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Global Medical Technology

Export Opportunities and Challenges for Device Manufacturers

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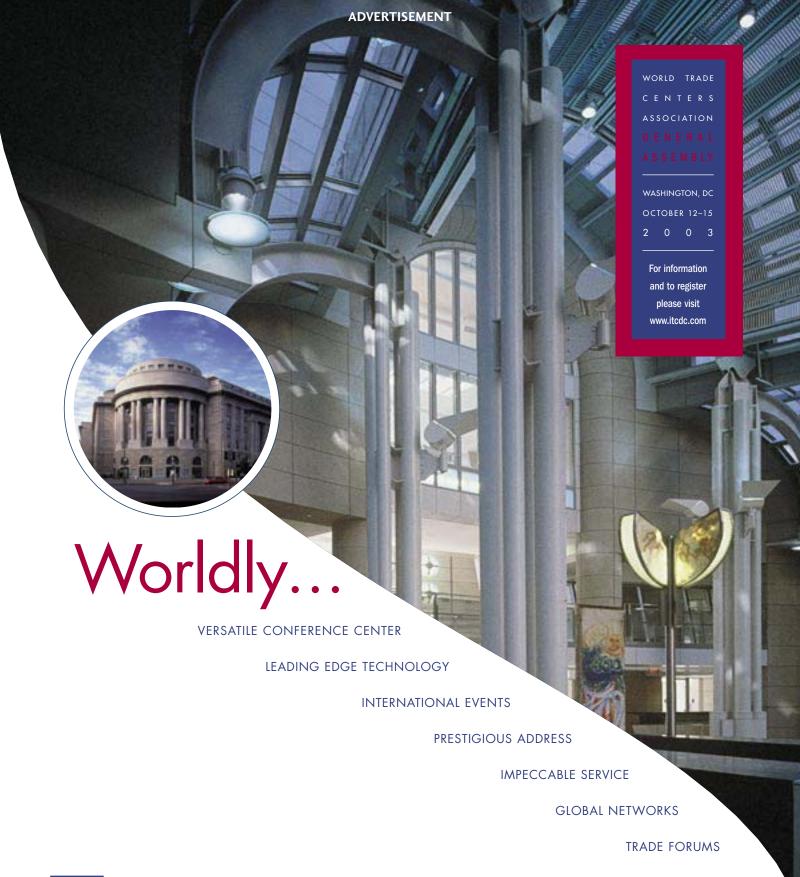
Ask the TIC: An Update on Pre-shipment Inspections

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Vikings and Visionaries: Three Nordic Markets

Share Culture and Technology









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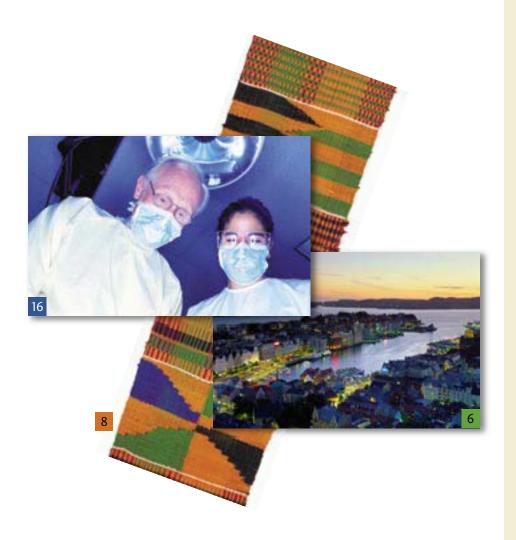
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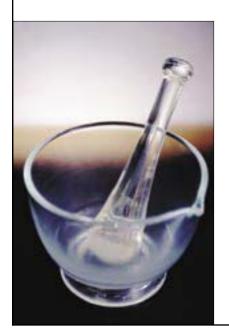
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edicine, according to Webster, is the science and art of diagnosing, treating, and preventing disease and injury.

Its goals are to help people live longer, happier, more active lives with less suffering and disability. Medicine goes beyond the bedside of patients. Medical scientists engage in a constant search for new drugs, effective treatments, and more advanced technology. In addition, medicine is a business. It is part of the health care industry, one of the largest industries in the United States, and among the leading employers in most communities.

Disease has been one of humanities' greatest enemies. Epidemics occur less frequently than in the past. However, the recent outbreak of SARS illustrates the resilience and adaptability of diseases, and—a side effect of our global society—the ease with which they can spread to far-flung regions of the world. While treating illnesses and diseases with modern drugs, vaccines, and procedures has advanced significantly in the past 50 years, some of the most substantial advances in medicine have been in diagnostic equipment and medical devices. Modern technology has allowed medical practitioners to evaluate the health and status of patients with minimally invasive procedures, thanks to advancements in magnetic resonance imaging, computed tomography, and other computer-assisted diagnostics.

American manufacturers of medical and dental devices are world leaders, incorporating advancements in other industries such as new materials, manufacturing processes, and information technology application. This month, our feature article focuses on global medical technology and issues that are affecting the health care industry in developed and developing economies. Advances in medical and dental devices contribute to improved patient care around the world, and the United States drives the industry forward.

Other articles in this issue include a summary of the most recent U.S.-Africa Summit held in Washington, D.C., in June of this year and an update of the requirements of pre-shipment inspections. Next month's feature will look at commercial opportunities in South Africa, and will include an update on the progress of recently-launched negotiations on the proposed free trade agreement with the Southern Africa Customs Union. In between now and then, drop us a line or send feedback to us at export_america@ita.doc.gov or visit our Web site http://exportamerica.doc.gov.

Cory Churches

Cory Churches Editor

■ GLOBAL NEWS LINE

PORTUGAL

The Portuguese market for solid waste recycling equipment offers attractive opportunities for U.S. firms. The amount of urban solid waste in Portugal has increased rapidly in recent years due to the growth in urban population and consumption. Waste generation has increased faster than its elimination. Like other countries throughout the world, Portugal has moved from waste disposal to waste management, and finally to waste reduction. As a member of the European Union, Portugal is required to incorporate into its environmental laws all EU environmental directives, including standards for urban solid waste treatment and recycling. Demand for environmental products and services has been mainly driven by regulations. Polluting firms are changing their attitudes about the environment because the government of Portugal is encouraging them to invest in waste minimization, recovery, and treatment, and to develop clean technologies and products. Municipalities are also encouraged to recycle their urban solid waste. The total value of the recycling equipment market in 2001 was \$55 million. U.S. firms control approximately 7.6 percent of this market. Average annual growth of 10-15 percent is expected during the next two years.

EGYPT

After the creation of the new Ministry of Civil Aviation, the Egyptian civil aviation industry witnessed an acute shift. The new management is focusing not only on upgrading the overall condition and services of Egyptian airport facilities, but also on attracting the world's attention to the importance of Egypt's location and the possibility of acting as a hub for the Middle East and North Africa.

Through the new administration and the general desire to achieve strategic goals in upgrading the



civil aviation industry, plenty of opportunities are regularly available to interested U.S. companies.

VIETNAM

Access control security is a growing market in Vietnam, with good sales potential for U.S. companies in the medium- and long-term future. The total size of the safety and security equipment market is estimated to be \$65 million for 2003, of which safety products account for 60 percent and security 40 percent. Primary sales of safety and security equipment have occurred in the construction market, where the development of power (thermal and hydro), oil and gas (plant and pipeline), transportation (roads and bridges), and buildings (hotels and commercial sites) has outpaced other types of development projects.

The demand for safety and security equipment in Vietnam is also tied to the development of foreign-invested construction and property projects. The current growth of foreign businesses and government infrastructure development has stimulated the safety and security equipment market. In addition to the state budget, the government has relied on substantial assistance from outside sources, particularly official development assistance, to improve and upgrade the country's infrastructure systems. Official development assistance projects help initiate safety and security upgrades in many government-dominated fields, such as the banking, maritime, power, oil and gas, and transportation sectors.

In Vietnam, access control equipment covers fire, anti-theft and burglary, and anti-intrusion monitoring systems, as well as entry control and surveillance systems. Buyers often purchase multifunction products to ensure system compatibility. For example, fire alarm systems may also be incorporated with surveillance or door-entry systems. Security software, including anti-virus systems and low-level firewall solutions, are also found in most companies.

U.S. safety and security equipment is highly regarded in terms of brand recognition and quality. In the long term, the market offers opportunities for additional U.S. companies, as many local companies are eager to represent U.S. products in Vietnam. They are especially interested in U.S. suppliers of automated security systems, such as advanced closed-caption television systems, integrated security systems, electronic card access control systems, smart card technology, intruder detection equipment, and biometric systems.

SOUTH KOREA

The South Korean market for orthopedic artificial joints has been growing rapidly as a result of South Korea's expanding elderly population and patients' increasing awareness of artificial joint implant procedures. In 2001, the total market for artificial joints, based on end-user prices, was valued at \$76.2 million, an increase of 15 percent over 2000. In 2002, the total market value increased to \$91 million, or 19.4 percent over the previous year. Since demand for better health care is

becoming stronger as the South Korean standard of living improves, the market demand for artificial joints is forecasted to grow at an average of 15–20 percent for the next three years.

Currently, imports supply 100 percent of the South Korean demand for orthopedic artificial joints. Hip and knee joints account for 98-99 percent of this market, and extremity joints account for just 1-2 percent. Best prospects for U.S suppliers are knee joints, representing 63 percent of the total market, and hip joints, representing 35 percent. South Korea imports artificial joints for knees and hips from the United States and the European Union. According to industry statistics, imports of hip and knee joints had a total value of \$89.2 million in 2002. U.S. imports had an estimated value of \$58.9 million, while EU imports had an estimated value of \$27.6 million.

One important factor, which may slow the growth rate in market demand over the next few years, is recent medical insurance reimbursement price cuts for orthopedic devices. To address the growing deficit in the national health insurance system, estimated at \$1 billion as of September 2003, the South Korean government has implemented measures to reduce spending and introduced cost-containment policies in all areas, including reimbursement for medical devices.

TAIWAN

Taiwan has a fast-growing manufacturing sector that is oriented toward exports. Taiwanese authorities actively promote industrial upgrades to improve their competitiveness in world markets. Taiwan's manufacturers also continue to modernize their production equipment to hasten the shift toward automation. In addition, the authorities plan to expand public investment to stimulate the local economy. These circumstances will continue to provide a promising outlook for more advanced U.S. process control instruments and apparatus in the Taiwanese market.

The total market for process control instrumentation in Taiwan was \$328.4

million in 2002, of which \$292.6 million were imports. Taiwan imported about 89 percent of its process control instrumentation from Japan, the United States, and Germany. Japanese suppliers led this market, while U.S. suppliers were the second-largest suppliers. Imports of process control instrumentation from the United States were \$83.7 million, or about 28.6 percent of the import market in 2002. The Taiwanese market for imported process control instrumentation will grow as the authorities continue to encourage the importation of process control instruments as they contribute to the upgrading of Taiwan's industries. The market for process control instrumentation is forecast to grow at an average annual rate of 10 percent over the next three years.

VENEZUELA

Venezuela has suffered from economic turmoil and civil unrest this year, beginning with a two-month general strike, followed by exchange controls decreed in February, which are still in force and expected to last at least through the year. In addition, Venezuela has experienced 30 percent inflation and 25 percent unemployment. The country's aviation sector, both commercial and private, has therefore been greatly affected and as a consequence its maintenance, repair and overhaul industry.

Venezuela's maintenance, repair and overhaul industry, consisting of approximately 35 companies, is scaled to the requirements of the civil aviation fleet, not including the military demand for maintenance of its fleet of combat, transportation, and rotary wing aircraft. Venezuela's fleet of civil transports, the largest being of DC-9s, is quite small and does not exceed 100 aircraft total. The remainder of the commercial aviation fleet consists of regional aircraft, including Beech 1900s and ATRs carrying up to 72 passengers. One company, which had a fleet of 21 aircraft, went bankrupt and another, the only one flying to the United States, is presently under category II status imposed by the U.S. Federal Aviation Administration, uses

wet-leased aircraft belonging to a U.S. carrier.

The situation in general aviation is not much different. Many private and executive aircraft have been sold and exported; others are simply grounded permanently in the hope of better financial conditions. Many others are not being flown or very little and their requirements for maintenance and spare parts are extremely small. While part of the reason for the relatively low level of activity by the general aviation fleet is the general economic situation within the country, part is also the absolute scarcity of dollars for the purchase of spare parts by repair shops. Venezuela's general aviation community, which includes air taxi and on-demand leasing services, is almost entirely U.S.made. The fleet consists of about 2,500 airplanes, of which approximately 40 percent are jet or turboprop powered.

Because of the preeminent position of U.S. aircraft manufacturers in this market, the demand for parts, components, and repair or overhaul services is centered on U.S. suppliers. The proximity and the great number of airports within the Caribbean, allow even small aircraft to be flown to the United States for maintenance or overhaul or for the purchase and installation of components, avionics or amenities. Such purchases are not reflected in U.S. export or in Venezuelan import statistics. The same holds true for major work performed on larger aircraft. Reliable statistics are therefore not available. Interviews with facilities reveal that the total value of the market could be more than \$150 million annually. While there are a few non-U.S. airplanes, such as the French ATR, Russian Mi-7 helicopters, and a few Brittan-Norman aircraft, their requirements for spare parts are covered almost exclusively by U.S. dealers of such components.

NEED MORE DETAIL?

Ask a commercial officer at one of the Department of Commerce posts located around the globe. Contact information, including phone, fax and e-mail, is available by calling the Trade Information Center at (800) USA-TRAD(E).

The Information and Communications Market in Western Europe

Report Highlights Prospects in Italy and Spain

by the Office of Information Technology Industries, Trade Development

Western Europe represents the world's second-largest market for information and communications technologies (ICT) and services after North America. In 2002, the value of the ICT market in Western Europe was \$712 billion. According to the latest ExportIT report, the region offers many opportunities for U.S. companies, although the ICT sector is currently in the midst of a slowdown due to the collapse of the Internet sector in the United States. Italy and Spain, the fourth- and fifth-largest ICT markets in Western Europe, respectively, offer excellent opportunities for U.S. companies.

Economic growth remains stagnant in Western Europe, both generally and in technology sectors. Economists and industry analysts do not expect any appreciable general economic recovery before the end of 2003. Lower corporate profitability and lack of confidence have led European companies to focus on cost savings instead of expansion.

Overall, ICT spending is forecast to grow by 3.2 percent in 2003, 40 percent less than predicted two years ago. Other factors hamper ICT market growth in Western Europe.

These include overcapacity in the information technology sector, a critical re-examination of the benefits information and communications technologies bring to business after the drastic dotcom sector decline, and reassessment of the return on investment before a firm approves any new investment in such technologies.

The economic slowdown in Western Europe lagged the decline in the United States by about six months. Investment in information and communications technologies experienced a ripple effect as a result of the decline in Internet activity in the United States. Industry representatives, government officials, and corporate executives believe that the ICT market will not rebound until late 2003 or sometime in 2004.

TRENDS AND OPPORTUNITIES

Large enterprises are concentrating on back-office operations and will streamline them with customer relations management, supply-chain management, e-business, data storage, and IT security systems. Most mobile operators are deferring any further investment in wireless technologies until there is a clear commercial rationale for launching a 3G or universal mobile telecommunications system. New applications have not materialized as rapidly as

thought, and those that have emerged do not offer the kind of advances and efficiencies that were expected. The high cost of 3G mobile devices and the disappointment with 2.5G has not resulted in much enthusiasm for a technology whose benefits have yet to be defined. New applications are seen in the data communications field, as mobile technologies will offer Internet access, e-mail, and other e-business features that will enhance revenue for business users, who are the initial targets of 3G marketing.

Privatization and liberalization over the past decade in mobile and data communications, and wireline markets have introduced greater competition throughout the European Union. This development in turn has driven investments in leading-edge technologies, lowered many telecommunications costs, and encouraged e-commerce development and general Internet use. Nonetheless, competition in most EU countries' wireline markets, including Spain and Italy, remains limited because the telecommunications incumbents (which were recently privatized) still control more than 85 percent of their respective national markets. They remain the dominant providers of telecommunications services, including broadband. This phenomenon has contributed to

slower than expected Internet expansion. Internet penetration rates average 40 percent in the European Union, and less in Spain and Italy.

Electronic commerce is growing, albeit slower than in the United States. Business-to-consumer e-commerce in Spain remains at less than 1 percent of consumer spending, but its growth rate from 2000 to 2001 was an astounding 257 percent. Industry representatives and association executives expect that the economic slowdown will influence on-line consumer spending, and that growth will be minimal this year. Business-to-business transactions will experience a similar slowdown. Despite ambitious plans of the governments of Spain and Italy to encourage ICT diffusion via governmental policies, the private sector holds reservations about investing heavily in new Internet applications at this time.

ENCOURAGING INDUSTRY CONVERGENCE

The European Commission has worked diligently to harmonize telecommunications, Internet, and e-commerce regulations throughout the European Union to foster ICT convergence and trigger economic growth. A basket of initiatives including the eEurope initiative, as well as e-commerce and digital signatures directives, are expected to boost the region's ICT markets. National implementation of these directives is uneven, however, and Spain only recently implemented the e-commerce directive with passage of a law on information society services and electronic commerce. This law features several controversial provisions that have led to legal action in Spanish courts by several privacy advocates and Web site operators.

Additionally, the governments of Spain and Italy are working via their information society blueprints to broaden Internet use in schools and rural communities, promote the use of broadband, and introduce ICT training programs to provide digital opportunities to those

citizens who are not receiving the full benefits of the digital age.

In Spain and Italy, there are many niche opportunities for small and medium-sized U.S. enterprises, particularly with similar firms in both countries. The slowdown in economic activity will require a long-term outlook for those enterprises expecting to expand their business in southern Europe. Growing competition, narrow profit margins from voice services, and general economic contraction have led ICT providers in the European Union to concentrate on business communications, broadband, and mobile data communications. These are areas in which U.S. suppliers can make inroads with careful planning as well as cooperation with in-country partners.

Ultimately, U.S. companies will have to establish a local presence in order to successfully compete in Spain and Italy. The culture, size, distribution systems, and other characteristics of these markets require local organization and support, but the rewards could be worth the effort.

This article draws from the latest *ExportIT* report on Western Europe (highlighting Spain and Italy), which is available at www.export.gov/infotech. Jon Boyens, Damon Greer, and Myles Denny-Brown contributed to the content of this article as well as the full report.

ExportIT

ExportIT reports are a series of indepth studies of foreign IT and Internet markets. They describe and analyze trends, key issues, and events in telecommunications, Internet, and e-commerce adoption in individual and regional markets. These reports help create a framework from which small and medium-sized U.S. enterprises can make educated business decisions about entering foreign markets.

Analysis focuses on the status of telecommunications liberalization, competition in information and telecommunications services, deployment of new technologies, and how these changes are affecting the spread of Internet use and e-commerce.

Economic, cultural, historical, and political factors that influence the adoption of information, Internet, and e-commerce technologies are also vital pieces of these reports. Suggested market entry strategies for smaller firms, as well as U.S. Department of Commerce and other resources to assist U.S. firms in market entry endeavors, are provided.

Look for recently released reports on China and Western Europe (highlighting Germany and France) at www.export.gov/ infotech.





Conference Showcases U.S.-African Commercial Relations

by Robert Telchin

Office of Africa, Market Access and Compliance

Ten years ago, the world knew the tiny nation of Equatorial Guinea for two reasons: as the only Spanishspeaking country on the African continent, and as the producer of sea turtle stamps favored by collectors. For decades, Equatorial Guinea was one of the poorest nations on Earth. The country's dictator, in power until 1979, killed or banished more than a third of the population. Residents were so shut off from the rest of the world that they would greet the one weekly international flight to query disembarking passengers about the outside world.

Today, Equatorial Guinea is known largely for having the world's fastest-growing economy. The country is still far from problem-free, even when compared with neighboring countries. But it produces about one barrel of oil per day for every 1.25 people, a higher ratio than any other country except Qatar, Kuwait, and the United Arab Emirates, and foreign companies are now arriving from all over the world. American investment is estimated at more than \$5 billion, and the country is now of one of the largest destinations in Africa for U.S. exports, mostly in oil and gas-related equipment. The country is far better positioned to fund new schools, health care facilities, and

other projects that can improve the standard of living.

GRADUAL ECONOMIC DEVELOPMENT

Equatorial Guinea's experience is, to some extent, a snapshot of the entire African continent. Largely overlooked and greatly misunderstood by international businesspeople, Africa is finally rising from decades of hardship. President George W. Bush witnessed this firsthand during his five-country tour of the continent in July. Economic growth in Africa, more than 4 percent in 2001, was greater than any other developing region. Some of the biggest emerging market successes can be found in countries such as Senegal, Mozambique, Botswana, and Mauritius. Africa has never suffered from lack of natural or cultural wealth. The challenge has been conceiving ways to effectively channel resources into tangible success stories.

Anyone who attended the U.S.-Africa Business Summit in Washington, D.C., June 24–27, 2003, observed that this is beginning to happen. Most of the United States still undoubtedly views Africa as a place of dejection and despair, but such a perception was lost on the summit's nearly 2,000 participants—they were simply too busy arranging deals and doing business.

Held once every two years by the Corporate Council on Africa (CCA), the summit is the premier gathering of U.S.

and African decision-makers.

Attendees this year included approximately 15 heads of state or heads of government, including President Bush, Secretary of Commerce Donald Evans, and Secretary of State Colin Powell. Other senior Commerce Department officials, including Under Secretary Grant Aldonas, Assistant Secretary for Trade Development Linda Conlin, Minority Business Development Agency National Director Ronald Langston, and Deputy Assistant Secretary for Africa Molly Williamson, played major roles, from speaking at sessions to helping generate business linkages.

TRADE WITH AFRICA

U.S. trade with sub-Saharan Africa, roughly \$25 billion in 2002, is still small in volume and highly concentrated in the energy sector and passenger aircraft sales. But American exports to and investments in Africa are rapidly

diversifying, and there are far more resources available for small and medium-sized American companies to do business in Africa than even just a few years ago. The continent is constructing new airports, building roads, and revamping telecommunications systems. It is doing a great deal to enhance its Internet and IT capabilities. It is also slowly privatizing many of its state-run industries.

Foreign companies are, for the first time, approaching the continent's more than 600 million people as a legitimate market segment that cannot be ignored. And there are huge export opportunities for everything from refurbished construction equipment and frozen chicken to beauty products and solar lighting.

On the import side, the African Growth and Opportunity Act (AGOA) is offering 38 sub-Saharan African countries the most liberal access to the U.S. market available to any country or region that does not have a free trade agreement with the United States. In 2002, AGOA imports increased 10 percent to \$9 billion. Textile and apparel imports were \$803 million in 2002, more than double the 2001 figure.

In June, the United States and the five member countries of the Southern African Customs Union—Botswana, Lesotho, Namibia, South Africa, and Swaziland—launched negotiations toward a free trade agreement in Pretoria, South Africa. Such an agreement would give the United States preferential access to its largest export market in sub-Saharan Africa—worth more than \$2.5 billion in 2002.

The most important part of the U.S.-Africa Business Summit was arguably its private sector participants, who ranged from entrepreneurial shea butter producers from Mali and Rwandan apparel factory owners to Microsoft and General Motors executives. All across Africa, there are terrific commercial success stories. Affiliated Computer

Services (ACS), of Dallas, Texas, digitally processes health care claim forms for Aetna at a facility in Accra, Ghana. This arrangement has been so successful that ACS recently doubled its employees in Ghana from 1,000 to 2,000 people. Philadelphia-based FMC Biopolymer, the chemical unit of FMC Corporation, helps to employ thousands in coastal village communities in Tanzania, Mozambique, and Madagascar to collect and grow seaweed. FMC uses this "farmed" seaweed to manufacture a food-grade polysaccharide used as a gelling medium in consumer products such as toothpaste, pet food, and ice cream.

Largely because of AGOA, most of the 3-Series BMWs in the United States are manufactured at a facility in Rosslyn, South Africa. Dynamic Commodities, of Port Elizabeth, South Africa, is selling its Island Way brand fruit sorbet, duty-free, in 7-Eleven stores throughout the United States. Since October 2001, the Overseas Private Investment Corporation has approved more than three-quarters of a billion dollars for projects involving U.S. commercial ventures in sub-Saharan Africa.

OBSTACLES AND CHALLENGES

Vast obstacles still exist for the continent. No other people have to make more difficult decisions on such a routine basis. And perhaps no challenge is greater than sub-Saharan Africa's HIV/AIDS pandemic. On the continent today, approximately 30 million people have the AIDS virus, including 3 million children under the age of 15. In several African countries, more than one-third of the adult population carries the infection. Each year, 3 million people die from AIDS-related causes, and every day in Africa 8,000 families lose a loved one to AIDS. These figures are the reason why President Bush placed so much attention on the disease during his tour of Africa. They were also the impetus behind the signing of the HIV/AIDS Act, which provides \$15 billion over the next five years to fight AIDS around the world.

These figures are also why the U.S. Department of Commerce is focusing resources on the pandemic in Africa. The department is in the process of working with U.S. pharmaceutical companies as well as firms from other industries to encourage public-private partnerships that address global health care infrastructure problems in developing countries. As a follow-up to the health care infrastructure session it held at the January AGOA forum in Mauritius, the Commerce Department organized three workshops devoted to health care and HIV/AIDS at the June CCA Summit. It will also convene an industry forum on HIV/AIDS this fall.

BUILDING PARTNERSHIPS

And while multinationals have been the most visible face of the private sector in fighting the pandemic, there are opportunities for American companies of all shapes and sizes. As an example, ResourcelinC.com, a Philadelphia-based minority business enterprise, was recently selected by the U.S. Department of Defense to deliver HIV/AIDS education to the Defense Force of Botswana. ResourclinC was so successful it was asked to replicate the program for the Defense Force of Malawi.

In fact, the entire theme of the U.S.-Africa Business Summit was "Building Partnerships." As many of the African heads of state affirmed during the summit, long-term economic development cannot occur until the international community views African countries as legitimate counterparts. One of the week's best-received lines came during the summit's closing speech, from President of Sao Tome and Principe Fradique de Menezes, who asserted that partnerships go both ways: "To turn a phrase of John F. Kennedy, we should not only ask what America can do for us, but what we can do for America."



Ask the TIC

An Update on Pre-Shipment Inspections

by JoAnn Queen and Maria Mussler

Trade Information Center, Trade Development



WHEN IS A PRE-SHIPMENT INSPECTION REQUIRED?

Pre-shipment inspections are required of exports when mandated by the government of an importing country. Pre-shipment inspections may help ensure that the price charged by the exporter reflects the true value of the goods, prevent substandard goods from entering a country, and mitigate attempts to avoid the payment of customs duties.

The following countries currently require or request preshipment inspections:

Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Comoros, Republic of the Congo (Brazzaville), Democratic Republic of the Congo (Kinshasa), Côte d'Ivoire, Ecuador, Ethiopia, Guinea, India (see note below), Indonesia (see note below), Iran, Kenya (under review), Kuwait (see note below), Liberia, Madagascar, Malawi, Mali (under review), Mauritania, Mexico (see note below), Moldova (under review), Mozambique, Niger, Nigeria, Peru, Rwanda, Saudi Arabia (see note below), Senegal, Sierra Leone, Tanzania (Zanzibar only), Togo, Uzbekistan, and Venezuela.

Most countries on the list above request inspections for shipments above certain values. However, in some instances inspections are necessary for all imported products, regardless of value.

In some cases, a country may require pre-shipment inspections only for certain types of goods. For example, India requires a pre-shipment inspection only for certain steel products, and Indonesia for some steel and waste products. Mexico requires a pre-shipment inspection for a variety of goods if they do not qualify for NAFTA tariff preference. A few types of products shipped to Saudi Arabia and Kuwait must contain a "certificate of conformity." Though not referred to as a pre-shipment inspection, this certification verifies that the product conforms to the relevant standard by testing and inspection prior to shipment from the exporting county.

Pre-shipment inspection regulations change often, and contracts for pre-shipment inspections are reviewed periodically.

For more information, exporters can contact inspection companies, freight forwarders, or the U.S. Commerce Department's Trade Information Center.



WHO CONDUCTS THE PRE-SHIPMENT INSPECTION?

Private organizations typically perform pre-shipment inspections. In most cases, importers can select from a shortlist of these organizations when planning inspections. However, sometimes one firm is appointed to carry out inspections for a given country on an exclusive basis. The following is a list of the most widely used private inspection companies:

Bivac/Bureau Veritas

Tel: (305) 593-7878, www.bivac.com

Cotecna

Tel: (305) 828-8141, www.cotecna.com

Intertek

Tel: (305) 513-3000, www.itsfts.com

SGS

Tel: (305) 592-0410, www.gts.sgsamericas.com



WHAT IS THE PRE-SHIPMENT INSPECTION PROCESS?

Generally, an inspection company starts the inspection process when it receives a copy of the inspection order from the importing country. An inspection order states the value of goods, the names and addresses of the importer and the exporter, the country of supply, and the importer's declaration of customs code. The inspection company then contacts the exporter to arrange an inspection site and time.

The steps of the inspection are usually as follows:

- 1) The importer opens an import document or license.
- 2) The importer informs the inspection service in the country of import of a pending shipment, and either pays for the inspection up front or pays a percentage based on the value of the commercial invoice, depending on the terms of the importing country's inspection contract.
- 3) An inspection order is forwarded to the inspection company office in the country of export.
- 4) The inspection company contacts the exporter to arrange the date, time, and location for inspection. It also requests all required shipping documents and price information (invoices). The exporter must provide these documents in a timely manner to avoid demurrage or other penalties.

- 5) The inspection is performed.
- 6) If no discrepancies are noted during the inspection, and once all final documents are received from the importer and exporter, a "clean report of findings" is issued confirming the shipment's value, customs classification, and clearance. The final documents required for issuance of the "clean report of findings" vary by contract but most often include a final invoice and bill of lading or air waybill.
- 7) The goods are shipped to the importing country.
- 8) The importer uses the inspection report to get the imported goods released from customs. If goods reach the border of the importing country without inspection, they usually have to be re-exported to a nearby country for inspection prior to re-entry or are subject to heavy penalties.



WHO ARRANGES AND PAYS FOR THE INSPECTION?

Although the importer is responsible for arranging the pre-shipment inspection, the exporter must make the goods available for inspection in the country of origin. Delays in the process can lead to problems with the shipment and/or increased costs for the exporter. Therefore, it is in the best interest of exporters to work with their freight forwarders to ensure that all information is accurate and is provided to the inspection company immediately after notification of the requested inspection. Requirements for pre-shipment inspections are sometimes spelled out in letters of credit or other documents.

Inspection costs are generally paid either by the importer or by the government of the importing country. However in some cases, the inspection agency may invoice the seller in the event of supplementary inspection visits. The costs associated with presenting the goods for inspection (such as unpacking, handling, testing, sampling, and repackaging) are the responsibility of the seller.



HOW DO I APPEAL THE FINDINGS?

To appeal the findings of a pre-shipment inspection, contact the inspection company's appeals officer. Provide, in writing, to the inspection company the facts concerning the specific transaction in question, the nature of the grievance, and suggested solution.

If exporting to a member country of the World Trade Organization, the WTO agreement on pre-shipment inspections spells out the responsibilities of the exporter and the inspection company. Detailed information on the agreement is available at www.export.gov/tcc or by phoning the Office of Multilateral Affairs, U.S. Department of Commerce, at (202) 482-0603.



Several agencies within the U.S. Department of Agriculture provide inspection services when certificates are required to clear agricultural and food products through customs abroad. Sanitary and phytosanitary (plant health) certificates, which are normally issued to protect U.S. consumers, can also be used for international trade purposes.

The Federal Grain Inspection Service (FGIS) conducts inspections of rice, peas, beans, lentils, all grains, and grain-based processed products. Export quality inspection at the time of shipment is mandatory for bulk or bagged grains and oilseeds under the U.S. Grain Standards Act, including barley, canola, corn, flaxseed, mixed grain, oats, rye, sorghum, soybeans, sunflower seed, triticale, and wheat. (Non-waterborne shipments bound for Canada and Mexico are exempted, however, under the North American Free Trade Agreement.) FGIS is required by law to perform these inspections (for a fee), and it provides the only official grain quality and quantity inspections in the United States. However, some contracts may specify that a particular private firm must perform an inspection as well. For more information about grain inspection, please contact FGIS at (202) 720-0252.

The Animal and Plant Health Inspection Service (APHIS) assists exporters in meeting the plant quarantine import requirements of foreign countries. APHIS conducts inspections to certify that certain products, such as fruits, vegetables, plants, seeds, grains and grain products, lumber, and logs are free from quarantined pests and conform with the phytosanitary regulations of the importing country. For additional information about these inspections, phone APHIS at (301) 734-8537, or see the "Ask the TIC" article on inspection certificates in the March 2002 issue of *Export America*.

Additional certifications may be required in some cases. See other "Ask the TIC" articles on export procedures and requirements at www.export/gov/tic.

FOR MORE INFORMATION

The International Trade Administration of the U.S. Department of Commerce operates the Trade Information Center (TIC) for the 19 federal agencies comprising the Trade Promotion Coordinating Committee. These agencies are responsible for managing the U.S. government's export promotion programs and activities. You, too, can "Ask the TIC" by calling (800) USA-TRADE (872-8723), toll-free, Monday through Friday, 8:30 a.m. to 5:30 p.m. EST. Or visit the TIC at www.export.gov/tic.

Vikings and Visionaries

Three Nordic Markets Share Culture and Technology

by Export America

NORWAY

SWEDEN

The Nordic region is unique in its location between the Baltic region and Western Europe and is a gateway between them. A pan-Nordic identity is built on common culture, geography, history, ethnicity, love of nature, and Scandinavian languages. Three Scandinavian countries—Denmark, Norway and Sweden—are closely related but also differ in many ways. Each is a constitutional monarchy with a high standard of living and a propensity toward technology.

DENMARK

Denmark shares a border with Germany and is connected by bridge to southern Sweden. Its total area of 43,093 square kilometers is slightly larger than that of Massachusetts and New Hampshire combined. The country offers a domestic market of 5.4 million people. Its modern infrastructure, highly skilled labor force, and central location make it an excellent distribution point for the Scandinavian, northern European, and Baltic markets, which together total more than 50 million people. Denmark's standard of living, with a

per capita GDP of \$32,224 in 2002, is among the highest in the world.

Denmark is a member of the European Union, but the country is not a part of the euro zone. The economy is very oriented toward exports and is, therefore, a firm advocate of liberal trade and investment policies. There are 350 American subsidiaries operating in Denmark. Foreign investors in Denmark face very few ownership restrictions. From 1998 to 2000, U.S. direct investment in Denmark tripled to nearly \$21 billion. However, reflective of broader economic trends, U.S. direct investment dropped slightly to \$19.7 billion in 2001. Much of the increase in investment by the United States has been in the form of acquisitions of Danish information technology and telecommunications companies and the establishment of non-financial holding companies. Denmark has a well-established system of commercial law. Expropriation is almost entirely limited to public construction purposes, for which compensation is paid. Denmark has no restrictions on capital transfers and no foreign exchange restrictions. Worker productivity is high, in line with other EU countries,

and corporate taxation is among the lowest in the European Union. Danish wages are high, but employer contributions to social welfare are very low, which results in lower total labor costs than in most northern EU member countries. Intellectual property rights are well protected. The United States is Denmark's largest trading partner outside the European Union and has a 5.2-percent share of total Danish trade in goods. Political and commercial relations with the United States are excellent. Top exports from the United States to Denmark include industrial machinery and capital equipment, such as computers and telecommunications products, software, aircraft, and scientific instruments. Other important U.S. exports to Denmark are military equipment, chemicals, pharmaceuticals, tobacco, wine, fresh vegetables, nuts, and forest products. American-owned firms in Denmark are prominent in information technology and telecommunications products and services, as well as in offshore oil and gas exploration and production.

The most promising sectors for market growth for U.S. non-agricultural companies in the coming year include IT and

telecommunications equipment and services, biotechnology and pharmaceutical products, tourism services, environmental equipment, electrical power systems, offshore oil and gas field equipment, and advanced medical equipment.

U.S. companies are expected to maintain and expand their market share in the coming years. In high-technology areas, such as information technology and medical equipment, U.S. companies are already market leaders and are expected to increase their lead.

NORWAY

Norway is a modern, oil-rich country with 4.5 million people living in a 1,100-mile long, narrow, and mountainous country with a coastline three times its length and strong traditions of fishing and shipping.

Norway has one of the most financially healthy economies in the world, thanks in part to its status as the third-largest exporter of crude oil in the world and one of the largest exporters of natural gas. Other major industries, such as fishing and fish farming, information technology, pulp and paper products, and light metals processing are prospering as well, although Norway's shipbuilding industry is under increasingly heavy competition from foreign shipyards. Norway's unemployment rate has been one of the lowest in the world, but it is now edging above 4 percent. Inflation has been below 3 percent in recent years. With a per capita GDP of approximately \$37,000 based on purchasing power parities (\$50,000 based on current exchange rates), the Norwegian standard of living per capita virtually equals that of the United States. The vast majority of Norwegians are fluent in English, and many have very close cultural and familial ties to the United States. Norwegian business ethics are very similar to those of the United States.

U.S. companies have excellent opportunities to capture a significant share of new contract awards in Norway's defense sector, oil and gas sector, and information technology sector. Other sectors with significant opportunities are telecommunications equipment and services, tourism, drugs and health care technologies, and consumer goods.

Norway is not a member of the European Union, but is linked to the union through the European Economic Area (EEA) agreement, which provides for favorable access to the EU market for most non-agricultural products. By virtue of the EEA, Norway is virtually part of the EU single market, except in fisheries and agriculture. Norway implements most EU directives as a result of its EEA obligations.

The U.S. business presence in Norway is very broad and deep. Over 250 U.S. branches and subsidiaries operate in Norway, and their numbers are growing. An estimated 4,000 more U.S. firms are represented in Norway by nearly 2,000 Norwegian agents and distributors. The United States is Norway's fifth-leading source of foreign investment. The American Chamber of Commerce in Norway is a dynamic voice for American business in the country. The United States is Norway's fifth-largest source of imports.

Norway's market, with the notable exception of agricultural products and processed foods, is transparent and open. Few burdensome technical standards exist except in telecommunications equipment, although there are stringent regulations for chemicals and foodstuffs. Many of Norway's standards are harmonized with the European Union. No country of origin labeling is required.

SWEDEN

Sweden's information technology and telecommunications infrastructure is advanced. According to the latest International Data Corporation global survey, Sweden tops the list as the country with the best leadership in information technology. Sometimes referred to as Silicon Valhalla, or Wireless Valley, Sweden has become the preferred location of many of the top American IT and telecommunications firms, both hardware and software, for not only research and development but also regional headquarters. Few other countries can boast of both a top-notch domestic auto industry as well as a world-class aviation industry. Naturally, this has led to Sweden receiving significant amounts of foreign investment, largely in the mergers and acquisitions arena.

Nordic Public Holidays, 2004

January 1

New Year's Day

April 8

Maundy Thursday

April 9

Good Friday

April 12

Easter Monday

May 1

Labor Day (Norway and Sweden)

May 7

Prayer Day (Denmark)

May 17

Independence Day (Norway)

May 20

Ascension

May 31

Whitmonday

June 5

Constitution Day (Denmark)

June 20

Midsummer Eve

June 21

Midsummer

November 1

All Saints' Day (Sweden)

December 24

Christmas Eve

December 25

Christmas Day

December 26

Second Christmas Day

December 31

New Year's Eve

Sources: Country Commercial Guide: Denmark, FY 2004; Country Commercial Guide: Norway, FY 2004; and Country Commercial Guide: Sweden, FY 2004.

Sweden has not been immune from general economic downturn, but the country's solid infrastructure has contributed to positive developments in biotechnology and life sciences. Sweden's strength in pharmaceuticals and life sciences has led to applications development in information technology that is proving to be quite attractive for U.S. companies. Stem cell research and nanotechnology are flourishing.

While the image of Sweden as a country of lakes, forests, and islands dotted with pretty red cottages persists, this perception highlights a country with high environmental standards, renewable energy utilization, and a preference for "clean" solutions, which fits in well with U.S. technology offerings.

No longer an economy linked just to natural resources of iron, forests, and fish, Sweden today is characterized by its technological innovation, collaboration, and strong educational and research capabilities. Sweden is an ideal test market because of its high regard for U.S. products, coupled with the fact Swedes are known as "early adaptors" and are quick to start or follow trends.

Many Americans think of Sweden as being either Scandinavian or European. It may come as a surprise that a noted political scientist calls Sweden "the most Americanized country in the world, with the possible exception of the United States." Generations of Swedish emigration to America form part of the cultural fabric of Sweden, and few Swedes can claim that they have no relatives in the United States. Almost every Swede is fluent in English, and our cultures have much in common.

Sweden's commitment to exploiting new technology is clearly demonstrated by the level of investment in research and development. Relative to GDP, Sweden leads the world in R&D. This translates into Sweden being a center for collaboration, research labs, and innovation. But this investment is not all in physical hardware; Sweden has a tremendous pool of technical talent, and by virtue of its excellent educational system, the country offers U.S. companies great opportunities for international networking and joint projects. Sweden also ranks as one of the top recipients of foreign direct investment, much of it technology-based, as companies expand operations and acquire Swedish assets.

Sources: Country Commercial Guide: Denmark, FY 2004; Country Commercial Guide: Norway, FY 2004; Country Commercial Guide: Sweden, FY 2004 (all three guides: U.S. Commercial Service and U.S. Department of State, 2003); Survey: The Nordic Region (The Economist, 14 June 2003); and The World Factbook (CIA, 2003).

USEFUL RESOURCES

Denmark

U.S. Embassy, Copenhagen Tel: +45-35-55-31-44 http://denmark.usembassy.gov

U.S. Commercial Service, Copenhagen Tel: +45-35-55-31-44 www.buyusa.gov/denmark

Royal Danish Embassy, Washington, D.C. Tel: (202) 234-4300 www.denmarkemb.org

American Chamber of Commerce in Denmark www.amcham.dk

Danish-American Business Forum www.dabf.dk

Danish-American Chamber of Commerce www.daccusa.org

Norway

U.S. Embassy, Oslo Tel: +47-22-44-85-50 www.usa.no

U.S. Commercial Service, Oslo Tel: +47-21-30-87-60 www.buyusa.gov/norway

Royal Norwegian Embassy, Washington, D.C. Tel: (202) 333-6000 www.norway.org

American Chamber of Commerce in Norway www.am-cham.com

Norwegian-American Chamber of Commerce www.nacc.no

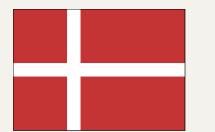
Sweden

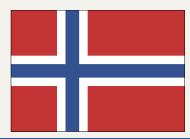
U.S. Embassy, Stockholm Tel: +46-8-783-53-00 http://stockholm.usembassy.gov

U.S. Commercial Service, Stockholm Tel: +46-8-783-5346 www.buyusa.gov/sweden

Embassy of Sweden, Washington, D.C. Tel: (202) 467-2600 www.swedish-embassy.org

Swedish-American Chamber of Commerce www.sacc-usa.org







EXPORTING TO THE NORDIC REGION

Basic Documentation

Commercial invoice: Two copies on seller's letterhead required. The invoice must list FOB and CIF values (itemizing all expenses), BTN number and commodity description, and gross and tare weights. It must also contain a signed declaration that the value stated is full, correct, and true. The shipper signs two copies of the invoice, and they are mailed directly to the importer. The commercial invoice should be dated and include details such as terms of payment and all sales conditions, including discounts granted as well as type of discounts. No certification or legalization is required.

Certificate of origin: Not required, but it may be requested by the importer or bank.

Bill of lading: Two copies required. No special form is necessary, but the bill of lading should include the following information:

- Shipper's name
- Consignee's name and address
- Destination port
- Description of shipment
- All charges
- Number of bill of lading full sets
- Carrier acknowledgment of receipt of shipment (Air waybills obviously replace bills of lading in the case of air shipments.)

Packing list: Not required, but recommended to expedite customs clearance.

Source: Handbook for International Trade (www.joc.com/handbook/exportdocuments.shtml).

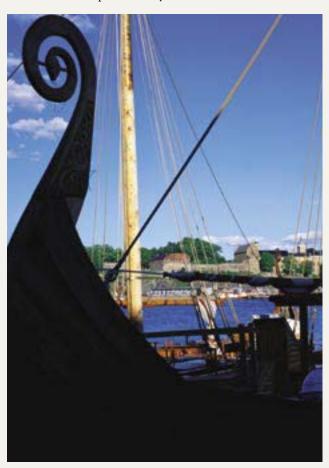
Taxes and Tariffs

As members of the European Union, Denmark and Sweden use the EU Harmonized Tariff Schedule. A copy of this schedule is available as a PDF file on the Trade Information Center's Web site: www.export.gov/tic. Follow the link to tariff and tax information.

Norway's customs tariff schedule is on-line at www.toll.no. The English translation is available by clicking on the Union

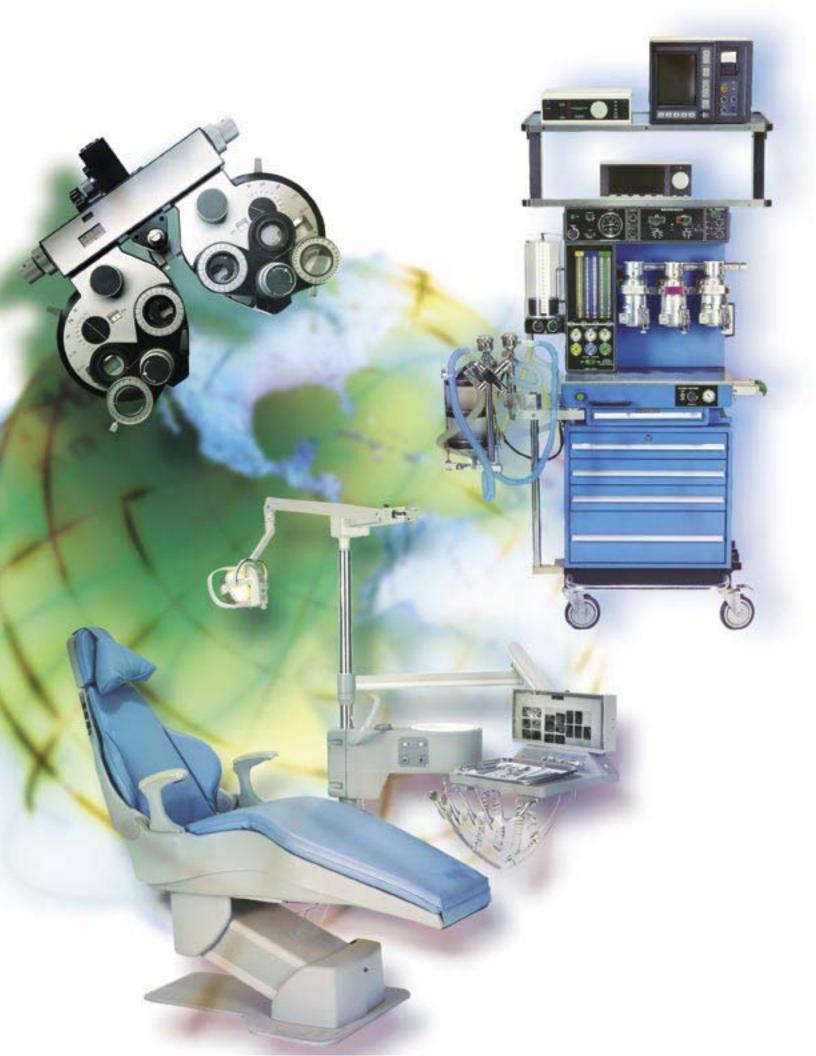
Jack in the top navigation bar. The tariff schedule is in Norwegian, but the tariff item numbers in the customs tariff are identical for both import and export purposes and follow HS nomenclature.

Value-added tax (VAT) for Denmark and Sweden is 25 percent. Sweden has a reduced VAT for certain products that are deemed essential. Norway's VAT is 24 percent. VAT is based on the CIF value plus the duty rate.



Source: Trade Information Center (www.export.gov/tic).

Note: Export and import requirements are subject to change. The information above regarding documentation, tariffs, and taxation is only a general guide. Before exporting, check with customs and export/import regulatory authorities in the Nordic countries and the United States.





Export Opportunities and Challenges for Device Manufacturers

by Richard Paddock

Office of Microelectronics, Medical Equipment and Instrumentation, Trade Development

These days, few topics can ignite the imagination more than the dramatic developments taking place in medical science. While advances in information technologies seemingly dominated the previous decade, biotechnology and medical science now appear to have taken over the limelight. Announcements of progress in medical technologies that allow for earlier detection of diseases and more effective treatment options are now almost daily occurrences. Recent breakthroughs in cardiac research, for example, have led to coronary stents, implantable defibrillators, and minimally invasive bypass surgery, which have together helped reduce the death rate from heart disease by 40 percent over the past 25 years. New advanced diagnostics, like gene-based testing and computer-generated assessments, are saving thousands of lives by detecting a variety of illnesses at more treatable stages.

The advances of the past few decades, however, are only a relatively modest precursor to the amazing developments that will follow in the next 10 to 30 years. Some future predictions boggle the mind—if you believe Ray Kurzweil's Age of the Spiritual Machine,

for example, medical science may well be rebuilding human body parts at the cellular level within the lifetime of many baby boomers. In any case, there are many reasons to believe that our children will witness remarkable events brought about by advances in biotechnology, pharmaceuticals, and medical devices. Organizations like the Advanced Medical Technology Association believe medical technology is on the "cusp of a revolution."

Among those at the forefront of leveraging these biological miracles are medical device companies that bring innovative, life-enhancing and life-saving products to market. The U.S. medical and dental equipment and supplies industry is the most dynamic and innovative in the world, and it is considered by many to be a crown jewel of the American economy. The industry is remarkably innovative-drawing from the technologies of other industries, it incorporates and commercializes advances from sectors including microelectronics, telecommunications, advanced materials, biotechnology, pharmaceuticals, and health care services. The industry is self-sustaining—new medical discoveries create and sustain demand for new innovations to serve those new advances. Also notable is how the sector benefits the overall economy-medical technology spurs economic growth through broad societal benefits and improved productivity.

The American medical device industry unquestionably leads the world, due largely to its commitment to investing heavily in product research and development and its close affiliation with medical and microelectronics research. The United States continues to make significant contributions to improving patient care around the world. The United States is the largest producer of medical technology in the world, as well as the world's largest exporter of medical devices. U.S. companies exported more than \$17 billion worth of medical devices in 2002. Despite past fluctuations in the domestic and world economies and future challenges from looming competition, the U.S. medical device industry remains a vibrant and progressive industry, and the United States is strategically positioned to remain a dominant player in the global market.

INDUSTRY OVERVIEW

The U.S. medical and dental equipment industry is characterized by the production of high-quality devices through the use of advanced technology brought about by heavy investment in R&D. There are 8.000 medical device firms

in the United States, mostly small and medium-sized. More than 80 percent of medical technology companies have fewer than 50 employees, and many, most notably innovative start-ups, have little or no sales revenue. These firms are spread across the country, but they are mainly concentrated in regions known for other high-technology industries, such as microelectronics and biotechnology.

As noted, American medical device companies are renowned for their innovations. Investment in research and development more than doubled during the 1990s and is now more than four times the average for U.S. manufacturers overall. Medical device manufacturers are also benefiting from a new generation of materials and manufacturing processes.

Over the past few years, annual industry production has exceeded \$70 billion and experienced nearly 6-percent annual growth. A source of high-paying American jobs, medical technology workers earn 49 percent more than private sector employees overall and 18 percent more than general manufacturing workers. In addition, the United States holds a competitive advantage in the complementary industries on which the medical device industry relies: microelectronics, telecommunications, biotechnology, and software

development. Medical device exports have generated a consistent trade surplus: more than \$50 billion over the last 15 years, and more than \$2 billion in 2002 alone.

Surgical and medical instruments and supplies comprise the largest subsector of the medical device industry in the United States. In 2002, the United States exported surgical and medical instruments and supplies valued at over \$9 billion, a 10-percent increase over 2001. While exports of this category have continued to grow overall, imports have also increased dramatically.

Surgical appliances also include a broad array of products for outpatient use. Growing reliance on outpatient rather than inpatient procedures, have helped fuel sales of items within this category, especially those intended to reduce labor expenses, curtail hospital stays, and permit patient care in less-expensive settings. The aging populations of developed economies, including those of the United States, Western Europe, and Japan, will also place a heavier demand on home health appliances and supplies.

The American dental equipment and supplies industry covers manufacturers of equipment, instruments, and supplies used by dentists, dental hygienists, laboratories, and institutions of higher education. The United States has historically accounted for about half of the world's market for dental equipment and supplies. U.S. manufacturers of dental equipment and supplies have clearly proven themselves to be competitive in recent years—the United States exported more than \$728 million of dental equipment and supplies in 2002, an increase of about 8.7 percent over 2001. Besides advances in technology, in which the United States has historically been a leader, a general increase in disposable income worldwide has allowed increasing numbers of people to opt for more elective dental procedures, especially cosmetic and restorative. Elective procedures are an ever-increasing source of revenue for the industry. Germany, Canada, and Japan were the top markets for American exports of dental equipment and supplies in 2002. Regionally, the European Union is still the most promising export market for the foreseeable future.

Electromedical equipment manufacturers produce a variety of powered devices, including pacemakers and patient-monitoring systems, as well as diagnostic imaging equipment. The value of U.S. exports in this category reached \$4.4 billion in 2002, a decline from \$4.8 billion in 2001, and imports totaled \$4.5 billion. Demographics and technological advances will continue to increase demand for pacemakers and defibrillators well into the 21st century. While under significant price pressure from group purchasing and heavy competition, leading manufacturers such as Medtronic and Guidant report significant growth in cardiac rhythm management products. Demand for automatic external defibrillators (AEDs) is also growing rapidly, due to technological advances and studies indicating that faster access to AEDs increases survival rates among victims of sudden cardiac arrest. The top three countries receiving U.S. exports—Japan, Germany, and Canada—represent about half of the exported pacemaker and defibrillator market.



U.S. exports of X-ray devices in 2002 totaled \$1.92 billion, a modest rise of 4.2 percent over the 2001 value of \$1.84 billion, and imports totaled approximately \$2.1 billion. The integration of radiology with information systems is the most significant trend affecting diagnostic imaging, and it will profoundly influence product development and purchasing decisions over the next five years and beyond. The initial indication of this trend is the growing popularity of picture archiving and communications systems (PACS). The United States is a world leader in PACS, which replace traditional film with digital technology that may be stored with a patient's medical history. Doctors have remote access to this information, reducing reviewing time and allowing for an increased caseload per doctor. PACS also eliminate the need for film, developing chemicals, and processing labor.

FUTURE OF THE INDUSTRY

Despite its current vibrancy, the U.S. medical device industry faces numerous challenges and is in the midst of radical changes. Generally, the trends, both domestic and global, that will have the most influence on the medical device industry over the next five years are cost-containment efforts, reimbursement processes, regulatory burdens and uncertainties, the availability of venture capital, technological innovations including product convergence, and e-commerce.

Attracting Venture Capital

Venture capital is extremely important in medical technology, especially for small and medium-sized companies with limited earnings in the early stages of development, a typical situation for many innovative firms. Companies state that venture capitalists need a predictable system in order to assess risk, and when obstacles (in the form of uncertainty) prevent access to venture capital funds, there tends to be a decline in innovative activity. Medical device company officials, who view the attraction of venture capital as a critical

Medical Device Manufacturing Roundtable

In July 2003, Commerce Under Secretary for International Trade Grant Aldonas chaired a roundtable in Minneapolis, Minn., that offered officials from medical device manufacturing firms a chance to discuss issues pertinent to their industry. Many of the issues raised at the event are common to other industry sectors, including concerns about the general state of the economy, tax reform efforts, looming competition from abroad, theft of intellectual property rights, excessive patent litigation, and concerns over the direction of science and math education. The issues described below, however, are fairly unique to the medical device and pharmaceutical industries.

Health care cost-containment efforts have had a serious impact on device firms for several years, in many cases changing the way they do business. It is estimated that by 2007, expenditures on health care in the United States will explode to \$2 trillion, thanks in large part to the growing number of elderly who will be eligible for Medicare. Employers and workers cannot keep up the pace in premium increases expected for the private sector, and taxpayers will not be able to shoulder the growing burden of Medicare spending. Cost-containment pressures may also have a dampening effect on innovation. In order to justify paying the costs of medical devices, insurance companies are increasingly demanding that firms offer "proof" that the new technology provides clear, outcome-based benefits, before they will agree to accept any new device as a reimbursable product. Since small firms are usually the innovators in this industry, many cannot afford to bear the burden of time and expense these proofs require.

Reimbursement rates are values at which medical devices are reimbursed to hospitals or other purchasers under health insurance or Medicare assigned by the Center for Medicare Services (CMS) in the U.S. Department of Health and Human Services. The reimbursement amount assigned by the CMS often determines the viability of a product on the open market. Some device manufacturers perceive these rates—and the way they are calculated by the CMS—as subject to uncertainties. The result of these uncertainties, according to some industry officials, is to reduce expected returns on investment and therefore discourage investment in smaller companies working on cutting-edge products. At the recent roundtable on medical device issues in Minneapolis, one company official noted timely patient access to innovative diagnostic tests and other new technologies requires creation of streamlined, transparent, and predictable Medicare procedures. Delays in coverage, coding, and payment procedures by Medicare are all issues that the health care industry is looking to the CMS to solve.

Government regulatory processes are a significant issue for medical device manufacturers. Due to the life-enhancing and life-saving nature of advanced medical products, the medical device industry is regulated to a significant degree and must gain approval for devices from the U.S. Food and Drug Administration (FDA). Approval requirements for medical devices are sometimes perceived as burdensome. The Food and Drug Administration Modernization Act of 1997 is designed to greatly improve the regulatory environment, and the Medical Device User Fee and Modernization Act was passed to try to help speed the process of bringing products to market. There is a perception in the industry, however, that the system of user fees is faltering, due to a lack of funding from Congress. The industry's position is that the FDA, Congress, and industry must work together to prepare the agency for the coming revolution in medical technology.

issue, complain that investors in medical technology must face greater regulatory and policy risk than virtually any other segment of the economy.

Product Convergence

As noted, the American medical device industry funnels a tremendous amount of money into research and development to fund innovation, which will have a significant impact on some medical equipment and supply markets. As medical and biotechnological products converge, one area that will see tremendous growth is drug delivery devices—many treatments and therapies derived from research will not necessarily be available in pill form. Medical devices will therefore act as delivery systems for new products resulting from genetic engineering and biotech research.

Electronic Commerce

E-commerce is significantly affecting the medical device industry, and its influences are likely to grow over the next decade. Most noticeable to consumers is the proliferation of on-line sites featuring product and purchasing information. Institutional purchasers of medical equipment in the United States and abroad are integrating online procurement into supply chain management programs, saving time and money. Patients are also accessing treatment and product information on the Internet and are having more input in decisions affecting their health care. Medical device manufacturers realize savings by publishing device manuals on-line and through "electronic labeling," which allows devices intended for use in health care facilities to use electronic labeling, as long as users have the option of obtaining labeling in paper form.

Reimbursement Issues

Global reimbursement practices have also had negative impacts on the U.S. medical device industry. Many countries around the world are facing the same skyrocketing costs of health care as in the United States, and are trying to trim reimbursement rates by making

it more difficult to even have a product approved for reimbursement at all, or by establishing price caps. Germany, France, and Japan are all examples of markets where the reimbursement rate has been set lower than what American medical device firms deem appropriate, given the level of technology and quality of production.

GLOBAL MARKET

The medical device industry has become increasingly global in scope. An ever-increasing number of multinational firms are aggressively pursuing the global market, focusing greater attention on international sales and revenue, joint ventures, and mergers and acquisitions. Many of the factors that are contributing to the growth in the domestic medical device industry are the same drivers of the global environment. As economies around the globe focus more attention on the health and well-being of their citizens, demand for hospitals and clinics, public health insurance, and general demand for a higher standard of health care will create opportunities for firms in all segments of the medical equipment industry. In order to facilitate expansion, the medical equipment industry is now, and will remain, a globalized industry.

While the United States, the European Union, Japan, and Canada are extremely large and lucrative markets for medical devices, they are mature markets with stable but low annual growth rates. Central Europe will prove to be a promising future market as integration into the European Union will improve the regulatory environment.

Increasing Competition and a Strong Dollar

Even though total U.S. industry shipment numbers remain solid, the rate of growth has slowed somewhat in recent years. Including diagnostic products, the United States exported more than \$20 billion in medical equipment in 2002, a modest increase over the \$19.4 billion in 2001, but a diminished rate

of increase compared with the 11.2-percent rise from 2000–2001. While the dollar's value has been dropping recently, in 2001–2002 the strong dollar made U.S. equipment more expensive overseas, dampening the level of exports. Conversely, the strong dollar has made purchasing foreign equipment cheaper, and imports have experienced double-digit growth for the past several years.

International Regulatory Environments

The medical device industry is a highly regulated industry, and regulatory environments at home and abroad have serious implications on industry performance. An increasingly common practice among developing economies is the establishment of national regulatory requirements in addition to the usual submissions required by developed countries. Device firms are devoting tremendous amounts of time and money to determine requirements, conduct additional overseas clinical trials, and pay for the user fees.

Harmonization of medical device requirements is one way to reduce the industry's burden and ensure maximum accessibility of safe, effective medical devices by patients. The Global Harmonization Task Force is a voluntary organization of regulators and the regulated industry from the United States, the European Union, Canada, Japan, and Australia that works on identifying feasible areas for harmonization of medical device regulation. American industry would like to see products "approved once, accepted everywhere." Many developing countries have been invited to participate in these meetings as observers, and regional working parties for Asia and Latin America have been established.

In the developed world, the regulatory environment is much less restrictive now than it has been in the past. In 1999, the United States and the European Union entered into a mutual recognition agreement which, once

implemented, will allow U.S. device firms to use American-based, third-party organizations called conformity assessment bodies to review products based upon criteria of the EU medical device directive for sale in the EU market, and EU firms to use EU-based, third-party organizations, to recommend approval to the FDA for some products based on FDA requirements for sale in the American market.

BEST OVERSEAS MARKETS

European Union

The European Union has historically been the largest regional export market for U.S. medical devices and is expected to continue to be fertile ground for exports of American high-tech products due to high per capita incomes in most EU countries, a generally favorable regulatory environment, and aging populations. Steady economic growth and political and currency stability make the European Union an attractive market, which accounts for 26 percent of the global medical device market. The largest individual European markets for American exporters, in descending order, are Germany, the United Kingdom, France, Ireland, Italy, Sweden, and Spain.

The European Union maintains a uniquely open and transparent regulatory system for medical devices, based on international standards. Medical devices sold within the European Union must meet the health and safety requirements of EU medical device directive No. 93/42/EEC. This directive consolidates regulatory requirements within EU member countries under one system, meaning if a device can be sold in one country, it is approved for sale in all EU countries. In this system, product approvals are based on evaluations of safety and effectiveness of a device. If a product satisfies the requirements of the directive, the manufacturer may affix the CE mark to the product so that it may legally enter the commerce of any EU member country. Some products may fall under the jurisdiction of more than one EU directive, and must therefore meet the requirements of all the applicable directives to receive the CE mark.

Shipments of U.S. medical equipment and supplies to the 15 nations of the European Union totaled \$5 billion in 2002, representing 44 percent of medical device exports from the United States. This represents a

4-percent increase from the previous year. Surgical and medical instruments, surgical and medical supplies, and dental equipment and supplies are the best-sellers in the EU market. All three of these categories have experienced steady increases in sales, and they continue to look promising in the future.

The success of the U.S.-EU medical device mutual recognition agreement (MRA) will be an important step toward global harmonization of medical device regulatory requirements currently being addressed by the Global Harmonization Task Force. Since the FDA and the EU regulatory systems are the two primary global regulatory systems, harmonization of these two systems will have a positive influence on global harmonization. The United States does not support or seek multiple MRAs with other countries since this goes against the concept of global harmonization and because the United States is using its limited resources to ensure the success of the MRA with the European Union.

Asia

Although buffeted by the financial crisis in the late 1990s, and the recent

Top 10 Markets for U.S. Exports of Medical Devices

Country	1998	1999 (in t	2000 bousands of do	2001 ollars)	2002	Percent Change 2001–2002
Japan	2,002,246	2,134,340	2,356,082	2,537,144	2,395,576	-5.6%
Germany	1,192,376	1,377,041	1,445,568	1,655,764	1,679,968	1.5%
Canada	1,282,051	1,414,021	1,411,291	1,512,893	1,487,074	-1.7%
The Netherlands	1,032,649	995,826	1,109,472	1,112,628	1,353,840	21.7%
United Kingdom	760,163	782,543	893,391	1,051,560	952,030	-9.5%
France	893,649	957,075	856,947	1,012,213	948,892	-6.3%
Mexico	555,981	605,950	773,369	814,688	946,289	16.2%
Ireland	212,700	227,904	346,898	723,510	879,437	21.6%
Australia	454,456	441,724	457,751	461,614	523,153	13.3%
Italy	357,183	429,588	471,780	491,683	518,304	5.4%
Belgium	421,704	498,586	518,632	642,326	514,741	-19.9%

Sources: U.S. Department of Commerce, U.S. Department of the Treasury, and the U.S. International Trade Commission. Data includes NAICS 334510, 334517, and 33911 except 339115.

SARS epidemic, U.S. exports of medical devices to Asia are on track to make significant gains in the near future. Relatively strong figures suggest that the governments and citizens of Asian nations greatly value health care and are willing to make sacrifices in other areas to preserve it. American manufactured medical devices, although more expensive than comparable equipment manufactured in Japan or the European Union, enjoy a reputation for quality and innovation throughout Asia. The recent SARS epidemic, while making

surgery equipment, and MRI systems. In addition, the Advanced Medical Technology Association, working in conjunction with the Office of the U.S. Trade Representative and the U.S. Department of Commerce, has aggressively advanced the economic benefits of innovative products and lobbied against price-control policies. As a result of bilateral negotiations on medical equipment and pharmaceuticals, local governments in Japan are authorized to base medical device purchases on the best overall value

for medical equipment and supplies was estimated at \$2.1 billion in 2002. With more than 1.2 billion people and steady economic growth for two decades, China is increasingly a target market for American exporters of high-technology medical equipment.

Latin America

Despite problems associated with some markets in Latin America in recent years—most notably economic downturns in Mexico, Argentina, and Brazil—Latin America continues to



a temporary dent in regional growth rates, has also reinforced the need for improved health care infrastructure in many countries.

The Japanese market for U.S. medical and surgical instruments amounted to \$917 million in 2002. The main forces driving Japan's demand for medical devices are its rapidly aging population and the escalating rise of health care costs. Thus far, American-manufactured devices have resisted government cost-cutting measures by appealing to the Japanese preference for high quality and innovation, particularly in such areas as CT systems, pacemakers, laser

for performance and specification requirements, not simply on the initial cost of the devices.

China, including Hong Kong, is the second-largest market for U.S. medical device exports in Asia. U.S. exports to China will increase 5 to 10 percent annually for the foreseeable future. American medical device exports to China totaled \$350 million in 2002, an increase of 3.2 percent over 2001. When Hong Kong is included, however, total U.S. exports reach \$624 million. Many in the industry believe these figures actually understate the actual size of China's market. China's overall market

be a promising market for U.S. medical device manufacturers. As one of the most highly dependent regions on imported medical products, Latin America currently provides significant opportunities to U.S. exporters. In 2002, sales to Latin American markets exceeded \$1.9 billion, roughly equivalent to sales for 2001.

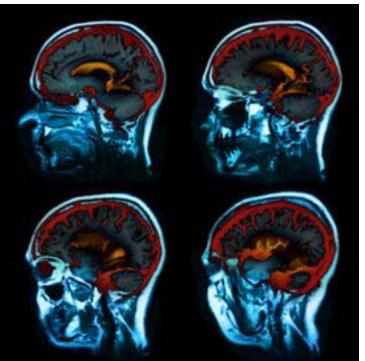
Several positive trends have emerged in the Latin American health care sector. For example, many countries in the region embarked on health care reform programs as early as the mid-1990s, and results are slowly emerging. In many developing countries, health authorities are reforming insurance regulation to ensure availability of comprehensive insurance coverage, both private and public, for citizens even of limited economic means. Mexico's National Development Program, created in 1995, has seen results through an increase in health care spending, an expansion of coverage under the government's social security program, and a decentralization of management. Chile's 1994–2000 Health Sector Reform Project has doubled the health budget since

1990 and increased construction of therapeutic diagnostic centers and hospitals to enhance primary care and improve emergency and ambulatory care services. In many developing countries, health authorities are reforming insurance regulation to ensure availability of comprehensive insurance coverage, both private and public, for citizens of even limited economic means.

Mexico remains the top market for U.S. medical equipment exports in Latin America, accounting for more than half of exports to the region. More than 50 percent of

the medical device import market in Mexico belongs to U.S. firms. While other countries showed diminishing numbers, total U.S. exports of medical devices and supplies to Mexico grew by about 18 percent from 2001 to 2002. Under the North American Free Trade Agreement, tariffs have been eliminated on almost all medical devices, providing an added incentive for interest in the market. Final elimination of tariffs on remaining medical devices will occur by the end of 2003.

Despite currency devaluation in recent years, which caused sales values to decline, Brazil remains a major market and the second leading importer of American-manufactured medical devices in Latin America. In 2002, Brazil imported American medical and ophthalmic equipment valued at \$328 million. Brazil's economic slowdown affected government investment plans for public hospitals, and the challenge for Brazil will be finding means to improve public health care facilities with less government funding. Brazil has taken significant steps to improve its regulatory environment including the creation of Agencia Nacional de



Vigilancia Sanitaria, but more needs to be done.

U.S. medical equipment is not only seen as desirable in the larger economies, but also in smaller economies such as the Dominican Republic, Costa Rica, Honduras, and Panama. High quality, reliability, durability, favorable prices, good maintenance service, and timely delivery are the main factors for increasing sales in the medical sector. In Central America, the aftermath of Hurricane Mitch brought funds for rebuilding the infrastructure of these nations, and a major emphasis is being placed on the health

of citizens. New hospitals and health clinics are being built, which provide numerous opportunities for American firms to supply the region with medical devices.

The U.S. medical device industry has a clear understanding of the future challenges it faces in the global marketplace and is taking steps to address them. Despite these challenges, the American medical device industry will likely remain dominant in the years ahead. The International

Trade Administration of the U.S. Department of Commerce stands ready to help the industry in global markets through a variety of trade-facilitating programs. The International Trade Administration has a number of market research products to help companies interested in selected markets. The Office of Microelectronics, Medical Equipment and Instrumentation (OMMI) maintains a Web site that offers profiles of regulatory environments in several countries, and the office will be releasing a study on Brazil's medical device marketplace in the fall of 2003. The Department of Commerce also has a

number of trade missions and other trade promotion events scheduled for the coming year, as well as an active project advocacy program. U.S. companies seeking assistance can contact OMMI at (202) 482-3360, or visit www.trade.gov/td/mdequip.

Thank you to Gerry Zapiain and Jay Biggs, in the Office of Micro-electronics, Medical Equipment and Instrumentation, for their contributions to this article.

Trade Events

September 2003-April 2004

DATES	EVENT	LOCATION			
September 21–23	Franchising Trade Mission Shanghai, China; Singapore The Commercial Service is organizing a franchising trade mission to Singapore and Shanghai, China. In Singapore, the mission will coincide with the largest franchising show in Asia, Global Franchising 2003.				
September 23–26	U.S. Building Products Trade Mission Sales of building products and construction materials will continue to flourish during the next five years in Canada's buoyant residential and renovation construction market. U.S. exporters, with building products for the housing and renovation sectors, can profit from Canada's booming residential construction/renovation markets and increase their export sales in Canada by participating in this event.				
September 24–27	Edifica 2003 Santiago, Chile This regional trade show includes building materials, construction equipment, and related services.				
October 5–7	Golf Europe Munich, Germany The Office of Consumer Goods, in conjunction with the U.S. Commercial Service in Munich, Germany, is sponsoring a U.S. product sample and literature center at Golf Europe. This promotion should help U.S. companies that are looking for distributors, joint venture partners, or new sales opportunities. Golf Europe is Europe's leading golf equipment trade show.				
October 6–10	Electronic Americas São Paulo, Brazil This biennial international trade fair is the largest event of its kind in South America for electronic components, assemblies, and electronics production. Electronic components constitute the best prospect for U.S. exports to Brazil. Participation in an event of this magnitude is an ideal venue for small and medium-sized U.S. enterprises to gain exposure or to expand their presence not only in the Brazilian market but also in the surrounding region.				
October 7–12	TIB 2003 Bucharest, Romania The Bucharest International Fair is the leading commercial event in Romania and one of the most prominent trade fairs in Eastern Europe. It is a general technical fair, with strong emphasis on industrial equipment and industrial consumer goods. The fair consists of 41 separate pavilions and includes 55,000 square meters of indoor space and 45,000 square meters of outdoor space.				
October 11–15	WEFTEC Los Angeles, Calif. The Water Environment Federation's 76th Annual Technical Exhibition and Conference will bring together water and wastewater industry professionals from around the world. WEFTEC is the largest water and wastewater show in North America.				
October 16–21	EquipAuto 2003 Paris, France EquipAuto is the world's most comprehensive exhibition for the automotive industry, covering new technologies in original equipment, spare parts, customer service, and garage equipment. There will be two specialized U.S. pavilions for which the Commercial Service in France will provide support. EquipAuto will offer workshops, conferences, and seminars to bring together engineers, managers, buyers, and sellers.				
November 12–14		Hong Kong largest showcase for products and services in cosmetics, toiletry, y sectors. Celebrating its eighth year in Asia, Cosmoprof will feature -scale U.S. pavilion.			
November 13–17	Moscow, Russia reat potential for U.S. companies. InterCHARM is the largest beauty tern Europe. In 2002, more than 600 companies from 23 countries ors. The cosmetics and health products market is one of the				

HIGHLIGHTED EVENTS

EXPO USA 2003

DOMINICAN REPUBLIC SEPTEMBER 16-17, 2003

Organized by the U.S. Commercial Service, this is the premier event of its kind in the Caribbean region. Through Expo USA, new-to-market U.S. companies have an excellent opportunity to contact potential agents, distributors and end users, not only form the Dominican Republic but from other Caribbean countries. In addition to the exhibition, participating firms obtain appointments with qualified sales representatives and buyers, as well as briefings on the individual markets of the entire region.

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AEROSPACE TRADE MISSION

POLAND, ROMANIA, AND THE CZECH REPUBLIC **NOVEMBER 3-7, 2003**

The U.S. Commerce Department's Office of Aerospace is organizing a trade mission to Poland, Romania, and the Czech Republic. A senior-level official will lead the mission. The delegation will include representatives from a variety of U.S. aerospace firms interested in Central Europe, as Poland, Romania, and the Czech Republic prepare to join the European Union. The mission will focus on aircraft products and services, but it will also be open to firms that offer solutions to airport infrastructure needs, including airport security.

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DATES	EVENT	LOCATION			
November 20–22	Expo Pesca 2003 Lima, Peru Expo Pesca 2003 is an international trade show of equipment, supplies, and services for the fishing and fish farming industries. The U.S. Commercial Service in Lima will have a booth at the show and will host a catalog exhibition for U.S. firms unable to exhibit directly. Fishing is the second-largest industry in Peru, representing more than 5 percent of GDP and over 10 percent of total exports.				
November 26– December 6	Essen Motor Show This show features automotive tuning and racing equipment and accessories, as well as classic and antique vehicles. In addition, a wide range of customizing items are displayed, and part of the show concentrates on auto high-fidelity equipment and related products. Although the Essen Motor Show mainly attracts consumers, wholesalers and distributors also visit the show to view the newest products in each sector.				
December 3–5	Natural Products Asia 2003 This show features all products, edible and non-edible, related to healthy lifestyles and developing a healthy planet. It includes 200 exhibitors and 5,000 professional buyers. This fair will allow U.S. companies in the natural products industry to establish ties, and demonstrate their products to buyers, in Asia.				
January 8–11, 2004	International CES International CES is the world's largest annual trade show for the broad-based consumer electronics technology market. It is the premier event bringing together consumer electronics manufacturers, distributors, researchers, and content developers.				
January 9–11, 2004	Reisemarkt Rhein-Neckar-Pflaz This regional consumer travel show attracts approximately 22,000 visitors from the Rhein-Neckar region of Germany (2 million inhabitants). In 2002, there were 240 exhibitors from 18 countries. U.S. tourism firms can benefit from increased exposure through a unified U.S. tourism presence. Literature should be in German if possible.				
January 19-22, 2004	International Builders' Show Las Vegas, Nevada This show is the largest building industry trade show in the United States and also includes the largest number of construction related meetings, seminars, and workshops in the world. There are more than 1,000 individual manufacturers and suppliers who exhibit.				
February 2–5, 2004	Environment and Energy 2003 Abu Dhabi, United Arab Emirates Environment and Energy 2003 will focus on relieving strains on the environment in Middle Eastern and North African countries. Emphasis is being placed on clean air, water supply, waste disposal, alternative energy sources, renewable energy, health, and safety.				
February 16–18, 2004	Stadia China 2004 In order to prepare for the 2008 Olympic Games, Chinese officials have scheduled this event to attract the world's best builders and managers of stadiums and arenas. There will be 300 exhibitors from 20 countries, including 100 U.S. participants.				
February 24–29, 2004	Asian Aerospace 2004 Asian Aerospace is the world's second-largest air show after the Paris Air Show. More than 700 exhibitors from 36 countries were at the last show, which attracted over 23,000 visitors from 78 countries. Approximately \$3.2 billion worth of trade deals were made as a result of the show. For more information, see www.asianaerospace.com.				
March 17–20, 2004	trendy topics as medical, beauty, nut	Brussels, Belgium an health, beauty, and fitness industry. This trade fair covers such ition, fitness, natural home life, and "wellness" services. Life2 2003 ,022 visitors (an increase of 56 percent compared with 2002).			

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Health Care Services

INFORMATION AND COMMUNICATIONS **TECHNOLOGY MISSION**

NORTHERN IRELAND AND THE REPUBLIC OF IRELAND NOVEMBER 17-21, 2003

Department of Commerce technology-sector leaders will convene a senior-level business development mission to Belfast, Northern Ireland, as well as Dublin, Republic of Ireland.

The focus of the mission will be to help U.S. companies explore business opportunities in both Northern Ireland and the Republic of Ireland. The delegation will include approximately 12 senior executives of small, medium-sized, and large U.S. firms representing the information and communications technology sector. Technology products and services have become an increasingly important part of U.S. trade with Northern Ireland and the Republic of Ireland, with both regions possessing highly skilled technology workers and end users.

Meetings will be arranged with senior government officials and potential business partners. Representational events also will be organized to provide mission participants with opportunities to meet Northern Ireland's and the Republic of Ireland's business and government representatives, as well as U.S. business people living and working in Northern Ireland and the Republic of Ireland.

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MEDICARE INDIA 2004

INDIA APRIL 6-8, 2004

With a market of \$21 billion and an estimated 17-percent annual growth rate, India's health care industry is a prime target for medical and health care equipment and services. About 80 percent of India's medical equipment is imported. U.S. companies should take advantage of this opportunity to garner their share of this growing market by participating in Medicare India 2004. This event is expected to be the largest international medical and health care exhibition in India and to attract a large number of trade visitors.

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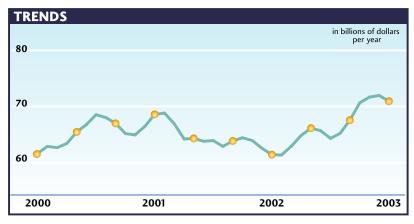
E-mail: Steven_Harper@ita.doc.gov

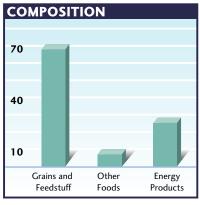
A full listing of trade events is available via www.export.gov.

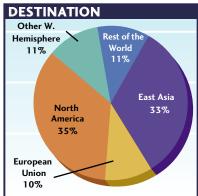
Quarterly Trade Data

As of First Quarter 2003

FOOD AND ENERGY







MATERIALS

Monthly data are centered, three-month moving averages, based on seasonally adjusted figures and expressed as annual rates.

Product categories (except for services) are based on end-use classification. Commercial services include all private services.

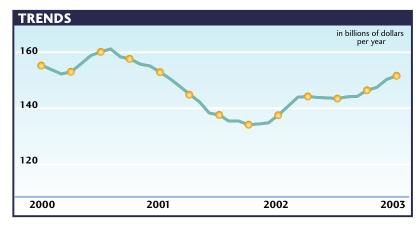
North America: Canada and Mexico.

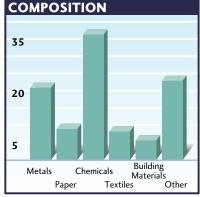
European Union: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

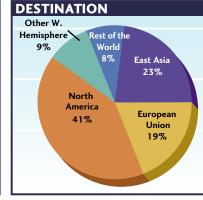
East Asia: China, Hong Kong, Indonesia, Japan, Malaysia, the Philippines, Singapore, South Korea, Taiwan, and Thailand.

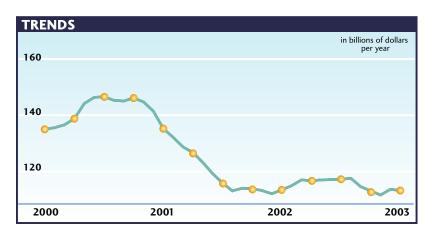
The chart showing exports of services by region is based on data for the 2001 calendar year. Other charts showing product mix and destination are based on data for the year ending April 2003.

Sources: Bureau of the Census (goods), Bureau of Economic Analysis (services).

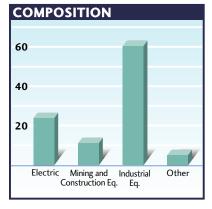






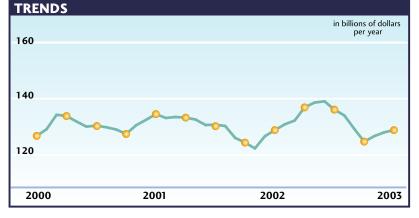


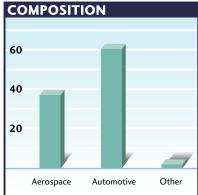














Additional information is available from the International Trade Administration (www.export.gov/tradestats),

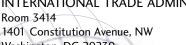
the Bureau of the Census (www.census.gov/foreign-trade/www),

and the Bureau of Economic Analysis (www.bea.gov).

U.S. DEPARTMENT OF COMMERCE

INTERNATIONAL TRADE ADMINISTRATION

Room 3414 Washington, DC 20230







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