗆 No

BI.6 Manufacturing Assistance

What types of manufacturing assistance would increase your firm's output?

equipment demonstration	process verification
ISO 9000	metrology

- CE Mark (demonstrating compliance with European safety requirements)
- other:

BI.7 Changes in Product Line

Select (\checkmark) the option that best represents your company's approach to new **products:**

- □ Actively seeking new products from outside sources
- □ Not active but willing to review new products from outside sources
- □ Not willing to review new products from outside sources but have capacity to develop new products internally
- Have more new products internally than we are able to introduce
- □ Not developing or seeking new products

BI.8 Emerging Technologies

BI.8a. Select the option that best represents your company's approach to new technologies:

- □ Actively seeking technologies from outside sources
- □ Not actively seeking technologies but willing to review new technology opportunities as they become available
- □ Not interested in acquiring new technologies

BI.8b. For each of the following technologies, please indicate (by writing a **1**, **2**, **3**, **4**, **or 5** in the box next to each row) to indicate whether these technologies.....

1.....are *currently incorporated* into your products.

2.....<u>would improve</u> your firm's productivity if incorporated.

3.....<u>would improve</u> your firm's products if incorporated.

4.....<u>will be important</u> additions to your products in the next 5-10 years.

5.....<u>cannot be applied</u> to my product line

Also, indicate (\checkmark) if you are interested in free consulting assistance from the member laboratories of the Federal Laboratory Consortium (FLC) for any of the technologies listed.

Technology Description	1-5	Free FLC Consulting?(✓)
Electronic Components & Systems		
Board-level Electronics		
Lasers/Optics		
Integrated Circuits		
Software Programs		
Mechanical Components		
Fastening, Joining & Assembly		
Ferrous and Nonferrous Metals		
Composite Materials		
Plastics and Non-Metals		
Sensors/Transducers		
Test/Measurement Instruments		
Motion Control Equipment		
Fluid Power & Handling Devices		
Energy Cells		
Other:		
Other:		

BI.9 Potential Obstacles:

Please indicate your perception of the following as potential obstacles to your business. Use the scale below to score each item from 0-5.

3

- 0 Not an obstacle at all
- 1 Only a minor obstacle
- 2 Average difficulty obstacle

- Moderately difficult obstacle
- 4 Extremely difficult obstacle
- 5 Insurmountable obstacle

Competitiveness

- ____ Foreign Competition
- ____ Tariffs and trade barriers
- ____ Reliance on foreign parts and components
- ____ Lack of US suppliers for manufacturing equipment
- ____ General state of the U.S. economy
- ____ Other (specify)

Market Information

- ____ Inadequate information regarding the demand for your product
- ____ Inadequate information regarding the physical parameters of usability of your product for persons with disabilities
- ____ Other (specify)

Legal Issues

- ____ Generally litigious environment
- ____ Obtaining FDA approval
- ____ Environmental and health regulations
- _____U.S. Government auditing policies and tax laws
- ____ Other (specify)

Labor and Production

- ____ High U.S. labor costs
- ____ Problems with production scheduling and product development
- ____ Lack of automation/robotics
- ____ Poor education system
- ____ Labor turnover
- ____ Other (specify)

Other

____ Other (specify)

BI.10 Employment

BI.10a Workforce and Job Skills

For 1997, 1998, and 1999 (estimated), enter the total number of full-time equivalent workers for your organization employed in activities related to assistive technology devices at all facilities in the United States, including part-time employees, that are employed at year end.

	1997	1998	1999 (est.)
TOTAL			

For each year reported above, please divide your total number of employees into the following categories, estimating where necessary:

JOB CATEGORY	1997	1998	1999 (est.)
Scientists, Engineers and Technicians			
Healthcare Professionals			
Manufacturing			
Assembly			
Marketing/Sales/General & Administrative			
Other			
Other			

BI.10b Employment Issues

Are any of the following items current or projected employment issues that may adversely affect your assistive technology manufacturing or R&D operations? If so, please describe them below:

shortages of certain skills
excessive turnover
liability claims
other

BI.11 Government and Private Organization Funding

Choose a number from the scale below to indicate the impact of the following AT market forces:

Scale:

Negative impact:	-
ruganve impaci.	2
No impact:	3
Positive impact:	4
Very beneficial impact:	5

Description	<u>Enter 1-5</u>
Decreased Government R&D funding	
Access to low cost capital	
Managed care	
State Medicaid	
Medicare	
Private insurance reimbursement	
Workman's compensation	
Other sources of funding to consumer to offset purchase price	
Decreased vocational rehabilitation funding	
Tax credits and/or incentives for purchase of assistive technology devices	
Tax credits and/or incentives for creation of accessible facilities	
Other:	
Other:	
Comments:	

SECTION B II. FINANCIAL STATUS

BII.1 R&D Expenditures:

Please indicate your total expenditures for assistive technology R&D in dollars for 1997 through 1999, providing estimates for 1999. For each year, indicate the amount of funding received from the sources listed (both internal and external).

	1997	1998	1999 (est.)
TOTAL	\$00	\$00	\$00
Internal Funding	\$00	\$00	\$00
External Funding:			
Federal Government:			
SBIR Phase 1 (How many?)	\$00	\$00	\$00
SBIR Phase 2 (How many?)	\$00	\$00	\$00
STTR Phase 1 (How many?)	\$00	\$00	\$00
STTR Phase 2 (How many?)	\$00	\$00	\$00
Other Grants	\$00	\$00	\$00
Contracts	\$00	\$00	\$00
Other Federal	\$00	\$00	\$00
Other Public	\$00	\$00	\$00
Private Contracts	\$00	\$00	\$00
Private Foundations	\$00	\$00	\$00
Other Private Sources	\$00	\$00	\$00

BII.2 Capital Expenditures:

Capital Expenditures are costs incurred in the acquisition of assets used in the production of assistive technology-related capital plant and equipment. Please provide dollar amounts for the expenditures your firm *incurred* (whether paid in the year or in a subsequent year) in dollars for 1997 through 1999. For each year, indicate your sources (internal or external) for capital funding.

	1997	1998	1999 (est.)
TOTAL	\$00	\$00	\$00
Internally Funded	\$00	\$00	\$00
Externally Funded	\$00	\$00	\$00

BII.3 Sales by Region:

Please provide the sales by region for all assistive technology devices and equipment. Include all intracompany transfers/transports at their fair market value, reported in dollars.

	1997		-	1998	1999) (est.)
TOTAL SALES:	\$	00	\$.00	\$.00
United States	\$	00	\$.00	\$.00
Canada/Mexico	\$	00	\$.00	\$.00
Western Europe	\$	00	\$.00	\$.00
Eastern Europe	\$	00	\$.00	\$.00
South America	\$	00	\$.00	\$.00
Central America	\$	00	\$.00	\$.00
Middle East	\$	00	\$.00	\$.00
Asia/Pac. Rim	\$	00	\$.00	\$.00
Africa	\$	00	\$.00	\$.00
Australia	\$	00	\$.00	\$.00
Other	\$	00	\$.00	\$.00

Please provide your sales in units of assistive technology devices and equipment.

1997: _____ 1998: _____ 1999 (est.): _____

BII.4 Profitability

Please report your net income for all activities related to assistive technology.

1997: \$_____.00 **1998:** \$_____.00 **1999 (est.):** \$_____.00

What percentage of your firm's total net income is attributable to your assistive technology activities?

1997: ___% **1998:** ___% **1999 (est.):** ___%

FINAL REPORT. Would you like to receive a copy of the final report prepared in connection with this assessment?

⊐ Yes	🗖 No
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ADDITIONAL COMMENTS. If there are other issues not covered in this survey that you think are relevant to our analysis of this industry and that can assist your firm in becoming more competitive, please discuss them below. Thank you for your input.



Appendix G

Office of Strategic Industries & Economic Security
<u>Publications List</u>



Office of Strategic Industries and Economic Security STRATEGIC ANALYSIS DIVISION

PUBLICATIONS LIST March 17, 2003



are conducted on behalf of the U.S. Congress, the military services, industry associations, and other interested parties. The assessments are completed related industries and technologies. The studies are based on detailed industry-specific surveys used to collect information from U.S. companies and The U.S. Department of Commerce's Strategic Analysis Division is the focal point within the Department for conducting assessments of defensewith the assistance of industry experts both from the private sector and other government agencies. **Halice** indircte forthcoming studies

with the assistance of industry experts, both from the private sector and other government agencies. Inducate indicate forthcoming studies	orning siudies	
PUBLICATION TITLE	GPO ORDER #	PRICE
Industry Attitudes on Collaborating with DOD in R&D – Air Force – Fall 2003		
8th Offsets in Defense Trade - Conducted under Section 309 of the Defense Production Act of 1950 – Fall 2003		
National Security Assessment of the U.S. Shipbuilders' Supplier Base – Fall 2003		
Critical Technology Assessment of Biotechnology in U.S. Industry – Summer 2003		
National Security Assessment of the Munitions Power Sources Industry – Summer 2003		
National Security Assessment of the Air Delivery (Parachute) Industry – March 2003		
7th Offsets in Defense Trade - Conducted under Section 309 of the Defense Production Act of 1950- March 2003		
6th Offsets in Defense Trade - Conducted under Section 309 of the Defense Production Act of 1950- February 2003		
Technology Assessment: Assistive Technology – February 2003		
The Effect of Imports of Iron Ore and Semi-Finished Steel on the National Security – October 2001		
National Security Assessment of the U.S. High-Performance Explosives & Components Sector –June 2001	003-009-00714-3	\$22.00
National Security Assessment of the U.S. Shipbuilding and Repair Industry- May 2001	003-009-00719-4	\$22.00
Statistical Handbook of the Ball and Roller Bearing Industry (Update) - June 2001	Available on SAD Website	Vebsite
5 th Offsets in Defense Trade - Conducted under Section 309 of the Defense Production Act of 1950-May 2001	003-009-00722-4	
National Security Assessment of the Cartridge and Propellant Actuated Device Industry: Update - Dec. 2000	003-009-00710-1	
The Effect on the National Security of Imports of Crude Oil and Refined Petroleum Products-November 1999	003-009-00723-2	
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