

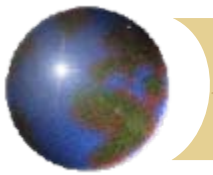
*Presentation to Medical Device
Industry Supply Chain Council Year-
End Meeting
November 28, 2007*

**Overview of Global Medical Device Market
and Available ITA Resources**

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Topics for Presentation

- ❖ DOC/International Trade Administration Services to Firms
- ❖ Global Medical Device Market
- ❖ Medical Device Supply Chain Issues
- ❖ Medical Device Reimbursement and Regulatory Issues
- ❖ Several Key Medical Device Markets
- ❖ Crystal Ball Predictions

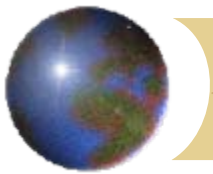


DOC/ITA Services to Firms

ITA's Mission

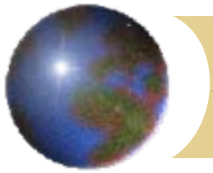
To create prosperity by strengthening the competitiveness of U.S. industry, promoting trade and investment, and ensuring fair trade and compliance with trade laws and agreements

- ✚ Trade Promotion/Expanding Exports
 - ✚ U.S. and Foreign Commercial Service (FCS)
- ✚ Trade Compliance/Barriers/"Country Experts"
 - ✚ Market Access and Compliance
- ✚ Competitiveness/Industry Outreach/"Sector Experts"
 - ✚ Manufacturing and Services
- ✚ Enforcing Trade Laws (AD/CVD)
 - ✚ Import Administration



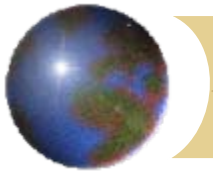
ITA Services to Firms--FCS

- ITA is the U.S. government's primary trade promotion agency
- Mission: To help all companies (particularly small and medium-sized) succeed in global markets
- ITA has over 2,000 trade professionals worldwide (mostly FCS), based at 160 offices in 82 countries
- Commercial officers based in markets representing 96% of world exports
- Trade specialists also in more than 100 export assistance centers across the U.S. and at our headquarters in Washington D.C.



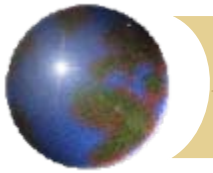
ITA Services to Firms—MAC

- ✦ Market Access and Compliance (MAC) has analysts covering countries worldwide
- ✦ Also have offices for activities relating to multinational agreements (EU, NAFTA, APEC)
- ✦ Leads Commerce team in trade negotiations
- ✦ Aware of broad trends in country/region
- ✦ Often leads when industry has complaint about market access/regulations in country



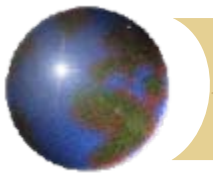
ITA Services to Firms—MAS

- ✦ Manufacturing and Services analyzes economic trends and important policy developments in manufacturing and services
- ✦ Offices include pharmaceuticals/medical devices (OHCG), aerospace/autos, and energy/environment (for manufacturing) and finance, travel and tourism, and other industries (for services)
- ✦ Promote U.S. and global competitiveness
- ✦ Data and descriptive analysis



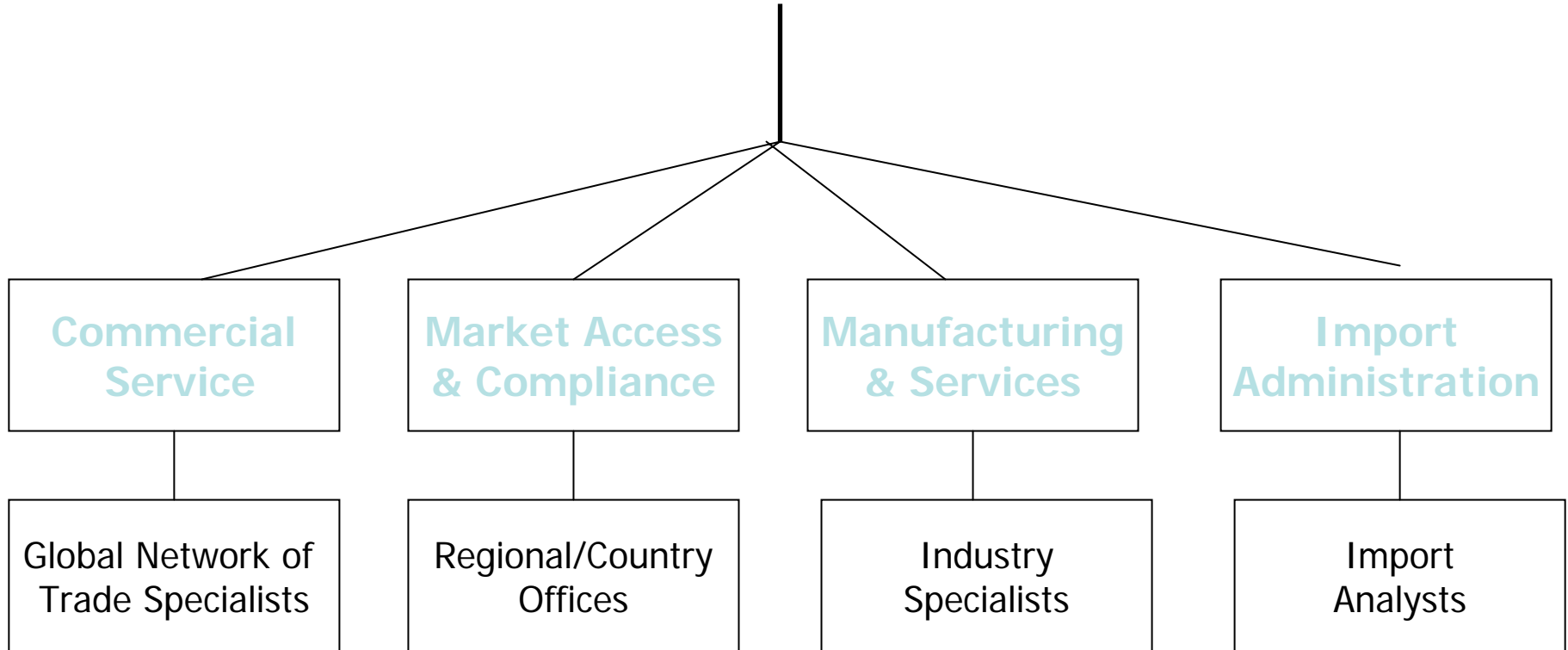
ITA Services to Firms—OHCG

- ❖ 2 teams: Health Products and Technologies (HPT—pharmaceuticals, medical devices, biotech) and Consumer Goods (nutritional supplements, toys, footwear, furniture, processed foods, motorcycles, alcoholic beverages, etc.)
- ❖ HPT covers markets globally, focusing on China, India, Brazil, EU, Mexico, Korea and Southeast Asia
- ❖ HPT analysts also take a lead role on global issues such as stopping the spread of counterfeit medical products, Health IT, biosimilars, global regulatory harmonization, etc.



DOC/ITA Services to Firms

International Trade Administration (ITA)



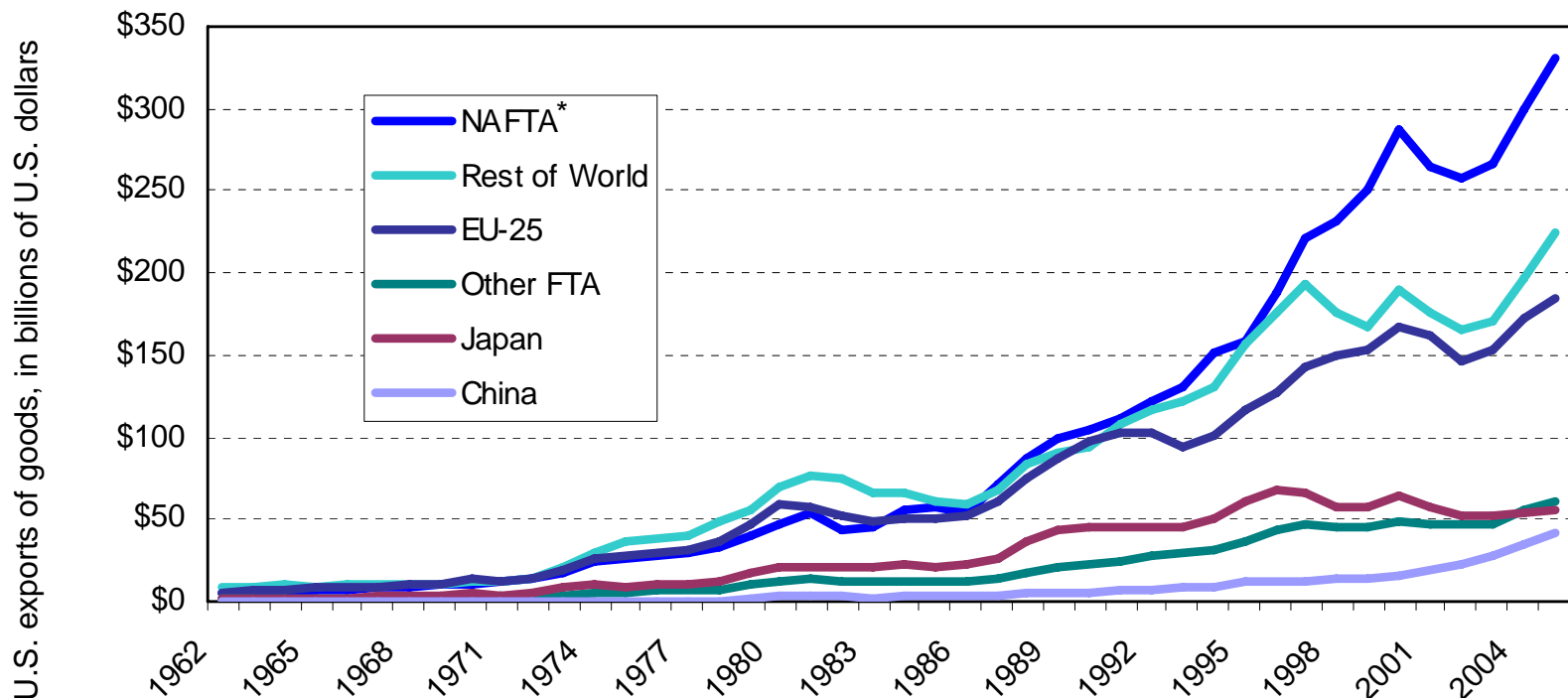


Trade Data (Source: U.S. Census Bureau, U.S. International Trade Commission)

- 2006 exports >\$1 trillion for 1st time ever (+14.4% compared to 2005)
- Exports to 59 of top 60 markets increased in 2006
- Canada: \$198.2 billion (21.3% of total exports; +8.2%)
- Mexico: \$114.6 billion (12.3%, +12.7%)
- Japan: \$55.6 billion (6%, +8%)
- China: \$51.6 billion (5.6%, +32.9%)



U.S. Goods Exports by Region

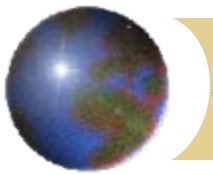


NAFTA = North American Free Trade Agreement. FTA = free trade agreement.

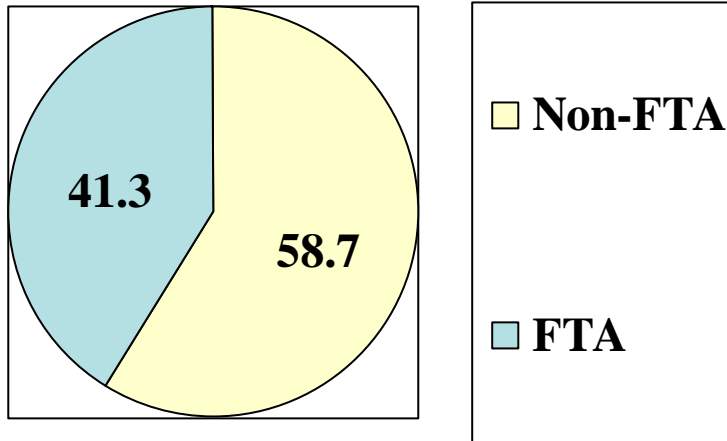
*Figures for the European Union include historical data for all current 25 member nations, excluding Estonia, Latvia, Lithuania, and Slovenia (data are for 1992-2005).

Note: Dollar figures are actual dollars.

Source: U.N. Merchandise Trade Data, SITC Rev1; U.S. Department of Commerce, International Trade Administration, Trade Policy Information System.



U.S. Free Trade Impact--% of Exports to Countries with FTAs



- Countries with FTA about 7% of 2006 global GDP
- U.S. exports to Chile have increased 155% since implementation (1/1/04)
- U.S. exports to Singapore have increased 47% since implementation (1/1/04)
- U.S. exports to Australia have increased 25% since implementation (1/1/05)



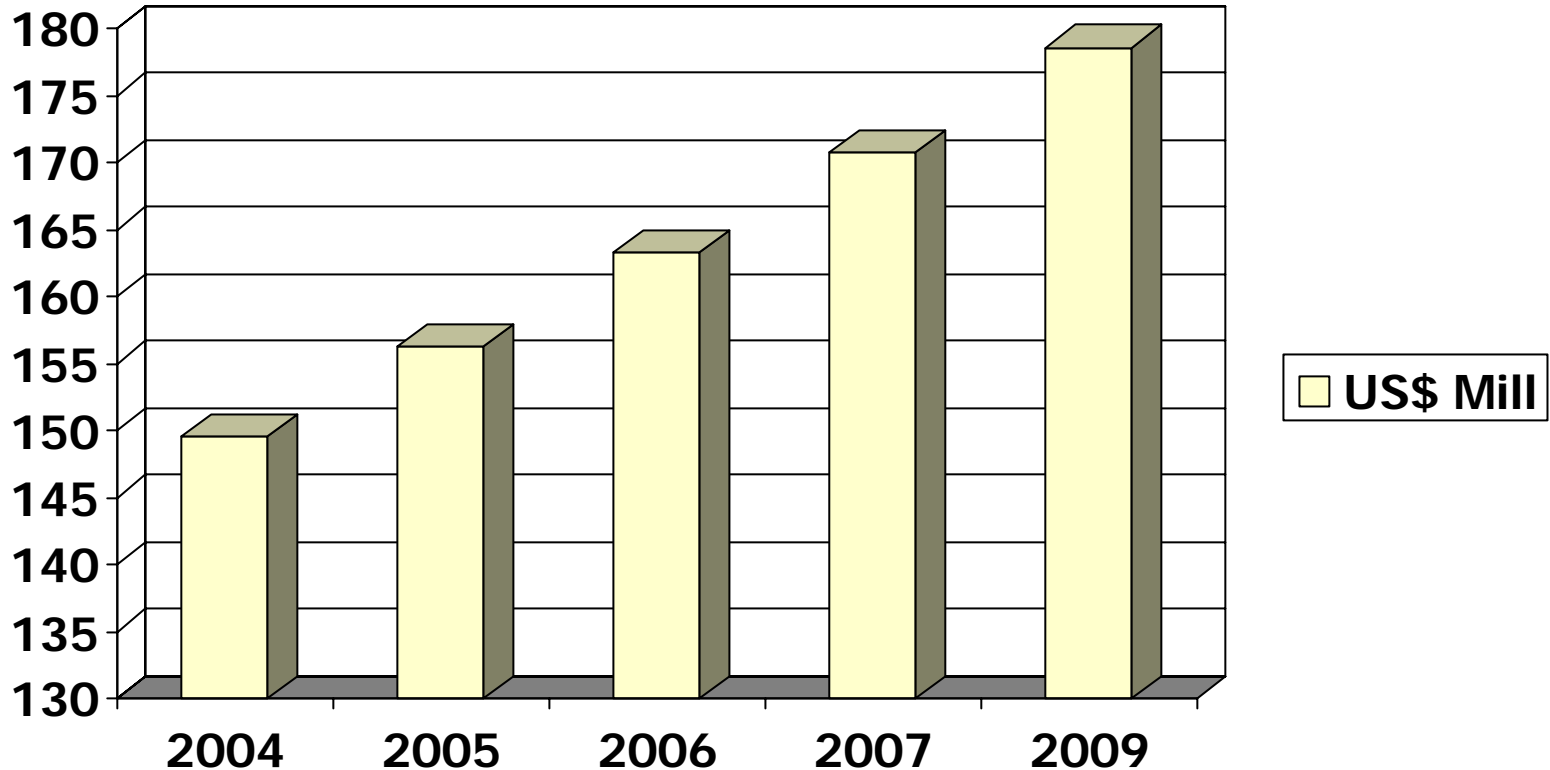
Global Medical Device Market-- Overview

- ❖ U.S. medical technology companies lead the world in medical device production
- ❖ Medical device R&D doubled during the 1990s and is currently more than three times the average for U.S. manufacturers
- ❖ The United States is by far the world's largest producer of medical technologies
- ❖ As you can see from the next chart (most recent data available), the global medical device market is projected to increase from 2004 to 2008 at an 4.5% annual growth rate to almost \$180 Billion in 2009



Global Medical Device Market

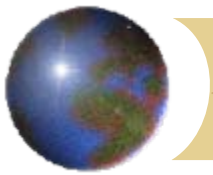
World Projected Medical Device Market 2004 - 2009





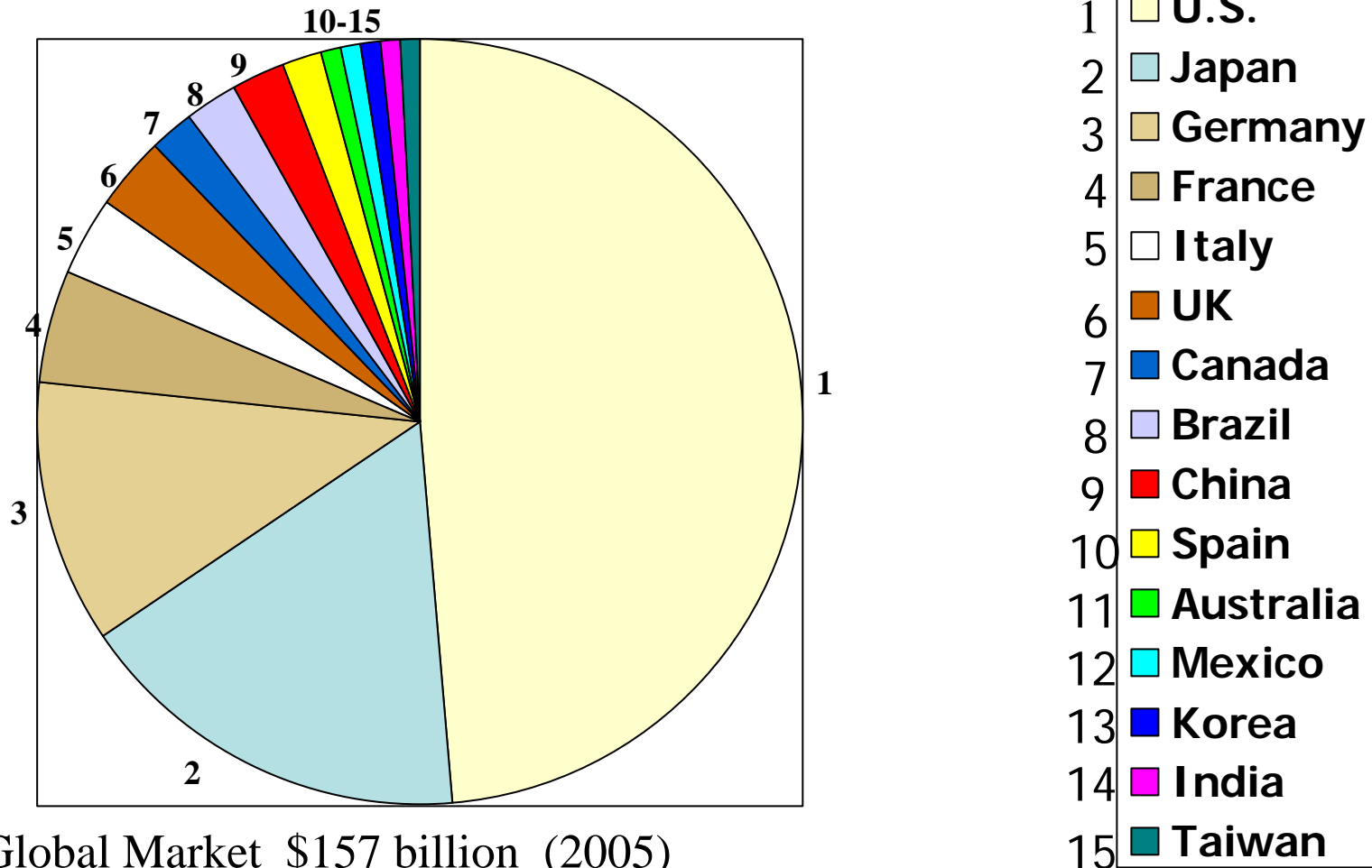
Global Medical Device Market— Major Consumers/Opportunities

- ✦ The five largest global markets for medical devices (U.S., Japan, Germany, France, and Italy) account for 13.1% of global population and 76% of global medical device use
- ✦ U.S. share of world medical device market has held around 50% in recent years
- ✦ Conversely, the five most populous countries (China, India, Indonesia, Brazil and Pakistan) account for nearly half of the global population but only 4.4% of global medical device use

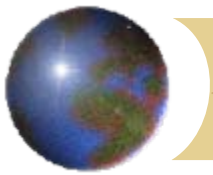


Global Medical Device Market

Relative Market Size for Major Consumers

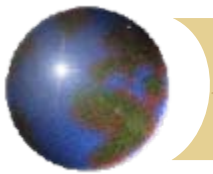


Total Global Market \$157 billion (2005)



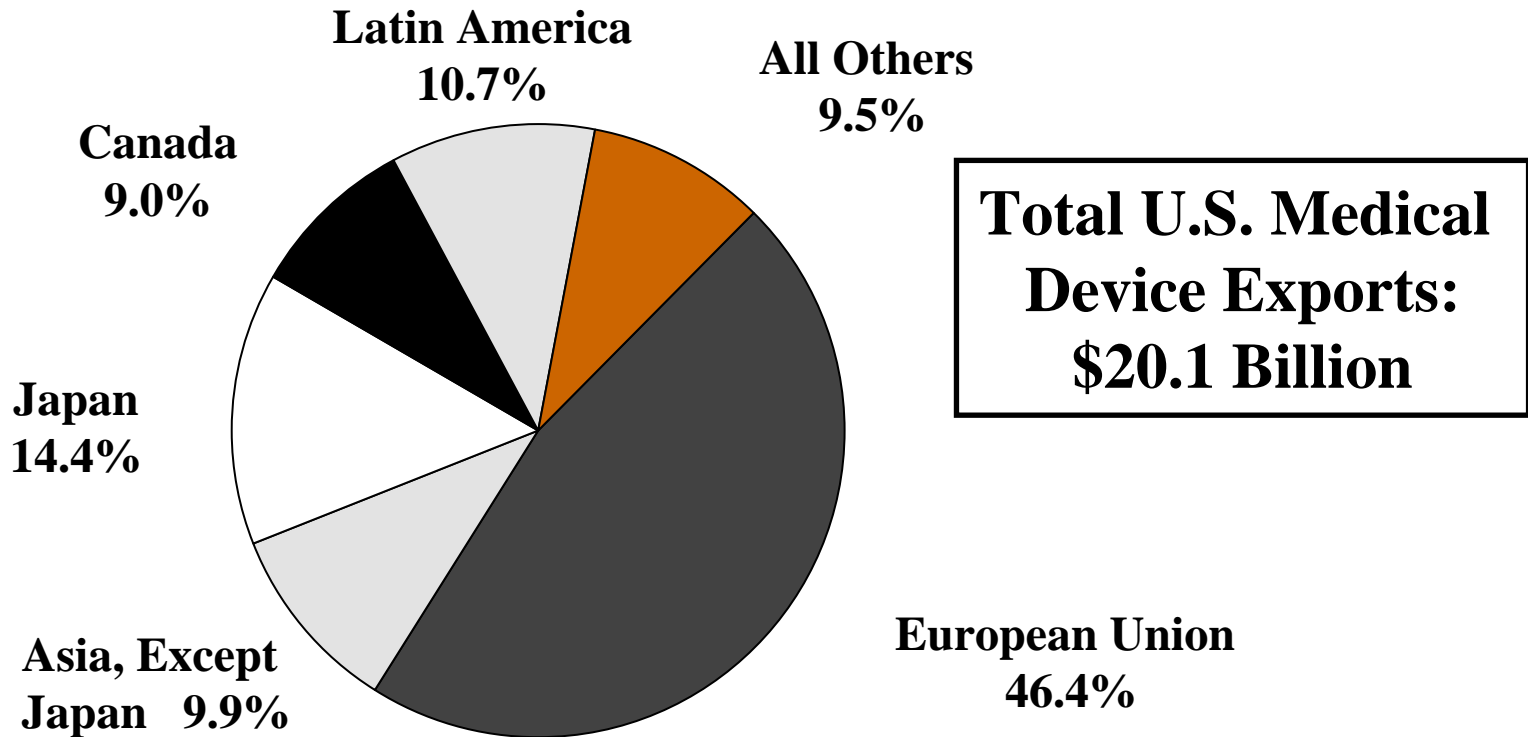
Global Medical Device Market

- ✦ In 2006 medical device two-way trade for the U.S. was approximately \$60 billion
- ✦ The U.S. medical device balance of trade has gone from a surplus of \$4.5 billion in 2000, to about even by 2003, to a \$630 million deficit in 2006 (mostly due to imports of consumer sunglasses)



Global Medical Device Market

U.S. Medical Device Exports, 2002

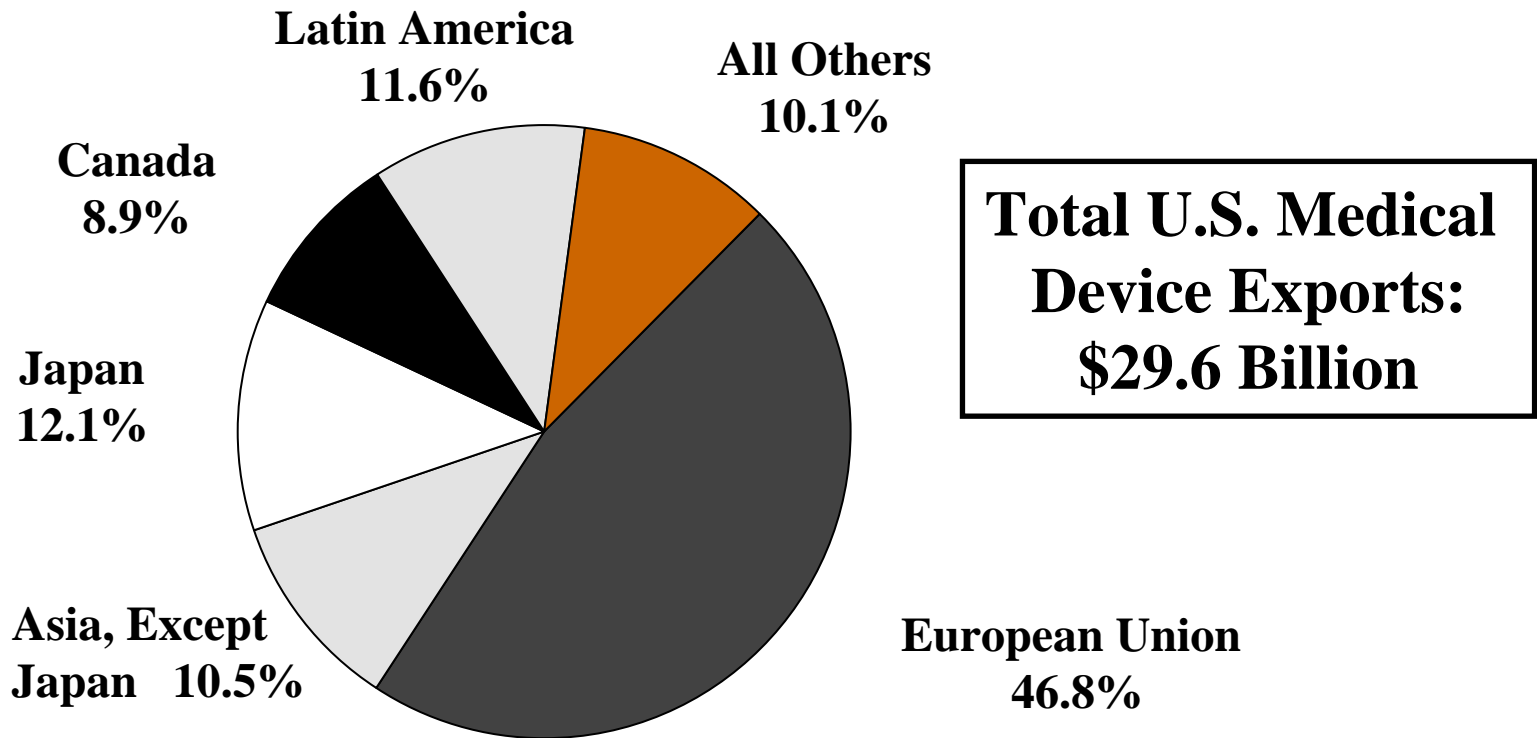


Source: U.S. International Trade Commission

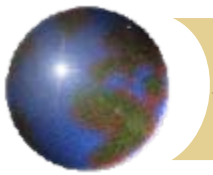


Global Medical Device Market

U.S. Medical Device Exports, 2006



Source: U.S. International Trade Commission



Medical Device Regulatory Issues

Two Competing Risks for Medical Device Regulators

- ⊕ **Allowing unsafe medical products** on the market that may cause injury or death
- ⊕ **Not allowing safe medical products** on the market that can save lives and improve the quality of life

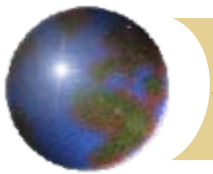


Medical Device Regulatory Issues

Appropriate Use of Medical Device Regulations

- ✦ Protect citizens from unsafe products
- ✦ Allow orderly entry of products through registration and notification procedures
- ✦ Monitor safety of products on the market
- ✦ Keep authorities and public informed of safety & maintenance problems and product recalls

**Applied even-handedly, such regulations
are not discriminatory**

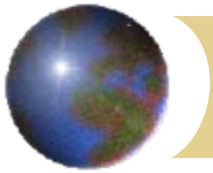


Medical Device Regulatory Issues

Inappropriate Use of Medical Device Regulations

- **Save money** by delaying approval of safe, advanced medical technologies
- **Generate revenue** through excessive fees
- **Create jobs** by requiring redundant local testing, reviews, and registration procedures
- **Protect local industry** by blocking approval of foreign products

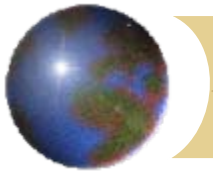
Always inappropriate because of impact on public health, such measures are also discriminatory if they target foreign manufacturers



Medical Device Regulatory Issues

How Other Countries Regulate Medical Devices

- ✦ No regulation
- ✦ Acceptance of devices approved by major developed economies (U.S. FDA, Japan, EU)
- ✦ Copy/replication of the EU model
- ✦ Have developed a unique system (often to the detriment of U.S. exporters)
- ✦ Based on pharmaceutical law (also detrimental)
- ✦ ASEAN possible model of regional cooperation

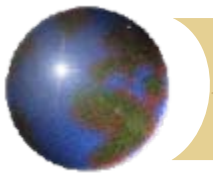


Medical Device Regulatory Issues

Improving the Global Regulatory Environment

ITA is actively supporting activities aimed at harmonizing global regulatory requirements for medical devices:

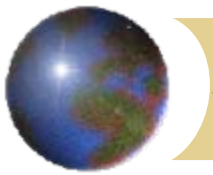
- ✚ Global Harmonization Task Force (GHTF)
- ✚ U.S.-EU Regulatory Cooperation
- ✚ APEC-Funded Regulatory Programs
- ✚ Online Database of Regulatory Profiles
- ✚ Country-Specific Activities: China, India, Brazil, EU, Russia, Korea, Taiwan



Medical Device Regulatory Issues

Global Harmonization Task Force (GHTF)

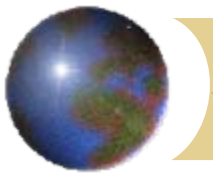
- ✦ An international organization working to develop common medical devices regulatory procedures
- ✦ Collaboration between regulators and industry
- ✦ Members: United States, European Union, Japan, Canada, and Australia; rotating chairmanship
- ✦ Working Parties: Asia and Latin America
- ✦ 5 GHTF Study Groups
- ✦ Last meeting in Washington, DC Oct. 3-4; 2008 meeting likely in Canada



Medical Device Regulatory Issues

Database of Regulatory Profiles

- ✦ OHCG, supported by USFCS, has developed an on-line database of regulatory profiles
- ✦ Purpose
 - ▣ Aid U.S. exporters as they seek to sell their products abroad
 - ▣ Serve as resource for policy-makers
- ✦ Available on the ITA web page:
 - ▣ www.ita.doc.gov/td/health



Medical Device Supply Chain

Issues

- ✦ These include labeling, packaging, global nomenclature
- ✦ To date, ITA/OHCG have only dealt with these issues occasionally, and often for a single country (e.g., Malaysia holograms for pharmaceuticals)
- ✦ OHCG has normally worked on regulatory issues in other areas (such as product registration, product approval, post-market issues); also starting to look at pricing/reimbursement issues
- ✦ As OHCG continues to work with MDISCC, we can learn more about your issues and determine if (and how) we can assist

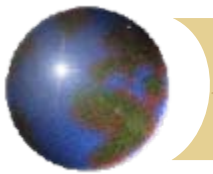


Medical Device Supply Chain

Issues

❖ *Unique Device Identifier (UDI)*

- ❖ Australian NEHTA (National e-Health Transition Authority) Initiative—National Product Catalogue
- ❖ U.S. FDA Meeting October 2006
- ❖ UDI included in MDUFMA reauthorization
- ❖ FDA currently considering UDI
- ❖ GHTF consultation with other countries to develop harmonized approach

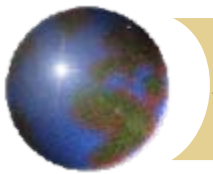


Medical Device Reimbursement Issues

Reimbursement Policies and Market Access

Reimbursement is a problem in all medical device markets:

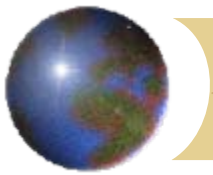
- ✚ Every market has its own unique set of issues
- ✚ A transparent and consistent regulatory system does not preclude significant reimbursement problems
- ✚ Reimbursement problems are rarely directly discriminatory, but they do adversely impact trade



Medical Device Reimbursement Issues

How Bad Reimbursement Policies Hurt U.S. Exporters

- ❖ Discourage exporters from entering certain markets because reimbursement rate is too low
- ❖ Discriminate against technological innovators by focusing on initial cost (and ignoring offsetting savings resulting from innovations)



Medical Device Reimbursement Issues

Characteristics of Good Reimbursement Policies

- ✦ Have clear and transparent rules for decision-making
- ✦ Set reasonable timeframes for decisions
- ✦ Allow input from suppliers and developers in the decision-making process
- ✦ Are sensitive to the medical-innovation process



Medical Device Reimbursement Issues

“Value of Technology” Concept

- ❖ Poorly designed reimbursement policies focus on initial cost for purchase and group lower and higher technology products together
- ❖ Well-designed reimbursement policies compare initial costs with the full economic and health benefits (value) offered by advanced technology products

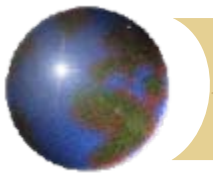


Medical Device Reimbursement Issues

Improving Reimbursement Environment for U.S. Exports

Because reimbursement policies are unique to each country and rarely directly violate trade agreements:

- ✿ Reform must be carried out on a country-by-country basis
- ✿ Addressing reimbursement-related market-access issues is very labor intensive
- ✿ There is no global forum to address reimbursement-related trade issues
- ✿ “Global budgeting” by governments exacerbates problem



Country Profiles – Selected Markets

China – General Background

- ⊕ Huge market potential due to robust economic growth (China fastest growing medical device market)
- ⊕ Estimated population of 1.3 billion
- ⊕ Estimated GDP of \$3.1 trillion*
- ⊕ Per capita income around \$2,390*
- ⊕ Healthcare provision uneven; varies by region (whether urban or rural)
- ⊕ Public insurance schemes relatively new

*(2007 Espicom estimate)



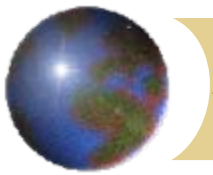
Country Profiles – Selected Markets

China—Medical Device Market

- ⊕ One of the fastest growing medical device markets in the world – currently estimated at \$3.7 billion*
- ⊕ Forecast for market growth ranges from 11%* to 18%** annually
- ⊕ Expected to surpass \$6 billion* by 2012, if not sooner
- ⊕ High end medical devices supplied largely by imports or multinational joint ventures
- ⊕ Market concentrated in larger cities (i.e, Beijing, Shanghai, Guangzhou and Tianjin)

*(2007 Espicom Estimate)

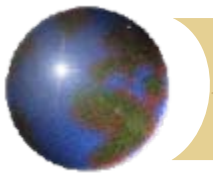
(**2007 AdvaMed Estimate)



Country Profiles—Selected Markets

China—Major Issues

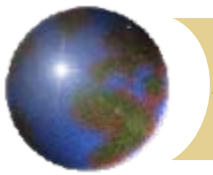
- ✦ Regulatory/Testing Redundancies and AQSIQ Decree 95
- ✦ Registration/Re-registration
- ✦ General Lack of Transparency
- ✦ Pricing Controls
- ✦ Centralized Tendering
- ✦ IVD Regulations
- ✦ BSE Restrictions
- ✦ SFDA—lack of people and other resources



Country Profiles – Selected Markets

U.S.-China JCCT Pharmaceutical and Medical Devices Subgroup

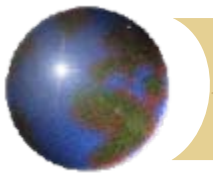
- ✦ Primary forum for U.S.-China dialogue on medical devices and pharmaceutical regulatory issues
- ✦ Includes DOC, industry and U.S. FDA representation
- ✦ Organized a variety of training workshops for SFDA, including GMP, GCP, and IVD
- ✦ Next meeting either in January or April 2008



Country Profiles – Selected Markets

Japan

- ✦ Largest single export market for U.S. medical device firms, and largest Asian market
- ✦ Regulatory and pricing concerns
- ✦ Highly fragmented healthcare system
- ✦ Medical Market Oriented Sector Selective (MOSS) talks—MAC office lead
- ✦ 2007 International Trade Commission Report
- ✦ Although many problems, good market

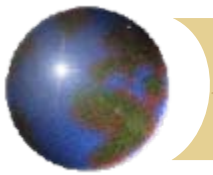


Country Profiles – Selected Markets

	USA	Japan
Number of Hospitals	~5,800	~9,000
Population Size (2003)	281 million	126 million
Hospital Beds per 1,000 population (1999)	3.6	16.4
Outpatient visits per capita per year (1996)	5.8	16
Average acute hospital length of stay (2000)	5.9 days	30.4 days

Source: World Bank compilation of health statistics; inpatient LOS data are from Health Affairs, May 2003, p. 97.

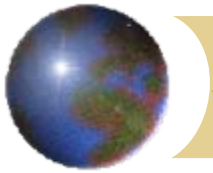
Courtesy of AdvaMed



Country Profiles – Selected Markets

Southeast Asia

- ✦ 5-7% annual growth rate—higher for medical devices
- ✦ Malaysia recently issued 1st draft set of medical device regulations based on GHTF guidance documents
- ✦ Hong Kong and Singapore have recently revised their regulatory systems based on GHTF guidance documents
- ✦ Some regulatory and pricing issues
- ✦ Generally good U.S. medical device export markets



Country Profiles – Selected Markets

Korea

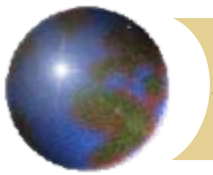
- ⊕ Third largest Asian market, high growth rate
- ⊕ US – Korea Free Trade Agreement concluded in April 2007—awaiting ratification
- ⊕ Separate chapter addressing pharmaceutical and medical device issues; OHCG actively involved in discussions on that chapter
- ⊕ Pricing/reimbursement, transparency, and valuing innovation primary issues
- ⊕ 1st FTA to explicitly include medical devices



Country Profiles – Selected Markets

Korea (continued)

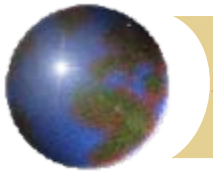
- ✦ Full cost of high tech medical devices likely not covered by insurance reimbursement
- ✦ Imports about 2/3 of total market
- ✦ Medical device reimbursement price cuts proposed in April 2007; US government involvement delayed imposition until November and added phase-in mechanism



Country Profiles – Selected Markets

Taiwan (Chinese Taipei)

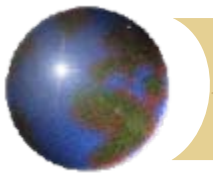
- ✦ Fourth largest Asian market, moderate growth
- ✦ Foreign import share $\sim = 75\%$
- ✦ U.S. has approximately 1/3 share
- ✦ Extensive product registration requirements makes it difficult to get advanced medical devices on the market (can take 1-2 years)
- ✦ Fast track approval available for some Class II devices



Country Profiles – Selected Markets

India – General Background

- ❖ Markets driven by private sector investment, increased government expenditures and rapidly growing middle class
- ❖ Estimated population exceeds 1 billion
- ❖ Per capita spending on health has plenty of room for growth
- ❖ High tech products in demand

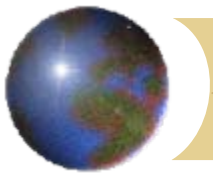


Country Profiles – Selected Markets

India – Medical Device Market

- ❖ Current estimated market size for medical devices: \$1.45 billion*
- ❖ Imports of medical equipment and supplies increased by an annual average of 18% between 1994-2004
- ❖ Forecast for market growth exceeds 6% annually* (considered conservative)
- ❖ Expected to surpass US \$2 billion by 2011*

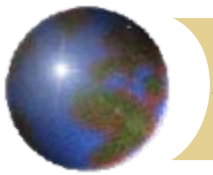
(* Espicom Business Intelligence)



Country Profiles – Selected Markets

India – Major Issues

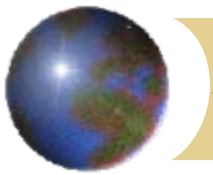
- ❖ Openness and transparency of regulation development process
- ❖ Adequate time for regulated industry to comply with new requirements
- ❖ Acknowledge differences between pharmaceuticals and medical devices
- ❖ Harmonize India's new regulatory requirements
- ❖ Participation in GHTF and AHWP
- ❖ Ongoing U.S.-India Cooperation on Medical Device Regulations



Country Profiles – Selected Markets

U.S.-India High Technology Cooperation Group

- ✦ Forum for the United States and India to address strategic and high technology trade issues
- ✦ The Biotechnology and Life Sciences Working Group has incorporated medical device and pharmaceutical issues since February 2007



Country Profiles – Selected Markets

Latin America

- ✦ Regulatory and market conditions vary by country
- ✦ Most Latin American countries do not have full-fledged regulatory systems
- ✦ Most countries simply require FDA-approved devices, as well as approvals from the country the medical device is manufactured in, to be registered before being imported, but do not require their own safety review
- ✦ Brazil has the most developed - and, in the view of many, the most misguided - regulatory system in Latin America

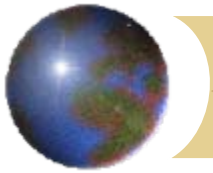


Country Profiles – Selected Markets

Brazil

Regulatory system has many features that make this a difficult and expensive market to enter:

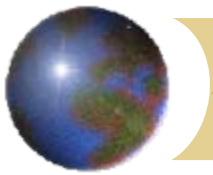
- ✦ Lack of clarity in the rules
- ✦ A regulatory agency dependent on user fees
- ✦ Long approval times (6 – 12 months)
- ✦ Requirement for submission of clinical data, as well as evidence of FDA approval



Country Profiles – Selected Markets

European Union (EU)

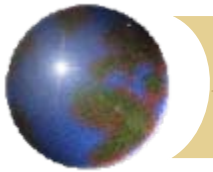
- ✿ Vast market, especially with EC Accession countries
- ✿ EU currently accounts for 47% of U.S. exports
- ✿ The EU has a regulatory system that is relatively easy to comply with
- ✿ Once a medical device has obtained CE Marking, it can be sold throughout all 27 member countries
- ✿ New members slow to implement EU regulatory system
- ✿ While the EU has a common medical device regulatory system for all member countries, medical device reimbursement and pricing policies vary significantly from country to country



Country Profiles – Selected Markets

EU (continued)

- ✿ Tight healthcare budgets, efforts to maximize the results for their spending
- ✿ All of them rely on several channels to fund and provide healthcare
- ✿ Many countries (Germany, France) have had excess capacity, poor incentives for efficiency
- ✿ A few European countries have traditionally underfunded their healthcare systems (UK)
- ✿ Both scenarios can create disincentives for the most effective, efficient care



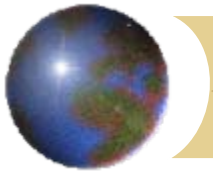
Crystal Ball Forecast – 2027

- ✦ Global Audit: One audit would be required and accepted for most markets
- ✦ Requirements for clinical trials will be the same for most markets
- ✦ Type testing will be eliminated and all major markets will rely on Quality Systems
- ✦ There will still be differences in product approval requirements for the highest risk products (Class III) between the U.S. and the EU



Crystal Ball Forecast – 2027

- ✦ There will be close global cooperation between regulators and industry on product vigilance
- ✦ Distinction between pharmaceuticals and medical devices will continue to blur
- ✦ No unique regulatory systems in major markets
- ✦ The world's regulatory systems will fall into the following models:
 - ✦ EU-based system with reliance on third-party organizations
 - ✦ FDA system with strong government role
 - ✦ Regulatory systems relying on FDA, CE Marking and other GHTF member approvals



Conclusion

- ✦ ITA can provide many services for medical device firms as they seek to expand their international reach
- ✦ Emphasizing innovation and the “value of technology” for medical devices is a key piece of that effort
- ✦ Services include market research, export assistance, trade promotion, and regulatory/pricing policy activities
- ✦ The medical device sector has demonstrated strong growth in recent years, with the potential for more gains in the future
- ✦ Ensuring the U.S. medical device industry can maximize its competitiveness in the global market (especially in the regulatory and reimbursement areas) is a primary objective for the Department of Commerce/ITA



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