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Medical Goods

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UNITED STATES INTERNATIONAL TRADE COMMISSION

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PREFACE

In 1991 the United States International Trade Commission initiated its current *Industry and Trade Summary* series of informational reports on the thousands of products imported into and exported from the United States. Each summary addresses a different commodity/industry area and contains information on product uses, U.S. and foreign producers, and customs treatment. Also included is an analysis of the basic factors affecting trends in consumption, production, and trade of the commodity, as well as those bearing on the competitiveness of U.S. industries in domestic and foreign markets.[1]

This report on medical goods covers the period 1988 through 1992 and represents one of approximately 250-300 individual reports to be produced in this series during the first half of the 1990s. Listed below are the individual summary reports published to date on the electronic and technology sector.

USITC publication number	*Publication date*	*Title*
2445	January 1992	Television Receivers and Video Monitors
2648	July 1993	Measuring, testing, controlling, and analyzing instruments
2674	September 1993	Medical goods

[1] The information and analysis provided in this report are for the purpose of this report only. Nothing in this report should be construed to indicate how the Commission would find in an investigation conducted under statutory authority covering the same or similar subject matter.

CONTENTS

CONTENTS—*Continued*

INTRODUCTION

The medical goods industry manufactures a broad range of products used in the professional practice of medicine, dentistry, and veterinary science for the prevention, diagnosis, and treatment of diseases and injuries, and the correction of physical deformities of the body. Such medical goods range from fairly homogenous, commodity-type items, such as tongue depressors, syringes, and needles, to sophisticated electromedical monitoring and scanning equipment. This report discusses key aspects of the global medical goods industry during 1988-92. Included are discussions of the U.S. and foreign industries, U.S. and foreign markets, U.S. and foreign trade measures, and U.S. industry performance in domestic and foreign markets.

The equipment covered in this summary is classified in Harmonized Tariff Schedule of the United States (HTS) headings 9018-9022. The medical goods covered under those headings may be grouped into three broad industry subgroups: (1) medical, surgical, dental, and veterinary instruments and appliances; (2) orthopedic and prosthetic appliances and devices; and (3) x-ray and other electromedical instruments, appliances, and apparatus. Not included are hospital furniture, such as beds and examining tables; wheelchairs; analytical instruments and chemical tests used in medical laboratories; and many commodity hospital supplies made from textile and latex materials, including surgical drapes, bandages, gauze, sutures, and surgical gloves. Each of the three major categories of medical goods accounted for roughly equivalent portions of total U.S. shipments in 1992. However, x-ray and other electromedical equipment accounted for, by far, the largest portion of U.S. trade in medical equipment.

Medical, surgical, dental, and veterinary instruments represent most of the nonelectronic hand tools and instruments used by physicians and surgeons in the many and varied operations performed on the human body. Such instruments include surgical knives, forceps, probes, saws, stapling devices, bone drills, and microsurgical tools. Also included are hypodermic syringes, needles, catheters, blood pressure apparatus, stethoscopes, endoscopes, percussion hammers, mechanotherapy appliances and massage apparatus, inhalation therapy equipment, blood and intravenous (IV) transfusion equipment, physicians' diagnostic apparatus, certain hemodialysis apparatus, eye-examining equipment and other ophthalmic instruments and apparatus, and veterinarians' instruments and apparatus.

Orthopedic, prosthetic, and surgical appliances are articles used primarily to correct certain deficiencies of the human body. Orthopedic appliances are employed primarily to prevent or correct deformities of the body while prosthetic devices are used to replace defective parts of the body. These articles include orthopedic braces, cervical collars, splints, abdominal supporters, trusses, fracture appliances, traction apparatus, artificial limbs and joints, surgical implants, hearing aids, oxygen respiratory equipment, and respiratory protection equipment.

X-ray and other electromedical apparatus includes all types of radiation, electrodiagnostic, and electrotherapeutic equipment. Included are radiographic x-ray apparatus and tubes, therapeutic x-ray apparatus, radium equipment, beta-ray and gamma ray irradiation equipment, computerized tomography (CT) scanners, positron emission tomographic (PET) scanners, magnetic resonance imaging devices (MRI), ultrasonic imaging and therapeutic devices, electrocardiographs, electroencephalographs, complete patient monitoring systems, electromedical (fiber-optic) endoscopic apparatus, electromedical dialyzers, heart pacemakers, defibrillators, and electrosurgical devices, including medical lasers.

Advances in technology have affected devices in all three categories of medical goods. Many of these advances have resulted in less expensive procedures that can be performed on an outpatient basis rather than in a traditional hospital setting. Some of the most recent developments include—

Angioplastic catheters that enable cardiovascular specialists to open blocked arteries by inflating a balloon at the end of the device after snaking it up into the heart area from a vein in the leg or arm. These devices have obviated the need for many persons to undergo much more expensive and invasive heart-by-pass surgeries.

Arthroscopic instruments utilizing microscopic fiber-optic endoscopic devices and tools for conducting knee and other joint surgeries. These techniques, which can be done on an outpatient basis, have replaced more invasive surgeries that required hospital rehabilitation.

Orthopedic implants, such as artificial hips, made from advanced polymer composite materials that reduce pain and improve patient mobility.

Extracorporeal shockwave lithotripsy, a nonsurgical technology for disintegrating kidney stones.

Medical diagnostic imaging technologies, such as CT scanning, MRI, ultrasound, and fiber-optic endoscopy, which have enhanced the ability of physicians to identify disease processes early and locate them accurately, improving on traditional x-ray technologies.

Complete patient monitoring systems that automate many patient chart functions in addition to monitoring critical bodily functions, such as temperature, blood pressure, and pulse. The newest systems can interface other manufacturers' devices to the bedside monitor.

Medical laser systems used to achieve major surgical effects of cutting, coagulating, and vaporizing, in a minimally invasive manner. Laser techniques are now commonly used in ophthalmic, urological, gynecological, and

orthopedic procedures, and currently are being tested for possible use in cardiovascular surgeries to remove plaque from arteries.

Metals and plastics make up a large portion of the materials used in the manufacture of medical, surgical, dental, and veterinary instruments as well as orthopedic and prosthetic appliances. Production of many of the components and housings used in these medical devices consists of injection molding and drawing processes that employ automated manufacturing techniques. However, the final assembly of these medical goods can range from fairly labor-intensive assembly and packaging processes to highly capital-intensive techniques using advanced robotics. The manufacture of orthopedic and prosthetic equipment generally continues to call for the most labor-intensive processes, but computer-assisted design and manufacturing (CAD/CAM) processes used with advanced composite materials are used increasingly to produce custom-manufactured prosthetic devices.

Microelectronics and steel constitute the major components and materials used in the highly capital-intensive electromedical segment of the medical goods industry. Much of the manufacturing of eletromedical systems consists of inserting and configuring electronic components, such as semiconductors, on circuit boards. The most advanced companies have replaced many labor-intensive circuit assembly processes with automatic insertion operations, which has enabled them to put more components on the circuit boards more quickly and accurately than before. After the electromedical circuitry is completed, it undergoes comprehensive testing to satisfy both company and regulatory quality assurance requirements.

The major consumers of medical goods are hospitals, physicians, alternate care sites, and home health-care providers. Other customers for medical goods include dentists, optometrists, nursing homes, and government. Hospitals continue to constitute the largest market for medical goods, accounting for almost 40 percent of total purchases. However, efforts by government and private insurers to contain escalating hospital costs have resulted in growing opportunities for sales of medical equipment to customers outside of the hospital setting. These growing markets include independent and group medical practices, health maintenance organizations (HMOs) and other managed-care centers, surgicenters, medical imaging centers, and other alternate care sites. Although still constituting a relatively small portion of all U.S. health-care expenditures, the home-health care market has been growing at an annual rate of about 20 percent over the past 5 years.

U.S. INDUSTRY PROFILE

Industry Structure

Industry Sectors

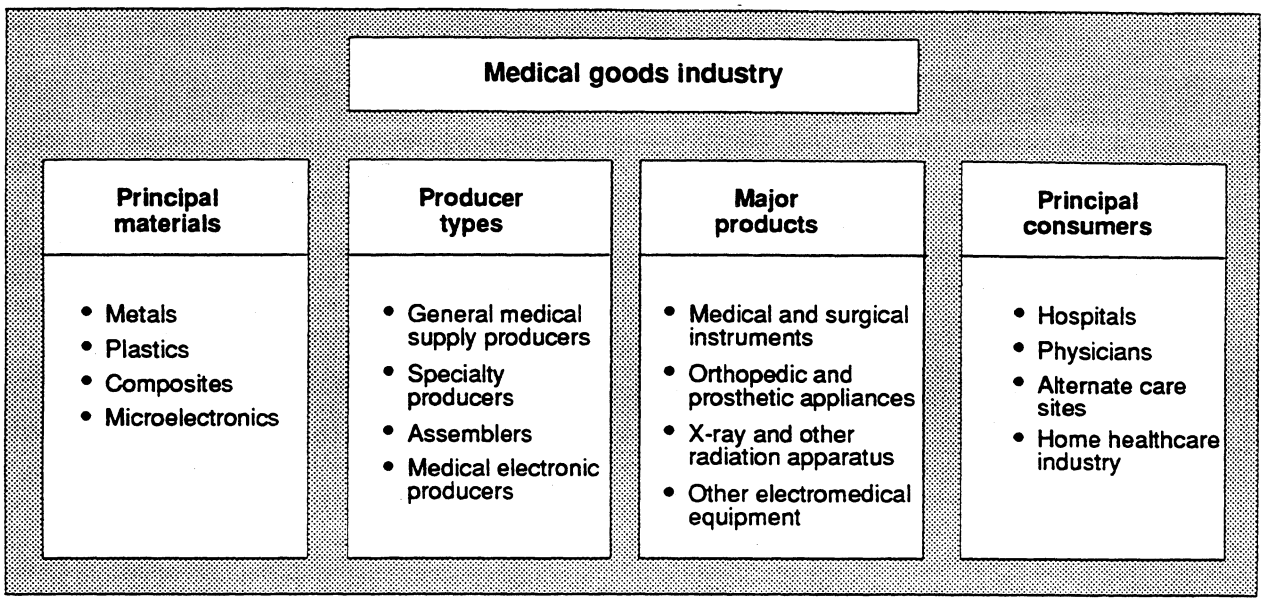
Standard Industrial Classification (SIC) categories for medical goods are surgical and medical instruments (SIC 3841 part), surgical appliances and supplies (SIC 3842 part), dental equipment and supplies (SIC 3843), x-ray apparatus and tubes (SIC 3844), and electromedical equipment (SIC 3845). Orthopedic and prosthetic appliances and devices are classified as surgical appliances under SIC 3842. Figure 1 illustrates the structure of the U.S. medical goods industry, including the principal materials and components used in production, the major producer types, the major products, and the principal consumers of medical goods. Figure 2 lists major U.S. producers of medical goods.

In 1992, there were an estimated 2,775 firms producing medical instruments and other apparatus in the United States, employing over 171,050 workers. The most concentrated sector of the industry was the electromedical and x-ray apparatus sector, where it is estimated that 65 percent of the shipments of the sector was accounted for by the top five firms. Total employment of the 225 firms constituting this sector amounted to 45,050 in 1992. This was also the most capital-intensive sector of the industry; production workers accounted for less than one-half of total employees in 1992. This was the lowest percentage among the different medical manufacturing groups, reflecting the large amount of scientific and technological expertise required for product design and product engineering. Most producers of x-ray and electromedical apparatus were concentrated in the Midwest, though a significant number of manufacturers were in the Northeast and Northwest, where large pools of employees skilled in electronics resided.

Less concentrated was the sector of the U.S. medical goods industry that manufactured medical, dental, surgical, and veterinary instruments and where the top eight firms accounted for less than one-half of total sector shipments in 1992. There were an estimated 1,550 establishments employing 64,000 employees in the surgical and medical instrument sector in that year. Production workers made up about two-thirds of the work force, making this a more labor-intensive sector than the electromedical segment of the industry. The principal locations for medical, dental, surgical, and veterinary instrument producers were the Middle Atlantic and Pacific Coast States, with particular concentrations in California, New York, and Illinois due to the proximity to important hospital and physician markets.

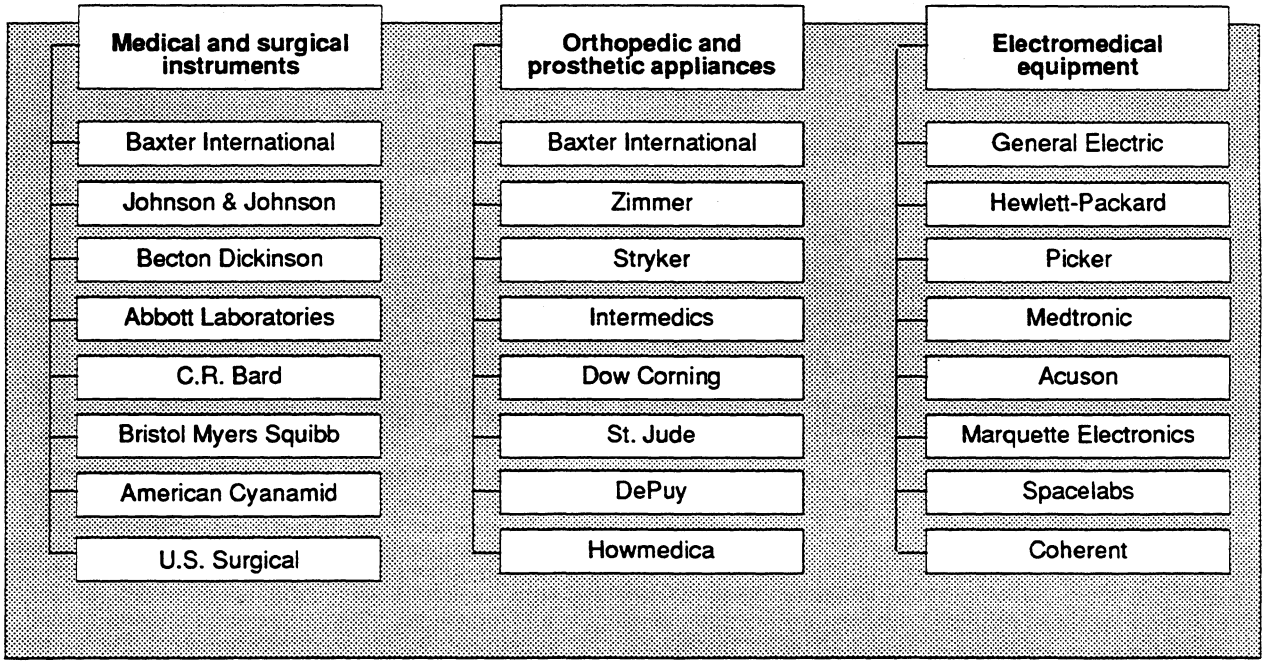
An estimated 1,000 establishments, employing about 62,000 workers, produced orthopedic, prosthetic, and surgical appliances and supplies in 1992. This sector of the industry was also less concentrated than the electromedical and x-ray sector, with about eight firms accounting for about one-half of total sector shipments in that year. The manufacture of most of the products in this sector is a labor-intensive process that requires semiskilled workers. Production workers accounted for about 65 percent of the workforce in 1992.

Figure 1
U.S. medical goods industry: Principal materials, producer types, major products, and principal consumers



Source: Staff of the U.S. International Trade Commission.

Figure 2
Major U.S. producers of medical goods



Source: Staff of the U.S. International Trade Commission.

Internationalization

The U.S. industry is highly integrated with foreign manufacturers of medical equipment. In 1982, U.S.-based General Electric Medical Systems (GE), the largest producer of medical imaging equipment in the world, established a joint venture with Yokogawa Electric Corp. to produce CT scanners, MRI devices, and ultrasound equipment in Japan. In 1987, GE acquired the worldwide manufacturing facilities of French-based Thomson CGR. GE currently supplements its U.S. production with imports of equipment manufactured in its overseas production facilities. Baxter International, Inc., of Deerfield, IL, the world's largest producer of general medical and surgical equipment and supplies, is also highly integrated with foreign contractors and assemblers, particularly in low-wage countries, such as Singapore, Mexico, and the Dominican Republic. Other U.S.-based firms possessing a significant degree of integration or arrangements with foreign-based firms or contractors include Hewlett-Packard Co., Abbott Laboratories, Coherent Inc., Spectra-Physics Inc., Johnson & Johnson, Diasonics, C.R. Bard Inc., Medtronic Inc., and Cordis Corp.

During the past decade, an increasing number of foreign-based companies became involved in the U.S. medical goods industry, primarily by acquiring U.S.-based, high-technology firms or by establishing manufacturing operations in the United States. The General Electric Corp.[1] of the United Kingdom (GEC) was one of the first major investors in the U.S. market in the early 1980s when it acquired Picker International Inc., of Cleveland, OH, one of the largest producers of x-ray and medical imaging equipment in the world. Siemens of Germany has acquired several U.S. companies, and now supplements its imports of x-ray and electromedical equipment into the U.S. market with U.S. manufactures of products ranging from hearing aids and pacemakers to digital subtraction angiographic radiographic units. Several other German manufacturers have acquired U.S. medical laser firms. Japanese-based Terumo Medical Corp. has established new production facilities near Columbia, MD where it manufactures blood collection needles, catheters, and insulin syringes to supplement imports of related devices from its Japanese-based facilities. Electromedical producers Hitachi and Toshiba have also invested in the U.S. market. Other foreign investors in the U.S. market include Philips Medical Systems (the Netherlands), Danavox (Denmark), Matsushita (Japan), and Elscint (Israel).

Marketing

As cost containment pressures on hospitals and other health providers have increased, there has been a trend toward greater concentration in purchasing and marketing medical goods in the U.S. market, particularly everyday hospital equipment and supplies. Hospitals have established group purchasing organizations that negotiate price concessions for large-scale purchasing contracts with major suppliers. Companies such as Baxter International, Abbott Laboratories, and Johnson and Johnson, in addition to supplying hospitals and other health care institutions with their own manufactured goods, serve as distributors for a range of small and medium-sized medical goods suppliers that previously marketed their products directly. In some instances, these large hospital and medical supply companies carry products directly competitive with their own line of manufactured products in order to procure an exclusive long-term contract. Some of these major suppliers of medical goods maintain comprehensive warehousing facilities throughout the country and provide their customers with computerized inventory management services. These services and facilities enable the large suppliers to provide just-in-time delivery of required products to their customers.

Large producers of expensive electromedical equipment continue to sell directly to hospitals and other health-care purchasing groups. Unlike suppliers of commodity medical and hospital equipment and supplies, producers of medical electronic equipment must often provide extensive sales, financing, and service support to major customers of their advanced-technology products and cannot depend on distributors to perform these functions for them. Major medical electronics producers such as GE, Picker, Medtronic, Acuson, ATL, and Coherent all sell directly to large hospital and group purchasing organizations.

Research & Development

U.S. medical goods companies have spent an average of about 6 percent of their total sales revenues on research and development (R&D) in recent years, about twice the average of U.S. manufacturers as a whole. Less is spent for development of day-to-day hospital consumables but an average of 10-12 percent is expended for developing high-technology electromedical products.[2] In general, however, the largest portion of the corporate R&D budget is focused on development rather than on basic research.[3] One major expert on research in the medical device industry believes that innovation in the medical device industry, unlike in the pharmaceutical industry, is often "based on engineering problem solving, and it is often incremental rather than radical. Innovation seldom depends on the results of long-term research in the basic sciences, and generally it does not reflect the recent generation of fundamental new knowledge."[4]

[1] Not related to the U.S.-based GE.

[2] Interviews with officials of U.S. electromedical producers during 1990-93, analysis of company annual reports, and "R&D Scoreboard," *Business Week*, June 28, 1993.

[3] Alan Kahn, "The Dynamics of Medical Device Innovation: An Innovator's Perspective," *The Changing Economics of Medical Technology*. Edited by A. C. Gelijns and E. A. Halm. (Washington, DC: National Academy Press, 1991), pp. 89-95.

[4] Edward D. Roberts, "Technological Innovation and Medical Devices," *New Medical Devices: Invention, Development, and Use*. Edited by Karen B. Ekelman (Washington, DC: National Academy Press, 1988), pp 35-47.

Although U.S. medical device manufacturers do not engage extensively in basic research, the development of medical devices usually depends on the broad base of biomedical knowledge that often is developed by public funds.[5] For example, in the early 1970s researchers recognized that MRI could provide advantages over traditional ionizing radiation used in x-ray systems by using radiowaves and powerful magnetic fields and had the potential to provide excellent soft tissue contrasts. These advantages, they believed, could lead to earlier detection of diseases and noninvasive diagnoses of pathological conditions. However, the high cost of magnetic resonance and difficult logistics of installing such large devices served as barriers of entry into this potentially lucrative market.

To support continued work in the MRI area, the Federal Government through its National Institutes of Health (NIH) supported research on MRI, biomedical application of MRI parameters, and biomedical application of magnetic resonance spectroscopy. In addition, the National Cancer Institute, the National Heart, Lung, and Blood Institute, and National Academy of Sciences also funded a number of MRI-related intramural and extramural projects. The effect of all of this Federal support over the decade of the 1970s was to provide a foundation that permitted industry to fund research on MRI applications. Presently, MRI is well accepted in the medical industry, and U.S. firms such as GE, Varian, Fonar, and Advanced NMR systems are world renowned for their products. Other technologies that have benefited from Federal support for basic research include patient-monitoring systems, kidney dialysis, cardiovascular devices, CT scanning, ultrasound, and laser surgeries.

NIH, the principal U.S. Government agency responsible for support of biomedical research, has an overall budget of over $7 billion per year.[6] As illustrated above such research investment creates a source of new scientific knowledge that creates opportunities for the development of new medical devices. However, investment in the fundamental areas of biomedical engineering constitutes only about 1 percent of the NIH budget. Due to increased competition for limited research dollars in recent years, NIH and other government agencies involved in biomedical research have begun to shift from using research grants as a form of direct investment in new medical technologies to using grants to procure new products. In the early 1980s, the Federal Government established the Small Business Innovation Research (SBIR) program. In 1983, NIH expended $7.3 million in the SBIR program. An analysis conducted by the Office of Technology Assessment of the U.S. Congress showed that approximately 40 percent of NIH's SBIR awards supported medical device applications.[7]

Regulation

One of the most important factors affecting production and development costs in the U.S. medical goods industry is regulation of medical devices by the U.S. Food and Drug Administration (FDA). The Medical Device Amendments to the U.S. Food and Drug Law (Public Law 94-295) in 1976 consolidated and expanded existing Federal authority over medical devices into a system of regulating the safety and effectiveness of medical devices in proportion to the degree of risk that they presented.[8] Prior to 1976, the FDA could impose premarket approval requirements only on a limited number of devices that could legally be considered new drugs. Under the new law, all new devices were categorized by the FDA, by type, into three regulatory classes reflecting their potential risk:

Class I—general controls,

Class II—performance standards, and

Class III—premarket approval.

Class I encompasses devices for which general controls authorized by the act were deemed sufficient to provide reasonable assurances of safety and effectiveness. Tongue depressors and other common medical and surgical instruments and supplies are examples of products fitting into this category. Manufacturers of class I and all other devices are required to register their establishments and list their devices with FDA, notify the agency at least 90 days before they intend to market their devices, and conform to good manufacturing practices (GMP). GMP apply to the manufacturing, packing, storage, and installation of devices.

Class II (performance standards) pertains to devices for which general controls are considered insufficient to ensure safety and effectiveness and for which information exists to establish performance standards. X-ray devices are an example of medical goods intended for this category.

Class III applies to devices that support life, prevent health impairment, or present a potentially unreasonable risk of illness or injury and for which general controls are insufficient to ensure safety and efficacy and for which information does not exist to establish a performance standard. Cardiac pacemakers and many other implantable devices are classified under this category. For a new class III device that is not substantially equivalent to a device already in use prior to 1976, information has to be provided to FDA to document its safety and effectiveness before marketing approval is granted.

FDA regulation of medical devices is currently undergoing significant changes as a result of the Safe Medical Devices Act of 1990 (SMDA).[9] The law

[5] Leo J. Thomas, Jr., "Federal Support of Medical Device Innovation," *New Medical Devices: Invention, Development, and Use.* Edited by Karen B. Ekelman (Washington, DC: National Academy Press, 1988), pp. 51-71.

[6] National Institutes of Health, Division of Research Grants.

[7] Thomas, "Federal Support."

[8] U.S. Congress Office of Technology Assessment, *Federal Policies and the Medical Devices Industry* (Washington, DC: U.S. Government Printing Office, Oct. 1984), pp. 97-136.

[9] Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511.

established new requirements for manufacturers to ensure that products entering the market are safe and effective, especially in the areas of premarket approval and postmarket surveillance. Premarket notification applications for some types of medical equipment now must include a summary of safety and effectiveness data. The law also requires manufacturers to conduct postmarket surveillance for high-risk devices introduced after 1990, to track the distribution and end uses for certain devices. Furthermore, it requires hospitals and other end users to report deaths associated with faulty medical devices. Finally, manufacturers that are not in full compliance with specified good manufacturer practices may now face civil penalties, recalls, or cessation of shipments.

Federal regulation in the medical goods industry has significantly increased costs of producers, who must generate and maintain substantial records concerning their products and activities. Some industry analysts believe that increased regulation has adversely affected innovation in the medical device industry.[10] A study of innovations in x-ray technology showed that increased FDA regulations led to decreased innovation of x-ray devices, particularly by smaller firms.[11] Another study completed in 1987 showed a dramatic decrease in the rate of new product introduction by young medical goods producers.[12] However, other analysts and officials believe that high standards have resulted in an increase in global competitiveness of the U.S. medical goods industry, pointing to the continued success of U.S. products in overseas markets.[13]

Consumer Characteristics and Factors Affecting Demand

Aggregate health care expenditures traditionally have been a major determinant of demand for medical equipment. The United States historically has outspent its major rivals by a large margin on health and medical care (figure 3) and has accounted for almost one-half of total world consumption of medical equipment (figure 4). The medical goods industry experienced a large growth in demand after enactment of the Medicare program.[14] From 1966, when the program was started, until 1982, hospitals were paid their "usual and customary" costs for providing hospital care. Backed by such a generous system of payment, hospitals increased their expenditures rapidly during the period, at rates well above inflation, expanding their services and bringing in new employees and equipment to provide those services.[15] The proliferation of similarly cost-based private and nonprofit plans for employees not covered by the Medicare programs also contributed to an increase in medical expenditures and in the demand for medical equipment during the period.

Physicians serving as department heads in hospitals traditionally were responsible for most purchasing decisions related to medical equipment in the United States. Typically the doctors would make their decisions based on technological and quality considerations rather than on the basis of cost. This practice was reinforced with the establishment of the Medicare program and on the proliferation of cost-based employee health insurance programs in the 1960s. Because hospitals were responsible for up to one-half of total purchases of medical equipment, most medical goods producers directed their marketing efforts to surgeons, radiologists, cardiologists and other specialists heading departments in hospitals. Independent physicians and physician groups were the next most important market for medical equipment.

With health care expenditures contributing to a rapidly growing Federal deficit, Congress approved legislation in 1983 changing the manner in which Medicare reimbursed expenditures for hospital care. The following year, a prospective payment plan was instituted to replace the old cost-based system. Under the new plan, rates of reimbursement were set in advance of the period to which they applied. The prospective rates were set for 467 diagnosis-related groups (i.e., groups of patients with similar conditions). Developed from costs historically associated with treatment for each condition, the rates for the groups would cover all hospital operating costs.[16] Under the new system, the rates constituted payment in full to the hospital. Hospitals could keep any profits but would have to absorb any losses.

After adoption of the new Medicare prospective payment system, hospitals became much more cost-conscious in their purchases of medical devices, and the market for such equipment has consequently become more price-sensitive. Although expenditures on equipment continue to grow, the growth is much slower than the double-digit growth characteristic of the 1966-83 period. Decisions on the purchases of medical devices are now being based on cost-effectiveness criteria rather than solely on the basis of physicians' perception of quality or preferences for particular devices. Many producers of medical goods have struggled to adapt to price pressures in the now price-sensitive market for medical equipment. Much of the price pressure comes from

[10] Roberts, "Technological Innovation," .

[11] P.H. Birnbaum, "The choice of strategic alternatives under increasing regulation in high technology companies," *Academy of Management Journal*, Sept. 1991, pp. 489-510.

[12] E.B. Roberts and O. Hauptman, "FDA regulation of product risk and its impact upon young biomedical firms," *Journal of Product Innovation Management*, Apr. 1992, pp. 138-148.

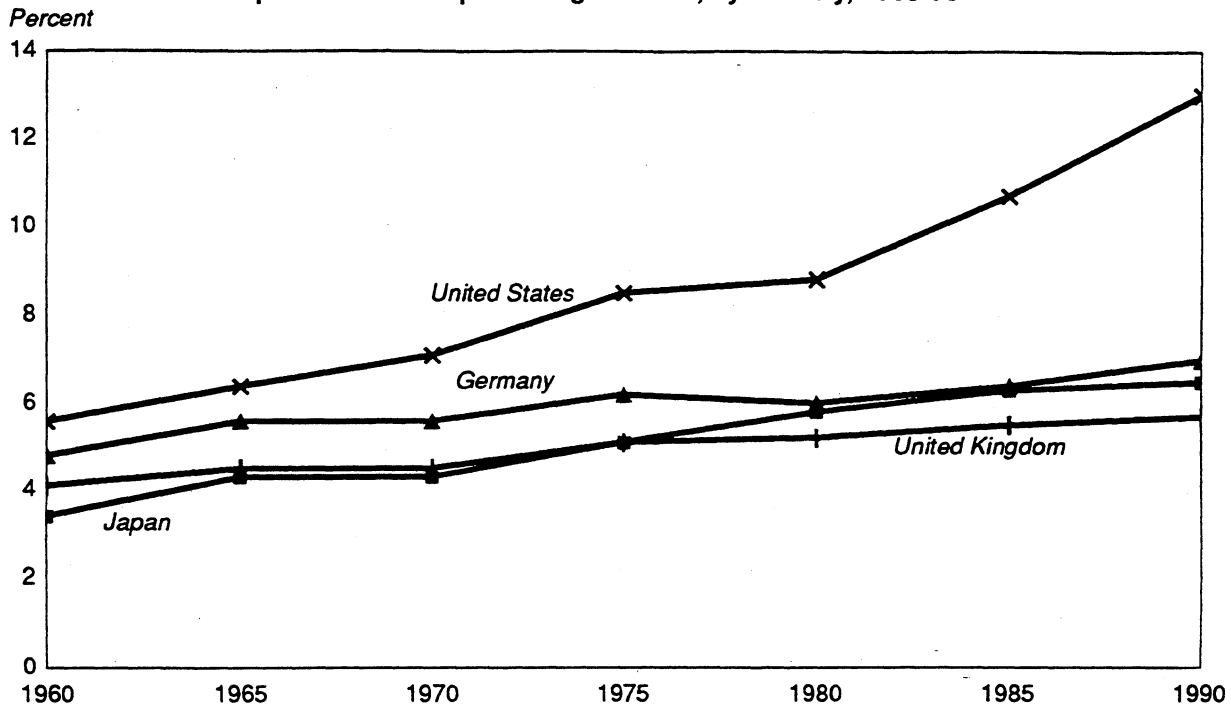
[13] Frank E. Samuel, "The Perspective of the Medical Device Industry: Ten Stages in the Innovation of Medical Devices," *New Medical Devices: Invention, Development, and Use*. Edited by Karen B. Ekelman (Washington, D.C.: National Academy Press, 1988), pp. 145-150; and "Face to Face with FDA: An Interview with David A. Kessler, MD," *Medical Device & Diagnostic Industry*, June 1992, pp. 36-40.

[14] Medicare is the Federal program that helps pay hospital and doctors' bills of the elderly, the disabled, and those with end-stage kidney disease.

[15] Louise B. Russell, *Technology in Hospitals: Medical Advances and Their Diffusion* (Washington, DC: The Brookings Institution, 1979).

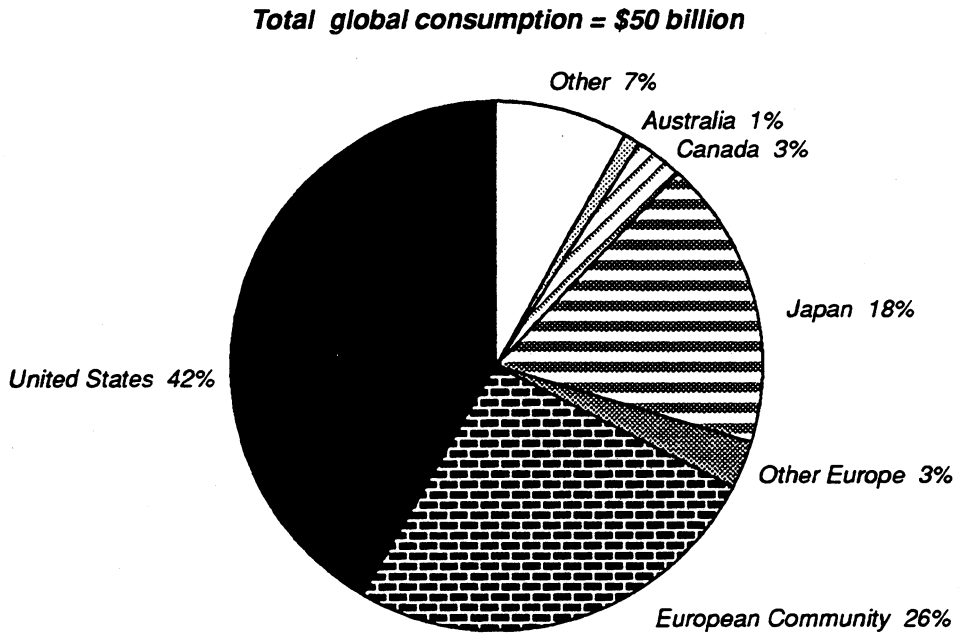
[16] Louis B. Russell, *Medicare's New Hospital Payment System: Is it Working?*, (Washington, DC: The Brookings Institution, 1989), p. 2.

Figure 3
Total health-care expenditures as a percentage of GDP, by country, 1960-90



Source: Compiled from OECD statistics.

Figure 4
Global consumption of medical goods, 1992



Source: Estimated by staff of the U.S. International Trade Commission based on official statistics of the U.S. Department of Commerce and on information from the Health Industry Manufacturers Association.

hospital materials managers and administrators, who have an increasingly important role in buying decisions, an area that used to be the domain of the surgeon or operating room supervisor.

Prospective payment has also changed the way care is given to elderly patients, causing a shift away from inpatient hospital care and toward other kinds of care. Hospitals, now facing indirect competition from alternate-site surgery centers, diagnostic imaging facilities, and other specialty facilities, are establishing their own alternate-site facilities. About 48 percent of all surgical procedures in 1990 were performed on an outpatient basis, up from 25 percent in 1984.[17] This percentage is expected to continue to expand as hospitals increase their investment in their own outpatient programs. Home health care has also benefited from new Government and private insurance policies encouraging care outside the hospital. Today, home health care represents the most rapidly growing market for medical goods. Skilled nursing facilities, adult day care, and rehabilitation-related services are also growing in importance as markets for medical equipment. Analysts project annual growth of 17 percent or more in the dollar value of rehabilitation-related services.[18]

Despite the somewhat slower growth in the more price-sensitive U.S. market for medical equipment, three other trends have somewhat ameliorated the adverse effect for U.S. medical goods producers. First, an aging population in the United States has required an increased number of surgical procedures. More than 32 percent of all surgical and medical procedures are performed on persons 65 years old or older.[19] That group now makes up 12 percent of the population and will continue to expand as the "baby boomers" age. Second, certain new procedures that have proven to be more cost-effective than traditional treatments, such as ultrasound, laser surgery, angioplasty and arthroscopy, have increased the demand for selected new high-technology devices. Third, demand for U.S.-made equipment in overseas markets has grown considerably in the past several years due to the weakened U.S. dollar and concerted efforts by a number of foreign governments to improve the health care infrastructure of their countries.

FOREIGN INDUSTRY PROFILE

Japanese and German firms are the most important competitors to the U.S. medical industry. The structures of the medical goods industries in Japan and Germany are similar to that in the United States. However, the Japanese industry is more specialized in producing electronic, x-ray, and optically based medical equipment, while Germany has a more broadly based industry that, in addition to manufacturing high-technology electronic and x-ray apparatus, is known for highly specialized precision medical and surgical instruments.

Other significant producing countries include France, the United Kingdom, the Netherlands, and Switzerland. While the United Kingdom possesses a fairly diversified medical goods industry, France and the Netherlands are predominantly involved in the manufacture of high-technology electronic and x-ray apparatus and equipment for export. The Swiss industry specializes in the manufacture of high-precision medical, surgical, and dental instruments.

Subsidiaries of U.S.-based medical goods manufacturers are responsible for a significant portion of the European manufacture of medical devices and instruments. A number of large U.S. firms, such as Hewlett Packard, Beckman Instruments, Varian, Litton, Baxter, Abbott, Puritan, General Electric, and Medtronic, have established manufacturing facilities in one or more EC countries to supply those markets as well as other third-country markets in Europe.

All of the major foreign producers of medical goods are very export oriented.[20] Germany, France, and the Netherlands all export more than one-half of their total production of such goods. The greatest portion of such exports consists of electromedical equipment and apparatus. Major European-based producers include Siemens and Electromedizin of Germany, ELA and ALA of France, and Philips of the Netherlands.

Although the larger size of Japan's market enables that country to absorb a greater share of its own domestic manufactures of medical equipment, 50 percent of Japan's production of electromedical equipment was exported in 1991.[21] Major Japanese producers of medical equipment include Toshiba, Hitachi, Yokogawa Medical Systems, Olympus, and Terumo.

French and Japanese producers have benefited more than other foreign producers from government policies promoting the manufacture and exportation of medical goods, particularly high-technology electromedical goods. French companies have been assisted by French Government trade and procurement policies to promote the development of an advanced electronics industrial base. Major Japanese electronics conglomerates, such as Toshiba and Hitachi, were encouraged to enter the high-value electronic imaging industry by the Ministry of International Trade and Industry through various tax incentives and research and development assistance in the 1970s and 80s.

In 1991, Japan's Ministry of Health and Welfare (MHW) initiated a commercial venture between Terumo, a Japanese medical device company, Yuasa Battery Company, and NTT Electronics, a telecommunications company to develop a clinical prototype of Japan's first cardiac pacemaker. The Ministry confirmed to U.S. Government officials in March that it had provided 30 million yen

[17] "Hospital high-tech spending lowers reserves," *Health Industry Today*, Nov. 1990, p. 14.

[18] "Slow growth, tight margins expected for '92," *Health Industry Today*, Mar. 1992, p. 21.

[19] "Price pressure slows instrument revenues," *Health Industry Today*, Feb. 1991, pp. 14-15.

[20] Health Industry Manufacturers Association, *The Global Medical Device Market Report*, 1992.

[21] Electronics Industries Association of Japan, letter dated Aug. 5, 1993.

(approximately $230,000) from MHW's special industrial investment account to invest in a 70-percent share of the capitalization of the project.[22] U.S. Embassy officials in Tokyo report that by providing substantial funding to the Japanese pacemaker project, the Japanese Government will enable Japanese companies to enter the market with little risk to compete with more established U.S. and German suppliers, such as Medtronic and Siemens.

Lesser developed countries, such as Mexico, the Dominican Republic, and Singapore, have benefited from increased price sensitivity in U.S. and other global medical goods markets to develop labor-intensive industries specializing in the manufacture of commodity medical and surgical items, such as catheters, needles, and intravenous and blood administration sets, and for final assembly of more advanced medical equipment from U.S. and Japanese-made components. A growing number of U.S. and Japanese firms have aided this development by establishing overseas operations in these countries to save on production costs.

U.S. TRADE MEASURES

Tariff Measures

General column 1 rates of duty for imports of medical goods range from a low of 2.1 percent ad valorem for medical x-ray apparatus[23] to a high of 10 percent for ophthalmic and optical instruments and appliances used in medical science.[24] However, the majority of medical instruments, appliances, and apparatus have rates falling in the 4- to 6.4-percent ad valorem tariff range. Imports of medical goods entered the United States duty free during 1988-92 from eligible countries under the Generalized System of Preferences (GSP), the Caribbean Basin Economic Recovery Act (CBERA), and the United States-Israel Free-Trade Area Implementation Act; and under reduced tariffs under HTS subheadings 9802.00.60 and 9802.00.80.

All of the medical goods covered in this summary are included in the United States-Canada Free-Trade Agreement (FTA) and are currently subject to gradual duty reductions or have been granted duty-free status under provisions of that agreement. Several products have been granted duty-free status under the Automotive Products Trade Act or the Agreement on Trade in Civil Aircraft. Table 1 presents individual tariff rates for products covered in this summary.

The North American Free Trade Agreement (NAFTA)[25] incorporates on a trilateral basis most of the provisions of the existing U.S.-Canada FTA, and in most instances expands upon those provisions.[26] The primary NAFTA provisions affecting U.S.-Mexican trade include the removal of tariffs. U.S. imports of medical goods from Mexico would enter the United States duty-free beginning January 1, 1994, if the agreement is enacted. Customs duties on Mexican imports of some medical goods from the United States will be removed in either five equal annual stages or ten equal annual stages beginning in Janaury 1, 1994. All others will be removed beginning January 1, 1994, under terms of the proposed agreement. It is believed tha the U.S. medical goods industry will not be adversely impacted by NAFTA. The United States, which is the leading supplier of medical goods to Mexico, is expected to retain this position in the foreseeable future.

There are no known nontariff measures to trade in medical goods in the United States.

Nontariff Measures

Foreign manufacturers consider the United States and France to have the toughest regulatory requirements in the world for gaining approval to sell medical devices. However, FDA requirements are not discriminatory and apply equally to domestic and foreign-made medical equipment. Some U.S. manufacturers believe that FDA regulations are more burdensome for domestic manufacturers and that they result in a loss of competitiveness for U.S. producers in global markets. They point to regulations that make it difficult for U.S. producers to export devices that have not been approved for sale in the United States. Foreign producers in Europe and Japan, reportedly, are not similarly inhibited by regulators in their own countries.

FOREIGN TRADE MEASURES

Tariff Measures

Tariffs do not generally serve as a barrier to trade in the principal foreign markets for U.S. exports of medical goods. Duties are slightly lower on average than in the United States in most overseas markets due to the historical dependence of many countries on U.S. imports for significant portions of their domestic requirements for medical goods. In the European Community (EC), the most-favored-nation (MFN) rates of duty for medical goods range from a low of 3.8 percent ad valorem for hearing aids and parts to a high of 6.2 percent for artificial joints and several other orthopedic and prosthetic appliances. The majority of other medical goods range fall in the 4.6 to 5.3 percent range.

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[22] U.S. Department of State, unclassified telegram (Tokyo), Apr. 30, 1992.

[23] Underwater breathing devices, which are not technically medical devices, but are included in this summary with other therapeutic and nontherapeutic oxygen therapy, respiratory, and other breathing devices, have a column 1 rate of duty of zero.

[24] Refer to appendix A for an explanation of tariff and trade agreement terms.

[25] NAFTA was signed by the heads of state of the United States, Canada, and Mexico, on December 17, 1992, and is scheduled to be in effect on January 1, 1994, subject to the approval by the legislative branches of the three countries.

[26] USITC, Potential Impact on the U.S. Economy and Selected Industries of the North American Free-Trade Agreement, USITC publication 2596, Jan. 1992, p. vii.

Table 1
Medical goods: HTS subheading; description; U.S. col. 1 rate of duty as of Jan. 1, 1993; U.S. exports, 1992; and U.S. imports, 1992

HTS subheading	Description	Col. 1 rate of duty As of Jan. 1, 1993 General	Special[1]	U.S. exports, 1992	U.S. imports, 1992
				Million dollars	
9018.11.00	Electrocardiographs, and parts and accessories thereof	4.2%	Free(A,E,IL,J) 2.1% (CA)	138.2	14.0
9018.19.40	Electrodiagnostic apparatus for functional exploratory examination, and parts and accessories thereof	7.9%	Free(A,CA,E,IL,J)	220.8	225.3
9018.19.80	Electrodiagnostic apparatus nesi, and parts and accessories thereof	4.2%	Free(A,CA,E,IL,J)	1,162.3	559.3
9018.20.00	Ultraviolet or infrared ray apparatus used in medical, surgical, dental or veterinary sciences, and parts and accessories thereof	4.2%	Free(A,E,IL,J) 2.1% (CA)	13.5	3.0
9018.31.00	Syringes, with or without their needles, and parts accessories thereof	8.4%	Free(A,E,IL,J) 4.2% (CA)	203.1	47.8
9018.32.00	Tubular metal needles and needles for sutures, used in medical, surgical, dental, or veterinary sciences, and parts and accessories thereof	6.4%	Free(A,E,IL,J) 3.2% (CA)	34.9	28.2
9018.39.00	Catheters, cannulae and the like, nesi, used in medical, surgical, dental, or veterinary sciences, and parts accessories thereof	4.2%	Free(A,E,IL,J) 2.1% (CA)	981.5	167.1
9018.41.00	Dental drill engines, and parts and accessories thereof	4.7%	Free(A,E,IL,J) 2.3% (CA)	39.1	4.1
9018.49.40	Dental burs	6.2%	Free(A,CA,E,IL,J)	48.2	20.9
9018.49.80	Instruments and apparatus used in dental sciences nesi	4.7%	Free(A,CA,E,IL,J)	181.2	115.4
9018.50.00	Ophthalmic instruments and appliances nesi, and parts and accessories thereof	10%	Free(A,E,IL,J) 5% (CA)	118.3	52.1
9018.90.10	Mirrors and reflectors, used in medical, surgical, dental, or veterinary sciences, and parts and accessories thereof	9%	Free(A,E,IL,J) 4.5% (CA)	8.2	1.0
9018.90.20	Optical instruments and appliances nesi, used in medical, surgical, dental, or veterinary sciences, and parts and accessories thereof	10.0%	Free(A,E,IL,J) 5% (CA)	40.2	94.3
9018.90.30	Anesthetic instruments and appliances nesi, used in medical, surgical, dental, or veterinary sciences, and parts and accessories thereof	5.7%	Free(A,E,IL,J) 2.8% (CA)	76.5	34.9

See footnotes at end of table.

Table 1—Continued
Medical goods: HTS subheading; description; U.S. col. 1 rate of duty as of Jan. 1, 1993; U.S. exports, 1992; and U.S. imports, 1992

HTS subheading	Description	Col. 1 rate of duty As of Jan. 1, 1993 General	Col. 1 rate of duty As of Jan. 1, 1993 Special[1]	U.S. exports, 1992	U.S. imports, 1992
				Million dollars	
9018.90.40	Percussion hammers, stethoscopes, and parts of stethoscopes used in medical, surgical, dental, or veterinary sciences	5.7%	Free(A,E,IL,J) 2.8% (CA)	7.1	8.0
9018.90.50	Sphygmomanometers, tensimeters and oscillators used in medical, surgical, dental, or veterinary sciences, and parts and accessories thereof	3.4%	Free(A,E,IL,J) 1.7% (CA)	30.3	45.6
9018.90.60	Electrosurgical instruments and appliances nesi, and parts and accessories thereof	7.9%	Free(A,E,IL,J) 3.9% (CA)	182.4	51.0
9018.90.70	Electromedical instruments and appliances nesi, and parts and accessories thereof	4.2%	Free(A,CA,E,IL,J)	412.8	367.0
9018.90.80	Instruments and appliances used in medical surgical, dental or veterinary sciences, nesi, and parts and accessories thereof	7.9%	Free(A*,E,IL,J) 3.9% (CA)	771.8	588.8
9019.10.20	Mechanotherapy appliances and massage apparatus, and parts thereof	4.2%	Free(A,E,IL,J) 2.1% (CA)	30.9	74.2
9019.10.40	Electrical psychological aptitude testing apparatus, and parts and accessories thereof	4.2%	Free(A,E,IL,J) 2.1% (CA)	4.1	14.2
9019.10.60	Psychological aptitude testing apparatus, other than electrical, and parts and accessories thereof	7.9%	Free(A,E,IL,J) 3.9% (CA)	7.0	1.3
9019.20.00	Ozone, oxygen and aerosol therapy, artificial respiration, or other therapeutic respiration apparatus and parts and accessories thereof	3.7%	Free(A,CA,E,IL,J)	245.7	109.0
9020.00.40	Self–contained underwater breathing devices designed as a complete unit to be carried on the person	Free		14.2	3.0
9020.00.60	Breathing appliances, nesi, and gas masks	3.7%	Free(A,C,E,IL,J) 1.8% (CA)	45.0	33.2
9020.00.90	Parts and accessories of breathing appliances and gas masks nesi	3.7%	Free(A,E,IL,J) 1.8% (CA)	25.1	13.1
9021.11.00	Artificial joints and parts for orthopedic use	7.2%	Free(A,E,IL,J) 3.6% (CA)	232.1	9.2

See footnotes at end of table.

Table 1—Continued
Medical goods: HTS subheading; description; U.S. col. 1 rate of duty as of Jan. 1, 1993; U.S. exports, 1992; and U.S. imports, 1992

HTS subheading	Description	Col. 1 rate of duty As of Jan. 1, 1993 General	Col. 1 rate of duty As of Jan. 1, 1993 Special[1]	U.S. exports, 1992	U.S. imports, 1992
				Million dollars	
9021.19.40	Bone plates, screws and nails, and other internal fixation devices or appliances, for orthopedic use	7.2%	Free(A,E,IL,J) 3.6% (CA)	169.1	42.3
9021.19.80	Orthopedic or fracture appliances nesi, and parts and accessories thereof	5.8%	Free(A,E,IL,J) 2.9% (CA)	76.4	47.8
9021.21.40	Artificial teeth, and parts and accessories thereof, of plastics	5%	Free(A,E,IL,J) 2.5% (CA)	11.0	5.5
9021.21.80	Artificial teeth, and parts and accessories thereof, other than of plastics	9%	Free(A,E,IL,J) 4.5% (CA)	10.3	2.8
9021.29.40	Dental fittings of plastics, and parts and accessories thereof	5%	Free(A,E,IL,J) 2.5% (CA)	15.5	(2)
9021.29.80	Dental fittings and parts and accessories thereof, and other than of plastics	9%	Free(A,E,IL,J) 4.5% (CA)	20.0	10.3
9021.30.00	Artificial parts of the body nesi, and parts and accessories thereof	5.8%	Free(A,E,IL,J) 2.9% (CA)	184.0	17.1
9021.40.00	Hearing aids	4.2%	Free(A,E,IL,J) 2.1% (CA)	35.5	5.1
9021.50.00	Pacemakers for stimulating heart muscles	4.2%	Free(A,E,IL,J) 2.1% (CA)	125.5	4.1
9021.90.40	Parts and accessories for hearing aids and pacemakers	4.2%	Free(A,E,IL,J) 2.1% (CA)	38.0	43.2
9021.90.80	Appliances nesi which are worn or carried, or implanted in the body, to compensate for a defect or disability	3.9%	Free(A,E,IL,J) 1.9% (CA)	150.0	12.0
9022.11.00	Apparatus based on the use on x–rays for medical, surgical, dental, or veterinary use	2.1%	Free(A,E,IL,J) 1% (CA)	399.4	733.3
9022.19.00	Apparatus based on the use on x–rays other than for medical, surgical, dental, or veterinary use	2.1%	Free(A,E,IL,J) 1% (CA)	41.2	31.0

See footnotes at end of table.

Table 1—Continued
Medical goods: HTS subheading; description; U.S. col. 1 rate of duty as of Jan. 1, 1993; U.S. exports, 1992; and U.S. imports, 1992

HTS subheading	Description	Col. 1 rate of duty As of Jan. 1, 1993 General	Special[1]	U.S. exports, 1992	U.S. imports, 1992
				Million dollars	
9022.21.00	Apparatus based on the use of alpha, beta or gamma radiations, for medical, surgical, dental, or veterinary use	4.0%	Free(A,CA,E,IL,J)	39.2	12.1
9022.29.40	Smoke detectors, ionization type	2.7%	Free(*A,B,E,IL,J) 1.3% (CA)	8.7	52.1
9022.29.80	Apparatus based on the use of alpha, beta or gamma radiations, other than for medical, surgical, dental, or veterinary use	4%	Free(A,CA,E,IL)	15.0	5.9
9022.30.00	X–ray tubes	2.5%	Free(A,E,IL,J) 1.2% (CA)	103.7	35.4
9022.90.20	X–ray generators, high tension generators, desks, screens, treatment tables, chairs, and similar apparatus	2.1%	Free(A,E,IL,J) 1% (CA)	28.9	54.3
9022.90.40	Parts and accessories of x–ray tubes	2.5%	Free(A,E,IL,J) 1.2% (CA)	18.7	18.5
9022.90.60	Parts and accessories of a apparatus based on the use of x–rays	2.1%	Free(A,E,IL,J) 1% (CA)	117.5	169.5
9022.90.70	Parts and accessories of ionization type smoke detectors	2.7%	Free(A,B,E,IL,J) 1.3% (CA)	([2])	1.0
9022.90.90	Parts and accessories of apparatus based on the use of alpha, beta, or gamma radiations	4.0%	Free(A,E,IL,J) 2% (CA)	18.4	10.1

[1] Programs under which special tariff treatment may be provided, and the corresponding symbols for such programs as they ar indicated in the "Special" subcolumn, are as follows: Generalized System of Preferences (A); Automotive Products Trade Act (B); Agreement on Trade in Civil Aircraft(C); United States–Canada Free–Trade Agreement(CA); Caribbean Basin Economic Recovery Act (E); and United States–Israel Free Trade Area (IL); and Andean Trade Preference Act (J).
[2] Less than $50,000.

Source: U.S. exports and imports compiled from data of the U.S. Department of Commerce.

In Japan, 1992 MFN tariffs on medical goods ranged from a low of duty-free on a number of nonelectronic surgical, orthopedic, and prosthetic instruments and devices to a high of 5.8 percent on certain x-ray and other medical imaging equipment such as CT scanners. U.S. exports to Canada benefit from the United States-Canada Free-Trade Agreement and Canadian tariffs on medical goods, which even prior to the agreement averaged less than 2 percent ad valorem, are currently subject to gradual duty reductions or have been granted duty-free status under provisions of that agreement. In general, tariffs on medical goods in the rest of the world are relatively low as most countries outside of the United States, Europe, and Japan are almost totally dependent on imports for their medical equipment needs.

Nontariff Measures

With few exceptions nontariff measures have not generally been used as obstacles to trade in foreign markets for medical goods. The exceptions are noted below for the most important markets for U.S. exports.

Japan

Some industry officials believe that excessive regulation of medical imports to protect a rapidly emerging electromedical industry in Japan served as nontariff measures to foreign imports.[27] In 1985, medical products were included with several other categories of manufactured goods in intensive market-oriented, sector-selective (MOSS) negotiations between the United States and Japan in an attempt to further open the Japanese market to U.S. suppliers.[28] The discussions focused on removing barriers to trade resulting from Japan's regulatory system for protecting public health and safety and its insurance system for reimbursing health-care expenses. The specific issues discussed involved—

1. Testing and test data;
2. Approval and licensing processes for medical products;
3. The National Health Insurance reimbursement system;
4. Linkages between approval and pricing for reimbursement purposes;
5. Transparency in regulatory processes.

After several meetings in 1985, the U.S. and Japanese negotiators reached technical agreement on most of the issues. With regard to pharmaceutical and medical equipment, foreign clinical test data would thenceforth be accepted for all examination and testing requirements except in instances where there were immunological and ethnic differences between Japanese and foreigners (excluding implantable devices and devices affecting organic adaptability).[29] Standard processing periods were adopted and published by MHW for approvals of pharmaceuticals, diagnostics, and medical devices.

The Japanese MHW also made it easier for firms to transfer manufacturing and import approvals when a company wished to change commercial arrangements or to change their country of manufacture. The customs clearance process for imported products was streamlined to provide "one stop" service. The negotiators agreed on significant increases in the frequency of pricing decisions for drugs and medical devices, therefore linking approval decisions more closely with pricing decisions. Finally, the formulas used for calculating new drug prices and for revising drug and device tariff standards were made public, thus increasing the transparency to foreign manufacturers and suppliers. U.S. trade negotiators continue on an annual basis to monitor Japanese compliance with the agreements achieved in the MOSS talks.[30]

Europe

With few exceptions, European countries have not been cited as having nontariff barriers to trade in medical goods. Of the European countries, Germany and France have been cited as having the most restrictive regulatory conditions for approving medical devices. Unlike the voluntary standards systems used in other major markets, including the United States and the United Kingdom, many German standards requirements affecting medical equipment are incorporated in German law. Standards issued by the DIN organization (Deutsche Institute für Normung) have to be met, and all medical equipment that is electrically or hydraulically operated must be approved according to the MED GV (Medizingerateverordnung) regulations for safety put into effect in January 1986.[31] Testing equipment to gain approval against these requirements is done by the Technical Inspectorates (TUV), and hospitals and doctors generally will not accept equipment that does not bear the TUV approval mark.

Medical equipment imported into France faces an official approval or "homologation" process required for all medical equipment destined for the public sector to be used in direct contact or relationship with a patient. Official tests covering safety and clinical efficacy are carried out under the control of the National Center for Hospital Equipment and in an appropriate hospital. Application for approval of medical equipment under this scheme can only be made by a manufacturer or representative in France. Although some smaller U.S. high-technology firms[32]

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[27] Joseph E. Flynn and Christopher Johnson, "United States and Japanese Competition in Medical Equipment," *International Medical Device & Diagnostic Industry* (Santa Monica, CA: Canon Communications, Inc., Jan.-Feb. 1991), pp. 19-24.

[28] General Accounting Office (GAO), *Report on Medical Equipment and Pharmaceutical Market-Oriented, Sector-Selective (MOSS) Discussions*, (Washington, DC, 1986).

[29] GAO, *Report on Medical Equipment*.

[30] U.S. Embassy officials, interviews by USITC staff in Tokyo, Japan, June 1990 and Apr. 1991.

[31] Healthcare Equipment International: Market Trends, Companies, Statistics (Burnt Mill, UK: Longman Group Ltd., 1989), p. 79.

[32] Officials of U.S. medical laser and imaging producers, interviews with USITC staff, May 27-29, 1992.

say France uses its rigid approval process to protect the French medical equipment industry, French officials state that their laws and regulations apply equally to national and foreign medical equipment and, thus, technically are not in themselves nontariff measures. France has also been accused of using its centralized Federal Government procurement process to favor French producers for major purchases of high-technology equipment.[33]

U.S. MARKET

Consumption

Apparent U.S. consumption of medical goods increased at an average annual rate of 9 percent during 1988-92 to almost $20 billion (table 2). This was less than the double-digit growth reflected in the market in the 1970s and early 1980s, before Federal Government and private sector insurance cost containment measures were implemented. However, taking into account the fact that price margins have been lowered in the more cost-sensitive U.S. market, volume sales of medical equipment and apparatus do not appear to have slowed in the United States. Industry analysts explain that although sales of some types of equipment have fallen off, there has been an increase in purchases of certain newer high-technology devices, such as lasers, fiber-optic endoscopes, and angioplasty catheters, that have proven to be more cost-effective than traditional medical procedures and devices.

During 1988-92, the ratio of imports to consumption increased slightly from 19 to 20 percent as the greater price sensitivity in the U.S. market led to a greater amount of consideration being given to nontraditional sources of equipment, including foreign suppliers. Much of the increase in imports occurred in the electromedical segment of the medical goods sector where imports accounted for over one-third of U.S. apparent consumption by 1991, before falling to 32 percent in 1992 (table 3). Imports of surgical and medical instruments (table 4), and orthopedic and prosthetic appliances (table 5), accounted for smaller shares of the remaining segments of the U.S. medical goods market in 1992.

Competition among U.S., Japanese, and European manufacturers of medical goods has become very intense in the U.S. market, particularly in the medical electronics sector. For example, the U.S.-based GE Medical Systems competes against German-based Siemens in the premium, high-price ranges of the medical imaging market, whereas, the Japanese electronics producers, Toshiba and Hitachi, concentrate in the middle and lower price ranges for most medical imaging devices, including CT scanners, MRI, and nuclear imaging devices. However, Toshiba competes in the high end of the U.S. ultrasound market primarily against U.S. specialty ultrasound manufacturers, Acuson and ATL, rather than against the major U.S. and foreign imaging companies. U.S.-based Medtronic competes in the cardiac pacemaker market against Siemens and other smaller U.S. producers. Japanese producers do not yet compete in that market.

In the highly internationalized global medical goods industry, an increasing share of the U.S. market is supplied either by intracompany imports of products by U.S.-based corporations that have established overseas manufacturing or assembly facilities, or by imports of foreign-based firms to supplement production in facilities they have established in the United States. GE Medical Systems supplements its premium high-end medical imaging equipment with imported equipment from its Japanese- and French-based subsidiaries to fill market niches for smaller, less expensive imaging equipment. Minneapolis-based Medtronic imports pacemakers from its Vitatron subsidiary in the Netherlands to complete its product line of mostly U.S.-manufactured pacemakers. Baxter International imports catheters and blood administration kits from manufacturing and assembly facilities it has established in Singapore and Mexico to save on labor costs. German-based Siemens imports pacemakers and patient-monitoring equipment to supplement product lines manufactured in its U.S. subsidiaries. The Netherlands-based Philips sells European- and Japanese-manufactured equipment under its label in the U.S. market.

Production

The United States is the largest producer of medical goods in the world (figure 5). Despite the slowdown in U.S. apparent consumption, U.S. shipments of medical goods increased by an average annual rate of 10 percent from 1988 to 1992 (table 2). The greater rate of increase in shipments was largely due to improved conditions in overseas markets that enabled U.S. companies to increase exports. U.S. market demand for innovative high-technology products that reduced overall costs of delivering health care also contributed to the increase in U.S. shipments. As indicated by figure 6, each of the three major segments of the medical goods industry was responsible for roughly equivalent portions of total U.S. shipments in 1992.

Medical and surgical instruments, and orthopedic and prosthetic articles, each experienced 11-percent growth rates in U.S. shipments during 1988-92 (tables 4 and 5). Advanced Cardiovascular Systems (ACS), owned by Eli Lilly and Co., rapidly increased its shipments of cardiovascular balloon catheters as procedures utilizing these devices reduced the need for many persons to undergo much more expensive and invasive heart-by-pass surgeries. ACS has about 50 percent of the U.S. market for such devices.[34] The previously sluggish orthopedic and prosthetic sector of the medical device industry was revitalized with its development of effective artificial joints from composite materials. Companies such as Zimmer (a subisidiary of Bristol-Myers Squibb Co.), Howmedica Inc. (Pfizer Inc.), Osteonics Corp. (Stryker Corp.), and DePuy Inc. (Boehringer Mannheim Corp.) have led in

[33] USITC, *The Effects of Greater Economic Integration Within the European Community on the United States (Investigation No. 332-267)*, USITC publication 2204, July 1989, pp. 4-24 and 4-25.

[34] Sharon Rosenbaum, "Catheter makers will capitalized on growth in angioplasty," *Health Industry Today*, Feb. 1992, pp. 1 and 14.

Table 2
Medical goods: U.S. producers' shipments, exports of domestic merchandise, imports for consumption, and apparent consumption, 1988-92

Year	Producers' shipments[1]	Exports	Imports	Apparent consumption	Ratio of imports to consumption
	Million dollars				Percent
1988	15,550	3,895	2,761	14,416	19
1989	17,500	4,493	2,799	15,806	18
1990	19,200	5,317	3,292	17,175	19
1991	21,200	6,206	3,762	18,756	20
1992	22,940	6,940	3,997	19,997	20

[1] Estimated by the staff of the U.S. International Trade Commission.

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce, except as noted.

Table 3
Electromedical and x-ray apparatus and equipment: U.S. producers' shipments, exports of domestic merchandise, imports for consumption, and apparent consumption, 1988-92

Year	Producers' shipments[1]	Exports	Imports	Apparent consumption	Ratio of imports to consumption
	Million dollars				Percent
1988	5,680	2,152	1,607	5,135	31
1989	6,348	2,137	1,777	5,988	30
1990	7,022	2,401	2,056	6,677	31
1991	7,305	2,796	2,304	6,813	34
1992	7,960	3,046	2,346	7,260	32

[1] Estimated by the staff of the U.S. International Trade Commission.

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce, except as noted.

Table 4
Medical, dental, surgical, and veterinary instruments and apparatus, and parts: U.S. producers' shipments, exports of domestic merchandise, imports for consumption, and apparent consumption, 1988-92

Year	Producers' shipments[1]	Exports	Imports	Apparent consumption	Ratio of imports to consumption
	Million dollars				Percent
1988	5,595	1,149	916	5,362	17
1989	6,350	1,620	780	5,510	14
1990	7,105	1,958	939	6,086	15
1991	7,675	2,303	1,141	6,513	18
1992	8,390	2,622	1,298	7,066	18

[1] Estimated by the staff of the U.S. International Trade Commission.

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce, except as noted.

Table 5
Orthopedic, prosthetic, and surgical appliances and supplies: U.S. producers' shipments, exports of domestic merchandise, imports for consumption, and apparent consumption, 1988-92

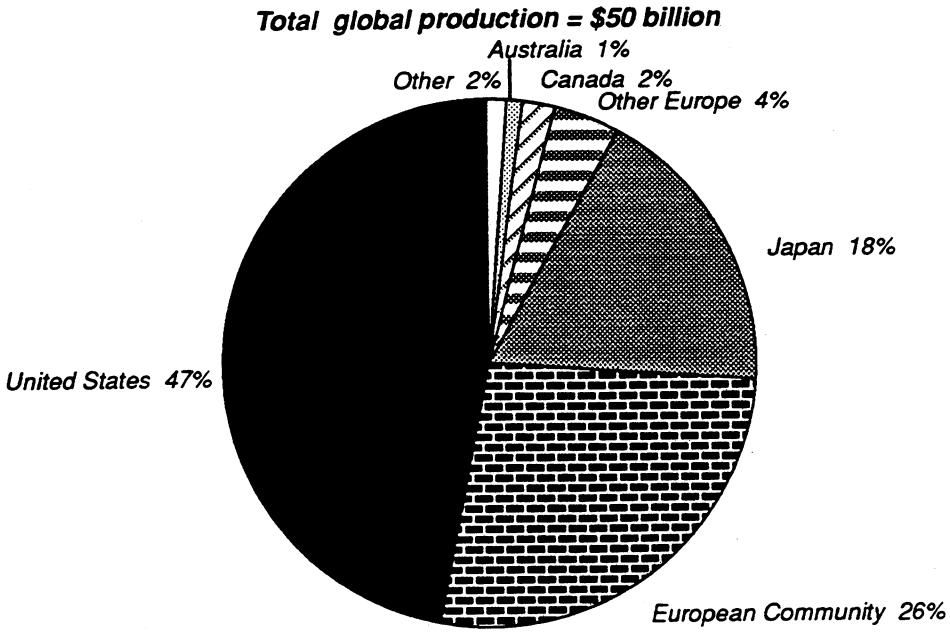
Year	Producers' shipments[1]	Exports	Imports	Apparent consumption	Ratio of imports to consumption
	Million dollars				Percent
1988	4,275	594	238	3,919	6
1989	4,802	736	242	4,308	6
1990	5,073	957	296	4,412	7
1991	6,220	1,107	318	5,431	6
1992	6,590	1,272	354	5,672	6

[1] Estimated by the staff of the U.S. International Trade Commission.

Note.—Because of rounding, figures may not add to the totals shown.

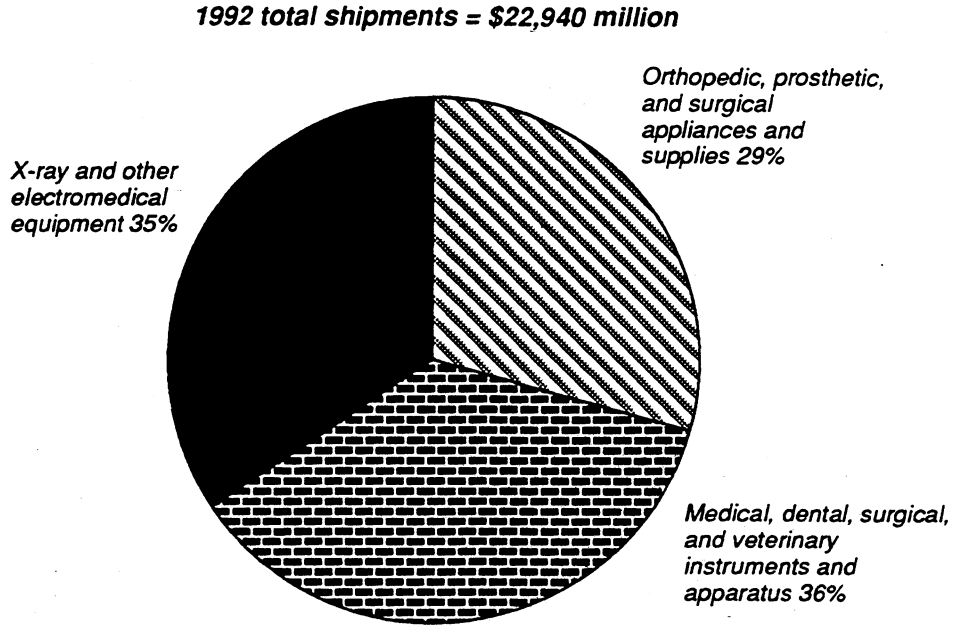
Source: Compiled from official statistics of the U.S. Department of Commerce, except as noted.

Figure 5
Global production of medical goods, 1992



Source: Estimated by staff of the U.S. International Trade Commission based on official statistics of the U.S. Department of Commerce and on information from the Health Industry Manufacturers Association.

Figure 6
Medical goods: U.S. shipments, by product line, 1992



Source: Compiled from official statistics of the U.S. Department of Commerce.

the development and sales of such devices. Boehringer Mannheim, through another subsidiary, Orthogenesis, developed a custom prothesis-manufacturing system, utilizing laser-measuring devices and CAD/CAM techniques to produce customized orthopedic implants in less than 1 hour while patients remain on the operating table. These advances helped the orthopedic and prosthetic sector to rebound from shipment growth of less than 5 percent in the mid-1980s to double-digit growth in the past several years.

Although shipments in the x-ray and electromedical sector of the industry grew more slowly, at an average of 9-percent annually during 1988-92, most of the sluggishness was represented in the more mature x-ray and CT scanner sector of the market. German and Japanese suppliers have increased their share of the U.S. market for commodity x-ray apparatus and equipment. However, U.S. firms continue to be responsible for a large portion of the increase in shipments of advanced-technology electromedical imaging and surgical devices. General Electric remains the largest supplier of magnetic imaging devices. Advances in digital ultrasound technology by a startup company, Acuson, have enabled that company to challenge Toshiba of Japan to become the second-leading producer of high-end ultrasound in the world. Hewlett Packard has incorporated its advanced computer technology in patient-monitoring and ultrasound equipment to become a major player in the medical market. U.S. shipments of electromedical equipment were also aided by the increased usage and demand for medical laser technology in advanced surgical procedures during the period. Laser surgery enabled many surgeons to move surgery out of the operating room into doctors' offices and offsite surgical centers. Some important companies responsible for increasing shipments in this sector were Coherent Medical, Sunrise Technologies, and Laserscope.

In general, increased price pressures in the U.S. market encouraged U.S. medical device producers to reduce product inventories during 1988-92. Large medical producers such as Baxter International, Abbott Laboratories, and Johnson and Johnson were able to rationalize product delivery systems by establishing just-in-time hospital and medical supply warehousing and delivery systems. Smaller producers took advantage of the chance to replicate these systems as these larger supply companies served both production and distributive functions for the industry. Lower inventories are expected to enable U.S. producers to continue to increase production in the future.

Imports

U.S. imports of medical equipment increased by an average annual rate of 10 percent to $4.0 billion during 1988-92 (table 6). Germany and Japan were, by far, the largest suppliers of imports, accounting for almost one-half of total medical goods imports in 1992 (figure 7). Although other European countries supplied a large portion of the remaining imports, the establishment of production and assembly facilities by large U.S.-based firms, such as Baxter International, Abbott Laboratories, and Johnson & Johnson, in

Table 6
Medical goods: U.S. imports for consumption, by principal sources, 1988-92

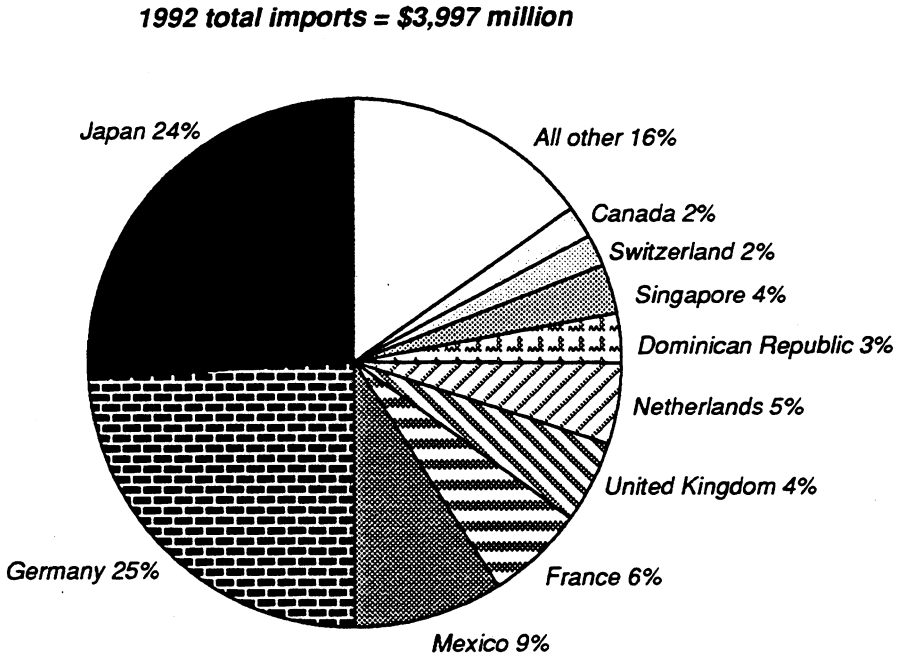
Sources	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Germany	(1)	730,460	814,331	911,394	989,779
Japan	(1)	688,740	845,366	969,131	960,140
Mexico	(1)	217,942	280,163	331,614	360,642
France	(1)	134,666	182,037	232,849	225,498
Netherlands	(1)	134,653	157,357	176,054	188,954
United Kingdom	(1)	146,468	164,540	195,453	175,703
Singapore	(1)	57,978	71,721	99,012	142,371
Dominican Republic	(1)	60,305	79,234	103,410	112,923
Switzerland	(1)	66,068	76,036	86,187	94,544
Canada	(1)	66,595	59,392	66,684	92,086
All other	(1)	494,692	561,462	590,660	654,838
Total	2,760,865	2,798,567	3,291,639	3,762,449	3,997,476

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Figure 7
Medical goods: U.S. imports from major sources, 1992



Source: Compiled from official statistics of the U.S. Department of Commerce.

Mexico and the Dominican Republic, to save on labor costs, resulted in substantial growth in imports from those countries. A significant portion of the imports from Mexico and the Dominican Republic benefited from reduced duties under HTS subheading 9802.00.80 or entered duty free under the GSP or CBERA. Duty-free imports accounted for about 10 percent of total U.S. imports in 1992. Reduced-duty imports of medical and surgical instruments under HTS subheading 9802.00.80 represented 12 percent of total imports of medical goods in 1992, up from 9 percent in 1988. The duty-free, or U.S.-manufactured content of such imports amounted to over 50 percent.

As indicated in figure 8, the largest portion of U.S. imports of medical goods consisted of electromedical equipment (table 7). This reflects the growing competitiveness of major Japanese, German, and other European electronics firms in the U.S. market for medical goods. Although surgical and medical instruments also represented a significant portion of U.S. imports of medical equipment (table 8), orthopedic and prosthetic appliances (table 9) accounted for less than 10 percent of U.S. imports though they represented over 25 percent of total U.S. consumption. Industry analysts speculate that because the United States has built up such a dominant position over the years in the manufacture of all types of medical equipment, foreign competitors have more success entering the newer high-technology segments rather than more traditional segments of the market for medical goods. Much of the newer technology is represented in the electromedical sector of the market.

Major foreign producers of medical equipment generally have established U.S. sales affiliates to handle the importation, sales, and service of their medical equipment. Similar to major U.S. electromedical producers, foreign producers, such as Siemens, Philips, Toshiba, and Hitachi, find that they must often provide extensive sales, financing, and service support to major customers of their advanced technology products and cannot depend on distributors to perform these functions for them. Such affiliates usually sell directly to large hospitals and alternate site imaging centers in the United States. Some of these companies have also acquired or established some manufacturing and assembly facilities in the United States to fill out product lines.

FOREIGN MARKETS

Foreign Market Profile

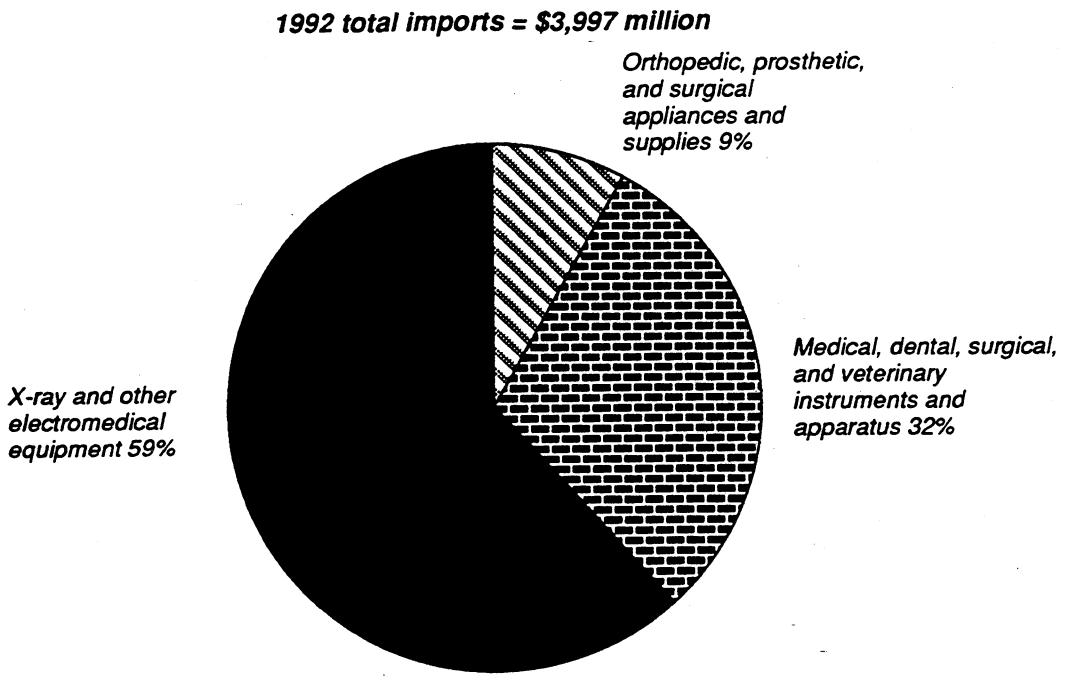
Europe and Japan are the largest markets for medical goods outside of the United States (figure 4) and as such represent the most important markets for U.S. exports of medical equipment. In Europe, the public-sector market for medical goods is moderately important relative to the total European market for such goods. In most European countries, a government ministry or department is responsible for supervising and organizing health insurance in the country and for funding public health facilities, including hospitals. Actual purchases of medical equipment, although government-funded, are usually handled in a decentralized manner at the local level. However, in France public-sector procurement is conducted on a more centralized basis.

Although Europe, and particularly the EC, historically has been the most important market for U.S. exports of medical equipment, U.S. producers have been greatly inconvenienced by substantial differences among European countries in their technical specifications for medical devices and in their administrative procedures for inspecting and authorizing sales of medical devices. Some countries, such as Germany, have placed greater emphasis on product testing, whereas other countries, such as the United Kingdom, have focused more on total quality assurance in the production of medical devices. Differences in standards and regulatory approval procedures have fragmented the EC market and added costs to suppliers who wish to sell in other member states and who must either modify their products or subject them to different national testing and certification procedures.

Recent efforts to harmonize conflicting EC standards and establish a single regulatory approval process in connection with the EC 1992 integration process have been encouraging to U.S. medical goods producers.[35] Proposed EC directives related to medical device standards and regulations are expected by many U.S. industry officials to improve trade prospects further in Europe. By harmonizing the various mandatory requirements and conformance procedures with respect to medical devices, the directives should enable U.S. suppliers to reduce costs associated with compliance to different individual EC country requirements, to benefit from economies of scale, and to increase productivity. However, discriminatory standards, lack of transparency in the single regulatory approval process, and duplicative testing and certification requirements could significantly inconvenience U.S. firms and lessen the competitiveness of their exports in the EC market. Accordingly, U.S. medical goods firms, trade associations, and standards bodies have been monitoring the EC 1992 process carefully to make certain that their concerns are taken into account. Because U.S.-based firms already have substantial investment and production facilities in major EC markets, they have had significant representation on European bodies advising the EC officials drafting the EC directives on medical devices.

[35] For more information see USITC, *Effects of Greater Economic Integration Within the European Community on the United States: First Follow-Up Report*, (investigation No. 332-267), USITC publication 2268, Mar. 1990, pp. 6-71, 6-72, and 6-81 to 6-84; USITC, *Effects of Greater Economic Integration Within the European Community on the United States: Fourth Follow-Up* Report (investigation No. 332-267), USITC publication 2501, Apr. 1992, pp. 5-55 to 5-57; and *Effects of Greater Economic Integration Within the European Community on the United States: Fifth Follow-Up Report*, (investigation No. 332-267), USITC publication 2628, Apr. 1993, pp. 64-66.

Figure 8
Medical goods: U.S. imports, by product line, 1992



Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 7
Electromedical and x-ray apparatus and equipment: U.S. imports for consumption, by principal sources, 1988-92

Source	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Japan	(1)	517,739	649,759	726,767	708,557
Germany	(1)	558,697	578,674	641,909	673,175
Netherlands	(1)	128,283	149,296	165,238	174,319
France	(1)	98,658	134,853	179,902	167,410
Mexico	(1)	72,660	99,903	120,441	152,154
United Kingdom	(1)	89,947	103,955	131,033	87,365
Canada	(1)	33,116	23,476	27,483	37,390
Israel	(1)	39,031	37,914	38,389	36,797
Italy	(1)	23,692	33,049	33,966	33,125
Ireland	(1)	39,788	40,701	29,602	32,473
All other	(1)	175,477	204,877	209,219	243,419
Total	1,607,054	1,777,089	2,056,457	2,303,950	2,346,184

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 8
Medical, dental, surgical, and veterinary instruments and apparatus, and parts: U.S. imports for consumption, by principal sources, 1988-92

Source	1988	1989	1990	1991	1992
			Value *(1,000 dollars)*		
Germany	(1)	134,452	189,997	229,713	272,329
Japan	(1)	160,840	187,016	229,464	237,640
Mexico	(1)	97,045	118,283	149,811	146,812
Dominican Republic	(1)	60,305	79,183	103,410	112,708
Singapore	(1)	55,818	70,044	90,870	111,346
United Kingdom	(1)	35,388	34,954	38,994	61,077
Switzerland	(1)	30,873	39,883	45,922	55,210
Canada	(1)	21,938	26,359	28,188	39,260
Pakistan	(1)	25,545	33,124	34,341	36,418
China	(1)	22,010	14,229	22,679	28,642
All other	(1)	135,648	146,201	167,446	196,089
Total	916,283	779,862	939,272	1,140,837	1,297,531

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 9
Orthopedic, prosthetic, and surgical appliances and supplies: U.S. imports for consumption, by principal sources,1988-92

Source	1988	1989	1990	1991	1992
			Value *(1,000 dollars)*		
Mexico	(1)	48,237	61,978	61,362	61,675
Germany	(1)	37,311	45,660	39,772	44,275
France	(1)	17,342	27,084	27,360	30,261
Sweden	(1)	22,878	34,251	24,144	29,835
United Kingdom	(1)	21,132	25,631	25,427	27,261
Taiwan	(1)	9,338	13,648	18,055	21,727
Switzerland	(1)	21,828	16,029	21,750	20,335
Italy	(1)	5,443	7,967	9,635	15,585
Canada	(1)	11,541	9,558	11,013	15,435
Denmark	(1)	8,960	8,327	15,395	14,824
All other	(1)	37,607	45,777	63,749	72,546
Total	237,528	241,616	295,910	317,663	353,759

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

In the past several years, European countries have significantly increased their expenditures on health care infrastructure. This has greatly benefited U.S. firms that compete with German firms as the principal foreign suppliers of medical goods to most European markets. Although, European governments face concerns similar to those faced by the U.S. Government with respect to containing escalating health care costs, a rapidly aging population and increased demands by the population for a high level of health care will continue to expand opportunities for sales of medical equipment in Europe.[36] Market opportunities in the southern tier of EC member countries, as well as in Eastern and Central Europe, are expected to expand for U.S. and other foreign suppliers of medical goods as those nations move to modernize their health care systems.

Japan remains the most important single country market for U.S. exports of medical goods. Differing from that in Europe where the market for medical goods consists largely of public hospitals and institutions, Japanese medical care is dominated by general practitioners who run small hospitals and clinics. As a result, the private sector owns about 75 percent of the general hospitals in Japan. Nevertheless,

[36] The Global Medical Device Market Report, 1992.

the Japanese Ministry of Health and Welfare exerts a significant amount of influence over the demand for medical equipment through its management of the country's health care reimbursement scheme. The remaining portion of the Japanese market for medical goods consists of public and nonprofit hospitals owned by insurance plans, unions, industries, companies, and various levels of the government.

Because Japanese hospitals and clinics tend to be much smaller than health care institutions in the United States and Europe, a premium is placed on medical instruments and equipment that consume a small amount of space. This has proven to be somewhat of a disadvantage to U.S. suppliers of premium high-power medical imaging and other large-scale hospital capital equipment. Japanese producers, such as Toshiba and Hitachi, have successfully entered this segment of the market by developing less sophisticated and less expensive medical imaging equipment that smaller institutions can afford and install more easily. To more easily penetrate this market, large U.S. suppliers, such as GE, have established joint ventures with Japanese companies to produce and supply smaller magnetic resonance, computed tomographic, and ultrasonic scanners assembled from U.S.-manufactured components and subassemblies.

As in the United States, the Japanese Government is taking steps to reduce treatment costs.[37] Current cost-containment measures include a reduction of reimbursements for certain expensive medical procedures, caps on some devices, and increases in patient copayments. Nevertheless, the Japanese health care market has experienced substantial growth during the past 5 years and is expected to continue to do so over the next decade. Reasons for this are a rapidly aging population and increases in per capita spending on health care for an increasingly prosperous population. Producers who are able to supply equipment that is demonstrated to be cost effective in the overall treatment of particular diseases or conditions will benefit the most in the Japanese market.

Resolutions of many of the issues discussed in the 1985 MOSS talks between the United States and Japan have increased opportunities for U.S. producers in the Japanese market as evidenced by increased U.S. exports to that market during 1985-92. The total share of Japanese imports supplied by U.S. companies in 1992 was 60 percent, up from less than 45 percent in 1985.[38] The U.S. medical device industry has also benefited by concerted Japanese Government efforts to increase overall Japanese imports of U.S. products to fulfill obligations committed to as the result of other U.S.-Japanese bilateral trade discussions, such as the Structural Impediments Initiative of 1990.

[37] Steven H. Reichman, "Penetrating the Japanese Device and Diagnostics Market," *Medical Device & Diagnostic Industry*, June 1992, pp. 60-64.

[38] Ibid; Japan External Trading Organization, *Your Market in Japan: Medical Electronics Equipment*, Tokyo, Japan, Mar. 1990, and information provided by Elctronic Industries Association of Japan, Jan. 1993.

Other countries of the world represent less than 12 percent of total global consumption of medical goods. Canada and Australia are the most important of these markets. Prospects for U.S. exports to Canada increased greatly with entering into force of the U.S.-Canada Free-Trade Agreement, which enabled a number of U.S. firms to close redundant production facilities in various Canadian Provinces and to supply those markets solely through exports. Although Australia is a very sophisticated consumer of medical goods, future growth in that market will be limited by the country's relatively small population. Industry officials believe that Mexico will grow in importance as a market for medical goods upon enactment of the NAFTA agreement. Though other less developed countries in Asia, Africa, and Latin America represent future potential growth in global markets for medical goods, economic conditions in those regions of the world have not yet permitted the countries to expend the resources necessary to develop adequate health care infrastructures.

U.S. Exports

U.S. exports of medical goods increased by an average annual rate of 16 percent during 1988-92 to $6.9 billion, or 30 percent of total U.S. shipments of medical goods in 1992 (table 10). Exports, in fact, were the major driving force behind increased U.S. shipments as consumption in the U.S. market slowed during the period. A decline in the relative value of the U.S. dollar versus currencies in the countries of major foreign competitors made U.S. medical instruments and equipment more competitive in important European and Asian markets. Moreover, U.S. suppliers were helped by efforts of a number of foreign governments to improve their health care infrastructures. In Germany, for example, efforts to bring the level of health care in eastern Germany up to west German standards has significantly increased opportunities for U.S. firms in the past two years.

Electromedical devices and equipment (table 11) constituted the largest portion of U.S. exports of medical goods, accounting for 44 percent of the total in 1992 (figure 9). Increased foreign demand for medical imaging equipment, complete patient-monitoring systems, and innovative high-technology medical laser systems benefited U.S. firms, such as General Electric, Hewlett Packard, Marquette Electronics, Acuson, Spacelabs, and Coherent. Medtronic, of Minneapolis, MN, remained the world's largest producer and exporter of cardiac pacemakers.

However, even though electromedical goods continued to dominate U.S. exports, compared to other major foreign producers of medical goods, the U.S. industry retained its position as the most broadly based supplier of medical goods in the world. U.S. exports of medical and surgical instruments (table 12), as well as of orthopedic and prosthetic devices (table 13), grew even faster than exports of electromedical equipment during the period. This is because the U.S. industry faces much less competition from its major foreign competitors, Germany and Japan, in these sectors compared to what it faces in the electromedical sector, where competition is much more fierce. Technological

Table 10
Medical goods: U.S. exports of domestic merchandise, by principal markets, 1988-92

Market	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Japan	(1)	699,136	757,829	861,300	937,013
Germany	(1)	488,549	542,303	681,527	771,976
Canada	(1)	463,929	699,357	721,398	765,110
France	(1)	294,516	352,234	401,860	432,698
Netherlands	(1)	272,117	334,228	360,326	400,772
United Kingdom	(1)	278,335	313,921	358,408	394,831
Mexico	(1)	208,236	260,072	322,108	363,627
Italy	(1)	191,003	223,554	258,788	274,829
Belgium	(1)	124,686	145,609	219,098	259,946
Australia	(1)	161,122	183,702	217,357	224,324
All other	(1)	1,311,358	1,503,957	1,803,504	2,115,326
Total	3,894,852	4,492,987	5,316,767	6,205,674	6,940,452

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 11
Electromedical and x-ray apparatus and equipment: U.S. exports of domestic merchandise, by principal markets, 1988-92

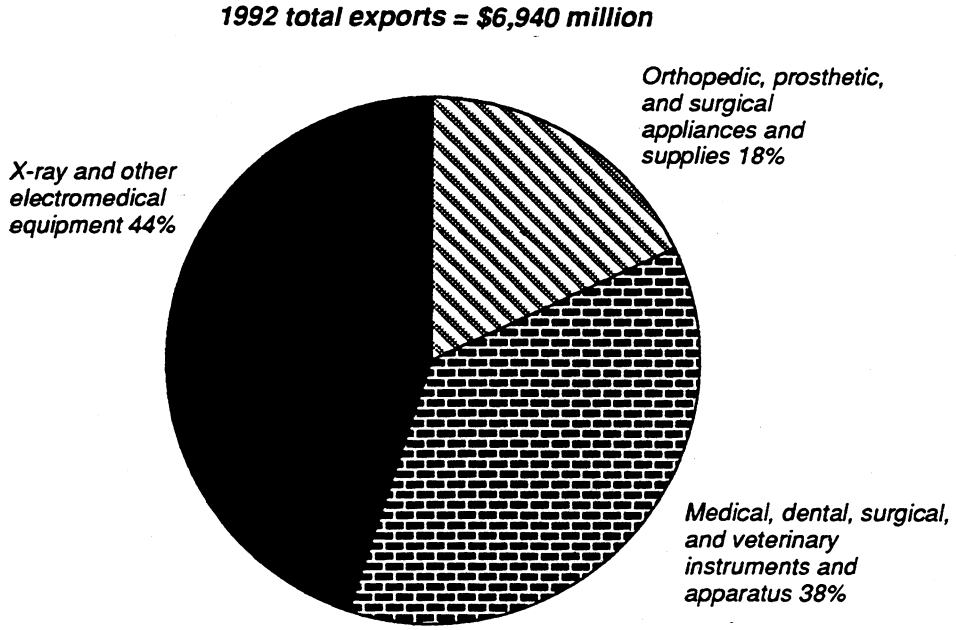
Market	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Japan	(1)	370,131	381,335	421,567	417,623
Germany	(1)	271,635	278,932	380,113	410,743
Canada	(1)	202,110	233,330	222,663	235,235
Netherlands	(1)	151,755	199,737	209,837	207,551
France	(1)	127,729	143,356	171,650	182,559
United Kingdom	(1)	117,733	132,107	156,059	171,022
Mexico	(1)	63,247	90,290	112,895	129,645
Italy	(1)	75,322	90,908	100,423	123,224
Australia	(1)	69,117	80,351	99,116	103,399
Belgium	(1)	61,918	63,579	85,589	90,937
All other	(1)	626,604	707,371	835,903	974,458
Total	2,151,663	2,137,301	2,401,296	2,795,815	3,046,396

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Figure 9
Medical goods: U.S. exports, by product line, 1992



Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 12
Medical, dental, surgical, and veterinary instruments and apparatus, and parts: U.S. exports of domestic merchandise, by principal markets, 1988-92

Market	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Japan	(1)	229,095	243,154	286,129	345,044
Canada	(1)	153,999	263,047	285,854	315,666
Germany	(1)	155,448	186,938	212,222	248,661
France	(1)	120,480	151,254	174,187	193,278
Mexico	(1)	98,297	117,994	165,060	191,578
United Kingdom	(1)	103,155	120,022	133,627	150,221
Netherlands	(1)	90,793	101,002	104,147	114,078
Italy	(1)	86,505	99,763	120,657	109,750
Belgium	(1)	53,719	69,487	84,332	103,624
Dominican Republic	(1)	33,467	60,568	70,123	79,816
All other	(1)	494,843	545,172	666,253	770,540
Total	1,149,027	1,619,800	1,958,401	2,302,592	2,622,256

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 13
Orthopedic, prosthetic, and surgical appliances and supplies: U.S. exports of domestic merchandise, by principal markets, 1988-92

Market	1988	1989	1990	1991	1992
	Value *(1,000 dollars)*				
Canada	(1)	107,820	202,981	212,881	214,209
Japan	(1)	99,910	133,340	153,604	174,347
Germany	(1)	61,466	76,432	89,192	112,572
Netherlands	(1)	29,569	33,489	46,342	79,142
United Kingdom	(1)	57,447	61,793	68,722	73,587
Switzerland	(1)	35,692	46,413	58,098	73,251
Belgium	(1)	9,050	12,543	49,178	65,386
France	(1)	46,306	57,624	56,023	56,861
Ireland	(1)	20,816	23,087	36,468	55,249
Australia	(1)	39,329	44,762	51,975	51,551
All other	(1)	228,481	264,606	284,785	315,644
Total	594,162	735,886	957,070	1,107,267	1,271,799

[1] Country-level detail is provided only for years in which there are actual trade data under the HTS and the new Schedule B (based on HTS).

Note.—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

advances by the U.S. industry in such areas as cardiovascular catheters, artificial heart valves, arthroscopic surgical tools, and orthopedic implants have also improved growth prospects for U.S. exports in these other sectors of the industry.

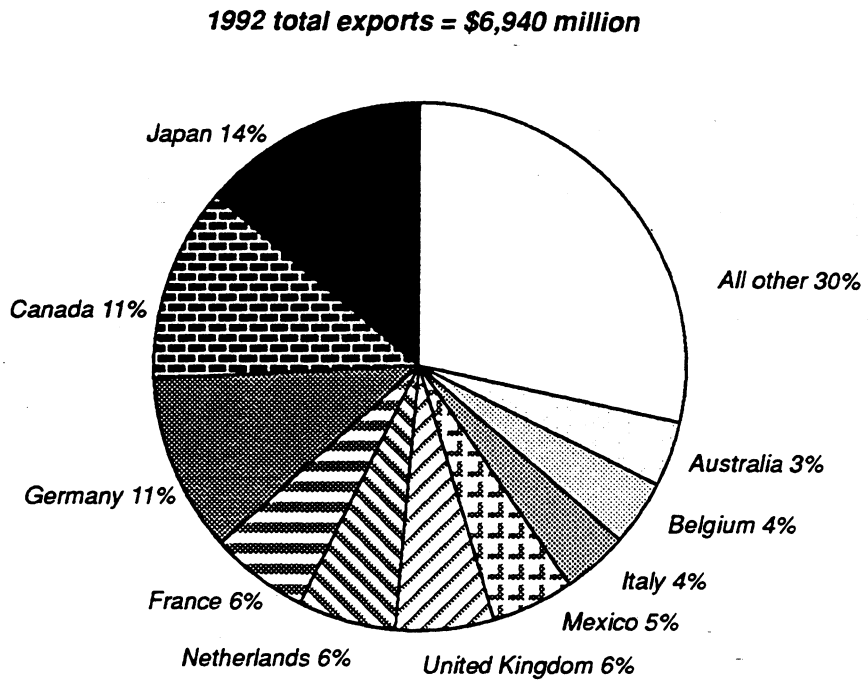
Japan remained the most important individual country market for U.S. exports of medical and surgical instruments during the period (figure 10). However, a more-than-100-percent increase in exports to Canada between 1989 and 1991, after the U.S.-Canada Free-Trade Agreement entered into force, caused that country to replace Germany as the second-largest market for U.S. sales of such medical goods. As a result of that agreement, which eliminated certain Canadian Provincial requirements encouraging domestic production, large U.S.-based medical producers, such as Baxter International, rationalized North American operations by closing some unproductive Canadian facilities. Instead these firms supplied the Canadian market through exports.

The EC continued to be the largest overall market for exported U.S. medical devices. U.S. firms paid increasing attention to that market as efforts were made to establish common standards and a single regulatory system for approval of medical devices as the EC has continued integration activities to form a single market by 1992. Mexico and the Dominican Republic also became increasingly important markets for U.S. exports as U.S. producers increased shipments of medical device components and subassemblies to those countries for low-cost assembly into completed medical devices. Preferential tariff treatment afforded imports of the completed goods under such programs as HTS subheading 9802.00.80, CBERA, and the GSP provided incentives for such exports.

U.S. TRADE BALANCE

The U.S. surplus in medical goods (table 14) improved by an average annual rate of 36 percent during 1988-92 to $2.9 billion in 1992 (figure 11). This reversed a trend in the early 1980s that saw significant annual declines in the level of the U.S. surplus. Much of the increase in the surplus resulted from increased exports to the European Community and Canada (figure 12). Despite these improvements, however, the U.S. industry continued to experience trade deficits with its major rivals Germany and Japan. Moreover, a large portion of the deficits with those two countries is in the medical electronics sector that is responsible for a significant proportion of better paying, high-technology jobs in the medical goods industry. Competition with Germany and Japan is expected to remain intense during the next decade.

Figure 10
Medical goods: U.S. exports, to major markets, 1992



Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 14
Medical goods: U.S. exports of domestic merchandise, imports for consumption, and merchandise trade balance, by selected countries and country groups, 1988-92[1]

(Million dollars)

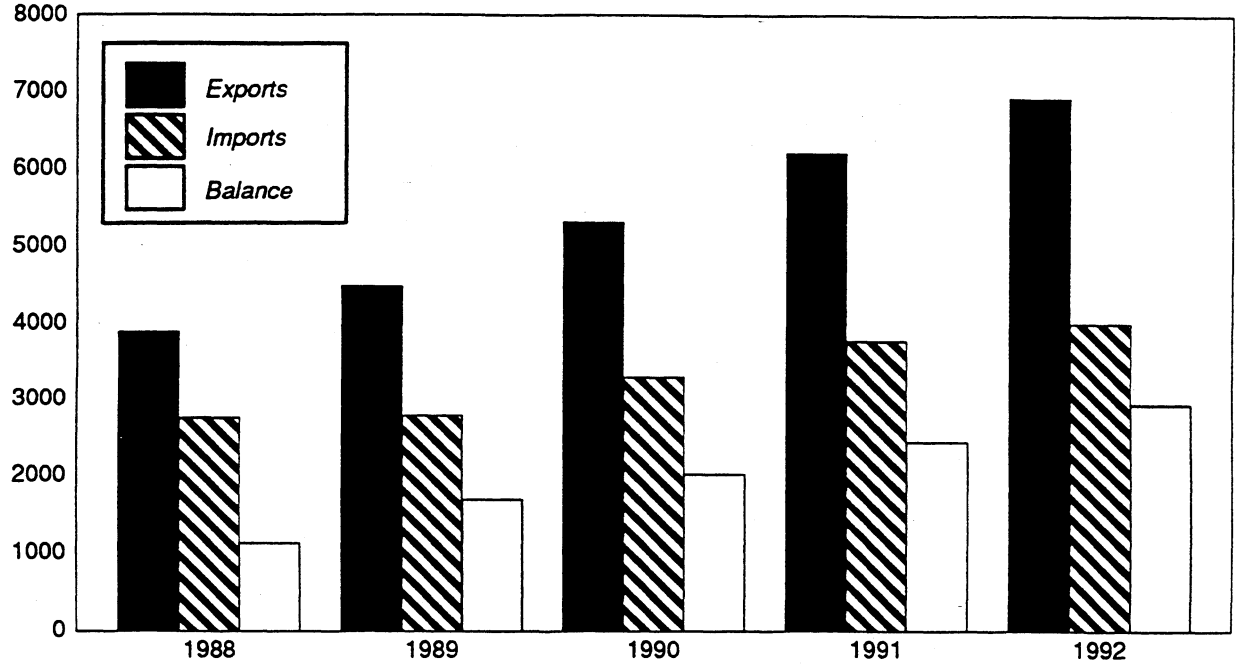
Item	1988	1989	1990	1991	1992
U.S. exports of domestic merchandise:					
Japan	(1)	699	758	861	937
Germany	(1)	489	542	682	772
Canada	(1)	464	699	721	765
Mexico	(1)	208	260	322	364
France	(1)	295	352	402	433
Netherlands	(1)	272	334	360	401
United Kingdom	(1)	278	314	358	395
Italy	(1)	191	224	259	275
Belgium	(1)	125	146	219	260
Switzerland	(1)	98	112	130	152
All other	(1)	1,374	1,575	1,891	2,187
Total	3,895	4,493	5,317	6,206	6,940
EC-12	(1)	1,855	2,140	2,580	2,874
OPEC	(1)	98	104	132	179
ASEAN	(1)	86	98	109	132
CBERA	(1)	87	113	116	134
Eastern Europe	(1)	12	23	24	33
U.S. imports for consumption:					
Japan	(1)	689	845	969	960
Germany	(1)	730	814	911	990
Canada	(1)	67	59	67	92
Mexico	(1)	218	280	332	361
France	(1)	135	182	233	225
Netherlands	(1)	135	157	176	189
United Kingdom	(1)	146	165	195	176
Italy	(1)	37	47	50	58
Belgium	(1)	7	15	17	29
Switzerland	(1)	66	76	86	95
All other	(1)	569	650	726	823
Total	2,761	2,799	3,292	3,762	3,997
EC-12	(1)	1,290	1,487	1,698	1,793
OPEC	(1)	0	0	0	1
ASEAN	(1)	75	100	133	184
CBERA	(1)	69	88	116	129
Eastern Europe	(1)	1	1	1	2
U.S. merchandise trade balance:					
Japan	(1)	10	-87	-108	-23
Germany	(1)	-241	-272	-229	-218
Canada	(1)	397	640	654	673
Mexico	(1)	-10	-20	-10	3
France	(1)	160	170	169	208
Netherlands	(1)	137	177	184	212
United Kingdom	(1)	132	149	163	219
Italy	(1)	154	177	209	217
Belgium	(1)	118	131	202	231
Switzerland	(1)	32	36	44	57
All other	(1)	805	925	1,165	1,364
Total	1,134	1,694	2,025	2,444	2,943
EC-12	(1)	565	653	882	1,081
OPEC	(1)	98	104	132	178
ASEAN	(1)	11	-2	-24	-52
CBERA	(1)	18	25	0	5
Eastern Europe	(1)	11	22	23	31

[1] Import values are based on customs value; export values are based on f.a.s. value, U.S. port of export. U.S. trade with East Germany is included in "Germany" but not "Eastern Europe".

Source: Compiled from official statistics of the U.S. Department of Commerce.

Figure 11
Medical goods: U.S. exports, imports and trade balances, 1988-92

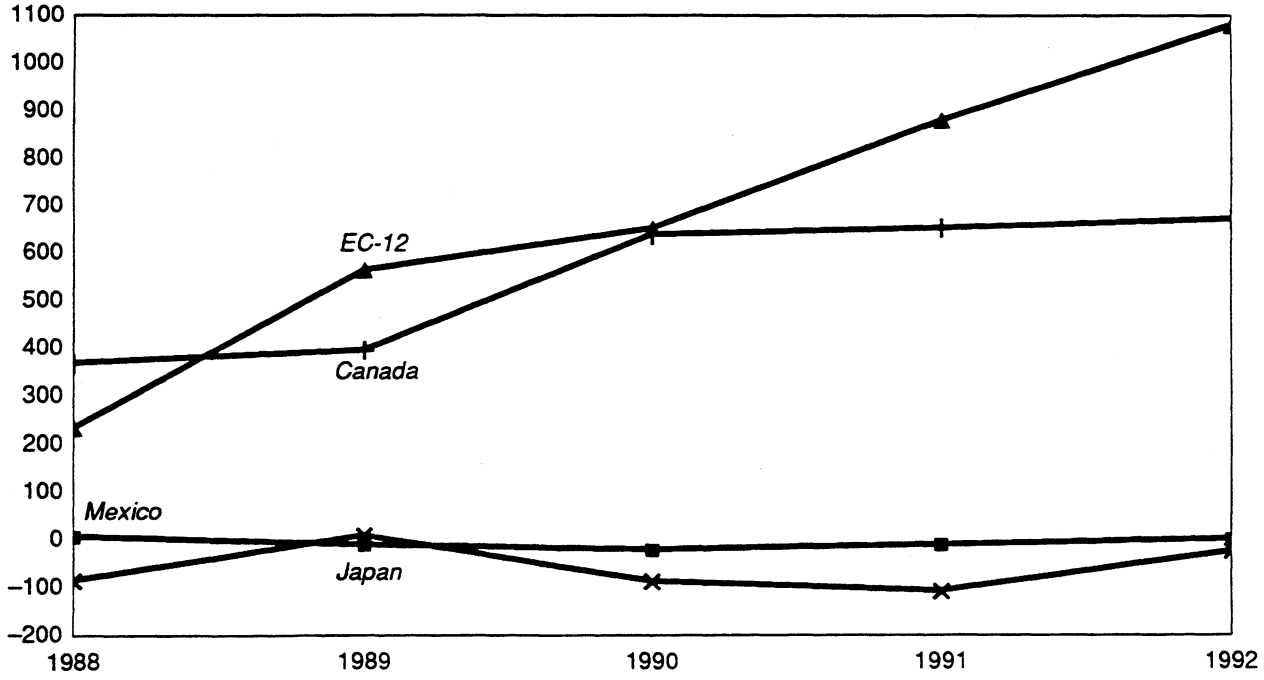
In millions of dollars



Source: Compiled from official statistics of the U.S. Department of Commerce.

Figure 12
Medical goods: U.S. bilaterial trade balance, 1988-92

In millions of dollars



Source: Compiled from official statistics of the U.S. Department of Commerce.

APPENDIX A
EXPLANATION OF TARIFF AND TRADE AGREEMENT TERMS

EXPLANATION OF TARIFF AND TRADE AGREEMENT TERMS

The ***Harmonized Tariff Schedule of the United States*** (HTS) replaced the *Tariff Schedules of the United States* (TSUS) effective January 1, 1989. Chapters 1 through 97 are based upon the internationally adopted Harmonized Commodity Description and Coding System through the 6–digit level of product description, with additional U.S. product subdivisions at the 8–digit level. Chapters 98 and 99 contain special U.S. classification provisions and temporary rate provisions, respectively.

Rates of duty in the ***general*** subcolumn of HTS column 1 are most–favored–nation (MFN) rates; for the most part, they represent the final concession rate from the Tokyo Round of Multilateral Trade Negotiations. Column 1–general duty rates are applicable to imported goods from all countries except those enumerated in general note 3(b) to the HTS, whose products are dutied at the rates set forth in ***column 2***. Goods from Albania, Armenia, Belarus, Bulgaria, the People's Republic of China, the Czech Republic, Estonia, Hungary, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Mongolia, Poland, Russia, Slovakia, and the Ukraine are currently eligible for MFN treatment. Among articles dutiable at column 1–general rates, particular products of enumerated countries may be eligible for reduced rates of duty or for duty–free entry under one or more preferential tariff programs. Such tariff treatment is set forth in the **special** subcolumn of HTS column 1. Where eligibility for special tariff treatment is not claimed or established, goods are dutiable at column 1–general rates.

The ***Generalized System of Preferences*** (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports. The U.S. GSP, enacted in title V of the Trade Act of 1974 and renewed in the Trade and Tariff Act of 1984, applies to merchandise imported on or after January 1, 1976 and before July 4, 1993. Indicated by the symbol "A" or "A*" in the special subcolumn of column 1, the GSP provides duty–free entry to eligible articles the product of and imported directly from designated beneficiary developing countries, as set forth in general note 3(c)(ii) to the HTS.

The ***Caribbean Basin Economic Recovery Act*** (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports. The CBERA, enacted in title II of Public Law 98–67, implemented by Presidential Proclamation 5133 of November 30, 1983, and amended by the Customs and Trade Act of 1990, applies to merchandise entered, or withdrawn from warehouse for consumption, on or after January 1, 1984; this tariff preference program has no expiration date. Indicated by the symbol "E" or "E*" in the special subcolumn of column 1, the CBERA provides duty–free entry to eligible articles, and reduced–duty treatment to certain other articles, which are the product of and imported directly from designated countries, as set forth in general note 3(c)(v) to the HTS.

Preferential rates of duty in the special subcolumn of column 1 followed by the symbol "IL" are applicable to products of Israel under the ***United States–Israel Free Trade Area Implementation Act*** of 1985 (IFTA), as provided in general note 3(c)(vi) of the HTS. Where no rate of duty is provided for products of Israel in the special subcolumn for a particular provision, the rate of duty in the general subcolumn of column 1 applies.

Preferential rates of duty in the special subcolumn of column 1 followed by the symbol "CA" are applicable to eligible goods originating in the territory of Canada under the ***United States–Canada Free–Trade Agreement*** (CFTA), as provided in general note 3(c)(vii) to the HTS.

Preferential nonreciprocal duty–free or reduced–duty treatment in the special subcolumn of column 1 followed by the symbol "J" or "J*" in parentheses is afforded to eligible articles the product of designated beneficiary countries under the ***Andean Trade Preference Act*** (ATPA), enacted in title II of Public Law 102–182 and implemented by Presidential Proclamation 6455 of July 2, 1992 (effective July 22, 1992), as set forth in general note 3(c)(ix) to the HTS.

Other special tariff treatment applies to particular ***products of insular possessions*** (general note 3(a)(iv)), goods covered by the ***Automotive Products Trade Act*** (APTA) (general note 3(c)(iii)) and the ***Agreement on Trade in Civil Aircraft*** (ATCA) (general note 3(c)(iv)), and ***articles imported from freely associated states*** (general note 3(c)(viii)).

The ***General Agreement on Tariffs and Trade*** (GATT) (61 Stat. (pt. 5) A58; 8 UST (pt. 2) 1786) is the multilateral agreement setting forth basic principles governing international trade among its 111 signatories. The GATT's main obligations relate to most–favored–nation treatment, the maintenance of scheduled concession rates of duty, and national (nondiscriminatory) treatment for imported products; the GATT also provides the legal framework for customs valuation standards, "escape clause" (emergency) actions, antidumping and countervailing duties, and other measures. Results of GATT–sponsored multilateral tariff negotiations are set forth by way of separate schedules of concessions for each participating contracting party, with the U.S. schedule designated as Schedule XX.

Officially known as "The Arrangement Regarding International Trade in Textiles," the ***Multifiber Arrangement*** (MFA) provides a framework for the negotiation of bilateral agreements between importing and producing countries, or for unilateral action by importing countries in the absence of an agreement. These bilateral agreements establish quantitative limits on imports of textiles and apparel, of cotton and other vegetable fibers, wool, man–made fibers and silk blends, in order to prevent market disruption in the importing countries—restrictions that would otherwise be a departure from GATT provisions. The United States has bilateral agreements with many supplying countries, including the four largest suppliers: China, Hong Kong, the Republic of Korea, and Taiwan.