2016 Top Markets Report Medical Devices

Overview and Key Findings

Introduction

The global medical devices market offers tremendous opportunity for U.S. manufacturers, as well as significant challenges, for government policymakers seeking to support U.S. export competitiveness in overseas markets. Creating new and sustained export opportunities for U.S. companies will require a concerted effort to remove or diminish market access barriers, helping U.S. firms to capture a larger share of the world import market. Encouraging and fostering U.S.-based healthcare industries is critical to the future of the U.S. economy, which is why medical technology is a National Export Initiative priority.

Despite uncertain economic conditions in key markets around the world, large and small players in the U.S. medical device industry show adaptability and tenacity, and companies are optimistic about the future. Medical device companies have found new opportunities for development in the face of uneven international economic growth and continually-changing regulatory systems.

Top Markets: Key Findings and Methodology

This *Top Markets Report* examines 57 different markets in terms of U.S. export history, forecasted market risk and rewards for exporters of medical technology; *per capita* spending in markets; and market size.

Methodology

This report uses a widely accepted definition of medical devices, similar to that used by the World Health Organization (WHO) and the United States Food and Drug Administration (FDA). A medical device is defined as any piece of equipment or apparatus used to treat or diagnose an illness and comes into direct contact with the patient. Pharmaceuticals and laboratory equipment are not within the scope of this report.

International industry information and market profiles have been provided by the International Trade Administration's (ITA) Global Health Team. ITA's Global Health Team, consisting of international trade experts at United States Embassies and Consulates worldwide, as well as in all fifty states, and industry experts in Washington, D.C., is dedicated to enhancing the global competitiveness of the U.S. health industry, expanding its market access and increasing exports. It accomplishes this through in-depth research and a variety of resources and services for U.S. companies, such as seminars, webinars and Gold Key and Platinum Key Services. Relevant data were collected by surveying international posts with the template questionnaire found at Appendix 2.

Data for current and forecast sales values of medical devices are sourced from statistics collected by the Census Bureau, the International Trade Commission (ITC) and Business Monitor International (BMI).

Market size and forecasts have been estimated using

Figure 1: Near-Term Medical Device Export Market Rankings

1. Germany	5. Belgium	9. France	13. Norway	17. Denmark
2. Japan	6. Switzerland	10. Australia	14. Sweden	18. Singapore
3. Netherlands	7. United Kingdom	11. Mexico	15. Italy	19. Ireland
4. Canada	8. China	12. Austria	16. Korea	20. Israel

a trade-based approach, as most countries are reliant on imports. Estimates have been derived by looking at imports while considering domestic production, including exports. For practical purposes, we define a generally-accepted range of HTS codes as the entire market.[i] HTS codes are used for export forecast calculations in this report as they most accurately encompass international trade in medical devices. This report uses trade data through the end of 2015.

Projections were based upon the current estimate size and conditions, considering factors such as expected need, propensity of lifestyle disease, proposed spending, regulatory developments and other social factors, such as international health projects, economic performance, trends in import levels, size and performance of domestic manufacturing sector, national healthcare development plans and currency issues.
Because of remarkable advances in science and technology, including those in the health care industry, life expectancy in many countries has been steadily growing. As a result, the expanding proportion of elderly people promises further growth of demand for medical devices. The total combined quantitative rankings reflect the degree to which they are existent in each market; aging populations in developing economies now tend to expect therapies for health conditions that previous generations simply endured or that were life-ending.

Aging populations worldwide, coupled with extended life expectancy, create a sustainable demand for medical devices. As elderly populations' healthcare is frequently government-subsidized in markets around the world, home healthcare is also becoming of increased importance, as related technologies become more effective, and healthcare budgets are more closely scrutinized.

Industry Overview and Competitiveness

U.S. medical device companies are highly regarded globally for their innovations and high-technology products. Investment in medical device research and development more than doubled in recent decades, and research and development investment in the domestic sector remains more than twice the average for all U.S. manufacturers.

The United States is expected to continue to play a leading role in medical device research and development. After declining in 2009, research and development spending rebounded to $2.9 billion in 2010 and $7.3 billion in 2011. From 2013 to 2020, larger medical device companies are expected to increase their research and development budgets by approximately 3 percent, while the rest of the industry is expected to increase spending for this element by more than 5 percent.[ii]

The U.S. medical device industry is highly diversified and produces a variety of products to diagnose and treat patients, ranging from tongue depressors to complex programmable pacemakers. The United States medical devices industry is known for producing high quality products using advanced technology resulting from significant investment in research and development. During the last decade, the United States medical device industry experienced unprecedented advancement in innovative and developed technologies, leading to the birth of new therapies and growth in overall healthcare industry.

The major U.S. medical device companies include: Baxter®, Beckman Coulter®, Becton Dickinson®, Boston Scientific®, GE Healthcare Technologies®, Johnson & Johnson®, Medtronic®, St. Jude® and Stryker Corporation®, to name a few. In addition, the following medical device industry trade associations closely follow the industry: Advanced Medical Technology Association (AdvaMed), Dental Trade Alliance (DTA), Medical Device Manufacturers Association (MDMA), Medical Imaging Technology Association (MITA) and the International Association of Medical Equipment Remarketers & Servicers (IAMERS).

<u>Size and Shape of the U.S. Medical Devices Industry</u>

For purposes of estimating of the size and shape of the U.S. medical devices industry, the U.S. Census Bureau (Census) uses the North American Industry Classification System (NAICS) codes in its five year Economic Census, which was most recently executed in 2012. Those NAICS codes used by Census for this estimation are as follows:

- 325413 *In-Vitro* Diagnostic Substances Manufacturing

- 334510 Electro-medical and Electrotherapeutic Apparatus Manufacturing
- 334517 Irradiation Apparatus Manufacturing
- 339112 Surgical and Medical Instrument Manufacturing
- 339113 Surgical Appliances and Supplies Manufacturing
- 339114 Dental Equipment and Supplies Manufacturing
- 339115 Ophthalmic Goods Manufacturing

- *In-vitro* diagnostic substances (NAICS 325413) account for about 14 percent of value of shipment (VOS) of total exports and includes chemical, biological or radioactive substances used for diagnostic tests performed in test tubes, Petri dishes, machines and other diagnostic test-type devices.

- Electro-medical equipment (NAICS 334510) represents the third largest subsector (17 percent of VOS) and accounts for a variety of powered devices, including pacemakers, patient-monitoring systems, MRI machines, diagnostic imaging equipment (including informatics equipment) and ultrasonic scanning devices.

- Irradiation apparatus (NAICS 334517); about 8 percent of VOS, includes X-ray devices and other diagnostic imaging as well as computed tomography equipment (CT).

- Surgical and medical instruments (NAICS 339112) comprises the largest subgroup (about 29 percent of VOS) of the U.S. medical device industry. The category includes anesthesia apparatus, orthopedic instruments, optical diagnostic apparatus, blood transfusion devices, syringes, hypodermic needles and catheters.

- Surgical appliances and supplies (NAICS 339113) is the second largest U.S. medical device subsector with about 22 percent of the total measured by VOS. The category covers a wide range of products, including artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves, and wheelchairs.

Generally accepted WHO definition of medical device and medical equipment:

Medical device (brief): An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

- Dental equipment and supplies (NAIC 339114; 3 percent of VOS) consists of equipment, instruments and supplies used by dentists, dental hygienists and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers and dental chairs.

- Ophthalmic goods (NAIC 339115; 6 percent of VOS) includes eyeglass frames, lenses and related optical and magnification products.

In 2015, the total value of U.S. industry shipments for the products covered by the NAICS categories identified above was worth $43 billion and, in recent years, has experienced approximately 1.5 percent annual growth. Median medical technology jobs paid 15 percent more than the average U.S. manufacturing job. In the 2012 Economic Census, it was reported that the medical device industry employed more than 356,000 people in the United States, at over 5,800 establishments, earning an average wage between $60,000 and $70,000. Most of these companies are small and medium-sized

enterprises (SMEs): 80 percent of these are estimated to have fewer than 50 employees, and many (notably innovative start-up companies) have little or no sales revenue. Taken together, these companies set up an explosively competitive industry profile flourishing on innovation. Larger players in this field carefully consider partnerships with their smaller counterparts and often enter into mergers or acquisition deals to increase their product lines and offer economies of scale resulting in more value-focused healthcare solutions.

Medical device companies are located throughout the country but are mainly concentrated in certain regions known for other high-technology industries, such as microelectronics and biotechnology. The states with the highest number of medical device companies include California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota and Georgia.

The United States also holds a competitive advantage in several industries upon which the medical device industry relies, including microelectronics, telecommunications, instrumentation, biotechnology and software development. Collaborations have led to recent advances, including health information technology ("Health IT"), neuro-stimulators, stent technologies, biomarkers, robotic assistance and implantable electronic devices. Certain areas of patient care and treatment have developed remarkably, and advancements in mobile applications and devices, such as health monitoring devices developed at one time for the U.S space program, have been modified and made practical for a widening number of patients. Health IT promises to have vast market potential, as it develops in a multitude of forms. Communications companies are progressively becoming players in this field, developing telemedicine applications and monitoring systems. Because the medical technology industry is fueled by innovation and the ongoing quest for better ways of treating or diagnosing medical problems, the future growth of this sector remains positive. For more information on Health IT, please see the related Top Markets Report at www.trade.gov/topmarkets.

The United States is home to 141 accredited medical schools and approximately 400 major teaching hospitals and health systems, many of which rank among the best in the world. Many of these academic institutions collaborate with medical device companies to develop new medical technologies.[iii]

The Made in America Movement (MAM) stated in 2015 that the United States has become an increasingly attractive location for business investment from global countries. According to AT Kearney's 2013 FDI Confidence Index, the United States surged past countries like China, Brazil and India to become the country with the top foreign direct investment (FDI) prospects globally, as ranked by 32 companies representing 28 countries in multiple industry sectors. More companies are looking to locate to the United States after considering competitive advantages, such as skills and productivity, innovation, energy reserves and access to the largest consumer market in the world.[iv]

Global Industry Landscape

Besides leading the world in the production of medical devices, the United States is the largest medical devices consumer. The United States medical device market is valued at more than $140 billion in 2015, which accounts for approximately 45 percent of the global market according to the U.S. Government Accountability Office's (GAO) 2014 statistics. U.S. exports of medical devices were valued at approximately $45 billion in 2015, and imports were valued at $54 billion.

Over the past decade the value of imported medical devices has steadily increased, gradually eroding the previous trade surplus. The majority of imports are lower-tech products, such as surgical gloves and instruments. Continuing shifts in trade patterns have resulted in China and Mexico becoming significant exporters of mid to lower-tech equipment and supplies to the United States.

The surgical and medical instruments category (NAICS 339112) represents the subgroup with the most activity in the United States medical device sector. This category includes numerous price-sensitive lower-technology devices which can be more easily substituted with higher technology medical device products. While exports of surgical and medical instruments grew by 27.5 percent from 2007 to 2012, imports grew by almost an identical rate.

Other NAICS product categories have also shown varying growth rates in both exports and imports between 2007 and 2012. For example, exports of surgical appliances and supplies (NAICS 339113) grew by 22.5 percent and imports by 26 percent; exports of ophthalmic goods (NAICS 339115) grew by 7.5 percent and imports by 33 percent.

The U.S. medical device industry is expected to remain highly competitive globally, partially because of national characteristics that facilitate bringing new and innovative technologies to market. The industry has increasingly embraced globalization, and an ever-growing number of multinational firms is aggressively pursuing markets around the world. These firms are focusing greater attention on international sales, joint ventures, mergers and acquisitions. Global demand for medical devices is driven by increasing expenditures and activities on health care by developing markets with the building of new hospitals and clinics, establishment of public health insurance and greater focus on health. In addition, global demand should continue to grow due to lifestyle diseases, aging populations in major markets, new and significant emerging markets and rising global income levels in developing countries. Further, global convergence of standards and regulatory requirements should help facilitate global market growth and trade opportunities.

Key Trends

Cost Efficiency

Increased competition, developed and cross-bred therapies, and cost containment have more keenly focused the medical device industry's attention on creating value for payers and patients rather than the traditional means of mining revenue by investing in research, development and innovation. Companies are looking toward holistic, coordinated therapies and healthcare solutions to shift to value-based healthcare, providing value with efficiency. By addressing therapies as an all-inclusive treatment package, medical device companies can better assist providers in delivering on their obligations to patients, controlling costs and simplifying transactions.

Export Market Mixture

As expected, the European Union (EU), Japan and Canada are extremely large and lucrative export markets for medical devices. These stable, mature markets, however, have relatively low (3 to 5 percent) annual growth rates. In order to facilitate expansion, medical device companies recognize that they must also look at developing countries for future growth. In some of these, demand for medical devices is growing at double digit growth in contrast to certain larger, slower growing markets in more developed countries. Significant yet underserved populations in developing markets often grow steadily, face similar aging populations and increasing lifestyle diseases and have an increased awareness of health technology development. Furthermore, many markets deemed as "developing" have highly urbanized population centers with rising expendable wealth, making certain sectors of markets interesting to exporters. A U.S. exporter would be best served by investigating both larger developed markets as well as emerging, raw markets in order to find the best export

Figure 2: Trade flows by NAICS for Medical Devices Sector

NAICS Code/Description	2014 Exports (USD Billions)	2015 Exports (USD Billions)	2014 Imports (USD Billions)	2015 Imports (USD Billions)
325413 – *In Vitro* Diagnostic Substance	$6.0	$6.1	$3.3	$3.5
334510 – Electro-medical Apparatus	$8.3	$7.5	$10.4	$10.3
334517 - Irradiation Apparatus	$3.4	$3.6	$3.8	$3.7
339112 - Surgical and Medical Instruments	$12.6	$12.4	$11.3	$12.3
339113 - Surgical Appliances and Supplies	$9.3	$9.6	$12.9	$13.7
339114 - Dental Equipment and Supplies	$1.2	$1.2	$1.2	$1.3
339115 - Ophthalmic Goods	$2.7	$2.7	$5.1	$5.1
Total	**$43.5**	**$43.2**	**$47.9**	**$49.9**

effectiveness.

Regulatory Convergence

For the medical device industry to fully realize its potential in developing markets, standards for regulatory approval, risk management and quality must improve and continue along the path of international convergence to meet global standards. To that end, the Global Harmonization Task Force (GHTF), formed as a voluntary organization comprised of regulators and industry with five founding members consisting of the United States, Canada, Japan, the European Union and Australia, had as its core objective streamlining and harmonizing regulatory standards. Developing countries like India, China, Mexico and Brazil benefited in the work of GHTF by considering that organization's guidance documents while designing their own regulatory systems.

In October 2011, representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, EU, Japan and the United States, as well as the WHO, met in Ottawa, Ontario, Canada to address the establishment and operation of a new vehicle to further expand the work of the GHTF. The new organization, the International Medical Device Regulators Forum (IMDRF), is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the GHTF. IMDRF aims to accelerate international medical device regulatory harmonization and convergence. The enhanced participation of developing countries' medical device regulatory agencies in IMDRF activities coupled with guidance issued by GHTF will be critical in establishing regulatory regimes for medical devices that are distinct from traditional pharmaceuticals. Upon further development in this area, the medical device industry will continue to evolve as a global industry and better direct its energies to the development of even more innovative, life-improving and life-saving medical technologies.

Challenges, Barriers and Opportunities

The U.S. industry primarily faces competition from Germany (Siemens® and Braun®), Japan (Hitachi® , Medical Corporation® and Toshiba®) and the Netherlands (Philips Electronics®), in high-technology products. Notably, as a result of its acquisition policy, Philips currently produces more medical devices in the United States than in Europe. It is important to note that most of these foreign companies manufacture significant amounts of medical devices (or components) in the United States. High quality but lower technology medical device firms are being challenged by numerous lower-cost producers from China, Brazil, Korea, Taiwan, Mexico and India, all of which are building up their domestic industries and beginning to compete globally. While the United States will likely retain its competitive edge for the foreseeable future, international markets are expected to remain competitive.

Key Export Policies

Opportunities for expansion of U.S. medical device exports will come from certain key ongoing policy and activities. With respect to accessing developing countries, the contributions of IMDRF will play a significant role in the international convergence of regulatory requirements that can lead to greater market penetration. In addition, continued focus on reducing or eliminating tariffs in key markets and higher reimbursement rates will also significantly influence growth. Further, assisting SMEs in export opportunities through market information, trade missions and other trade promotion activities can also increase overall U.S. exports for this industry.

The U.S. medical device industry needs and expects the U.S. government to remain involved in the several following areas that will establish and improve trade conditions:

- negotiate strongly to reduce or eliminate tariffs on medical devices
- address foreign governments' regulatory policies that are inconsistent with international regulatory convergence efforts and that may cause unfair discrimination against U.S. industry
- educate the industry on how to comply with foreign regulatory requirements
- provide export assistance opportunities similar to what foreign governments provide for their industries

U.S. medical device exports will need to understand what export requirements exist for their products. The rules that U.S. companies must follow when exporting medical devices depend on whether their

devices have been cleared by the U.S. Food and Drug Administration (FDA). Medical devices that are legally marketed in the United States may be exported anywhere in the world without prior FDA notification or approval. Devices that have not been approved or cleared in the United States must follow the export provisions of the Federal Food, Drug and Cosmetic (FD&C) Act.

Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply proof of the products' statuses as regulated by the FDA. An export certificate is a document prepared by FDA that has information about a product's regulatory or marketing status in the United States.
A Certificate to Foreign Government (CFG) is the most frequently requested type of export certificate, but a Certificate of Exportability may also be requested when exporting devices under sections 801(e)(1) and 802 of the FD&C Act or when exporting Non-Clinical Research-Use-Only devices.

Depending on the medical device, there are three possible sections of the FD&C Act that may be applicable, each with different requirements, if these have not been approved for sale in the United States.
Section 801(e)(1) of the FD&C Act governs the rules for exporting non-cleared Class I or Class II devices, not including Class II devices subject to performance standards.
Section 802 covers exporting non-cleared Class II devices subject to performance standards, unapproved Class III devices, devices for investigational use, devices intended for further processing and devices intended for treatment of diseases not prevalent in the United States.
Section 801(e)(2) governs export of non-cleared Class III investigational devices, banned devices, devices for which a premarket authorization (PMA) has not been approved as well as other devices which do not meet requirements of Section 802.
For more information on FDA export requirements for medical devices, please visit http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ExportingMedicalDevices/default.htm.

Export Barriers

Regulatory and reimbursement requirements for medical devices vary from country to country, creating complications for U.S. exporters. Certain countries, including India, some Latin American countries and parts of Asia, still maintain high tariffs on some medical products, reducing the net sale price of medical devices. U.S. firms also face increasing competition globally, especially from foreign firms that can successfully compete on the basis of price. U.S. firms without sufficient resources to conduct necessary market research are especially vulnerable.

- *International Regulatory Environments*: The medical device industry is highly regulated, and regulatory environments in the United States and abroad have serious implications on industry performance. An increasingly common practice among developing countries is the establishment of national regulatory srequirements above and beyond the requirements of developed countries. Device firms tend to devote tremendous amounts of time and money to determine such requirements, conduct additional clinical trials and pay additional user fees. These national requirements may sometimes be established to protect the domestic industry, to be a source of revenue for the government or both.

- *International Reimbursement Payment Environments*: Reimbursement or payment practices in certain countries have also had negative impacts on the U.S. industry. Many countries around the world are facing the same intensifying costs of health care as the United States and are trying to address costs by reducing reimbursement rates, establishing price caps, requiring mandatory price reductions, using diagnostic related groups (DRGs), limiting funds available for medical device purchases and/or requiring inappropriate information about the product or pricing data from the manufacturer. Germany, France, Japan, Taiwan, Korea, China and Brazil are all examples of major markets where industry has reported that prices for medical devices and reimbursement rates have been potentially set lower than the value of the technology, thus limiting the introduction of advanced technologies and making it difficult for U.S. firms to be profitable in these markets. Most medical

devices have a life-cycle of 18 to 24 months, which makes reimbursement key for continued product innovation, including incremental improvements. The U.S. government has encouraged foreign governments to take the overall value of advanced technologies and other costs in healthcare delivery into greater consideration when establishing their reimbursement rates.

- *Regulatory Convergence Efforts*: Convergence of medical device regulations is one way to reduce the industry's burden and ensure maximum accessibility of safe, effective medical devices by patients. U.S. industry would like to see products "approved once, accepted everywhere." ITA is encouraging foreign governments to make use of guidance documents produced by international bodies, most notably IMDRF, to encourage regulatory convergence and to eliminate or reduce redundant and unnecessary regulatory procedures.

- *IPR and Counterfeit Medical Devices*: Although intellectual property rights (IPR) and counterfeiting have not posed as significant a problem for medical device firms as they have in the pharmaceutical industry, the sector is beginning to face related revenue losses with increasing frequency. IPR violations include using medical device firms' patented technology to manufacture a competing medical device or unauthorized use of a registered trademark. Similarly, counterfeit medical devices are copies of patented medical devices that are manufactured and marketed without following the requisite approval process, which can result in unsafe products on the market. IPR violations occur in markets that may not fully respect or enforce patent protection, such as China. There is limited data on counterfeit medical devices, but based on feedback from industry, the most frequent incidences are in IVD reagents and solutions, contact lenses, medical test kits, combination products and components parts, such as semiconductors used in imaging equipment. U.S. industry loses market share to counterfeit products, and patients are subject to unnecessary risks. ITA, and other USG agencies like PTO and USTR, is actively engaged in global, regional and bilateral dialogues to address this problem.

- *SMEs' Lack of Resources*: The majority of the U.S. medical device industry consists of small and medium-sized firms that reinvest much of their revenue into research and development to make incremental improvements to their technology. A majority of these companies do not have the resources to conduct sophisticated export market research. In addition, many smaller companies are so focused on entering the U.S. market first that they put off exporting until they have become profitable in the United States. The domestic market, however, can be more difficult to enter than some foreign markets due to stringent FDA regulations and complex reimbursement policies with Medicare and Medicaid.

Opportunities

U.S. medical device exporters have and will continue to benefit from international trade agreements, such as NAFTA and TPP.

In 1994, the North American Free Trade Agreement between the United States, Canada and Mexico (NAFTA) entered into force, ultimately eliminating duties and quantitative restrictions for trade in medical devices. NAFTA created the world's largest free trade area to date, which now links 474 million people and produces roughly $20.5 trillion worth of goods and services.

Figure 3: Medical Devices Market: Forecast for Growth, in USD Billions

Region	2016	2017	2018	2019	2020
Americas	166.6	176.5	187.3	197.9	208.6
Asia/Pacific	68.7	72.6	77.6	82.9	88.6
Central/Eastern	14.6	15.7	17	18.1	19.1
Middle East/Africa	10	10.8	11.5	12.5	13.2
Western Europe	79.5	85.1	92.6	101.4	106.2
Total	**339.5**	**360.8**	**386.1**	**412.8**	**435.8**

Source: Worldwide Medical Devices Forecast to 2020

Trade between the United States and its NAFTA partners has soared since the agreement entered into force: U.S. goods exports to the NAFTA partners have increased by 289 percent from 1993 to 2014 from $142 billion to $552 billion. U.S. two-way goods trade with Canada and Mexico exceeds U.S. goods trade with the European Union and Japan combined. Annual exports of U.S. medical devices to Canada have more than tripled since the year before NAFTA was signed into law, and exports of the same to Mexico have more than quadrupled.

The Trans-Pacific Partnership agreement (TPP) is a trade agreement covering eleven U.S. trading partners: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. It is dedicated to increasing the trade of goods and services between member states. TPP goes beyond NAFTA in many important ways, effectively updating trade relations between the partners and setting new, higher standards for U.S. regional trade agreements. The agreement also includes dispute resolution mechanisms as well as regulations relating to government procurement practices and intellectual property protections.

The agreement removes tariffs on medical devices, supports increased regulatory coherence among the member states and widens stakeholder influence and transparency with respect to reimbursement and pricing. Ultimately, the TPP will result in quicker approvals of medical devices, benefiting U.S. companies that export to signatory partner countries. For more information on the benefits of the TPP including for the medical device industry, please visit www.trade.gov/tpp.

3D Medical Printing

3D medical printing is expected to develop and find its niche in several areas of medicine. U.S. universities and research hospital groups work with U.S. manufacturers to discover opportunities and meet challenges in this new field, including investigating applications for 3D printing of biomaterials and living cells; adapting 3D printing for surgical planning; and developing applications for tumor removal, spinal surgery and cranio-fallacial surgery and reconstruction.

A 3D printer "prints" in three dimensions, in layers, with each successive level of the substrate approximating the final product. The first 3D printers were developed in the 1980s in the United States and were used by car and airplane manufacturers to design specialized parts on a computer and then create prototypes for analysis. The medical device industry is finding applications for this technology, with custom-designed hearing aids, dental and other implantables, prosthetics and other devices that can be modified to best serve the user. Application of customized 3D printed implants reduces surgical complications and promotes patient compatibility.
The cost of producing 3D custom devices has limited the development of the science, but as the technology advances, overall costs should decline, making customized devices more accessible. The FDA is investigating how to regulate 3D printing of medical devices and is expected to release a guidance document this year. The European Commission has received requests to consider 3D printing regulations in its current review of the Medical Devices Directive (MDD). Interest in 3D medical printing is not limited to the United States and Europe and promises to remain at the cutting edge of personalized medicine.

[i] HTS codes used for forecasting and trade calculations: 300510, 300590, 300610, 300640, 300650, 300680, 300691, 300692, 340700, 401511, 401519, 420600, 420610, 611510, 611512, 611519, 611592, 611593, 630720, 630790, 650610, 681250, 681280, 681291, 841920, 841990, 854370, 854380, 854389, 871310, 871390, 871420, 901811, 901812, 901813, 901814, 901819, 901820, 901831, 901832, 901839, 901841, 901849, 901850, 901890, 901910, 901920, 902000, 902110, 902111, 902119, 902121, 902129, 902130, 902131, 902139, 902140, 902150, 902190, 902211, 902212, 902213, 902214, 902219, 902221, 902229, 902230, 902290, 902511, 902519, 940210, 981000, 382100, 382200.
[ii] *The State of the U.S. Medtech Industry,* January 2015, Anchin, Block & Anchin
[iii] *The State of the U.S. Medtech Industry,* January 2015, Anchin, Block & Anchin, LLP available at http://www.anchin.com/admin/Upload/Document/MDDI_2015-01_LS.pdf.
[iv] *The U.S. Medical Device Industry*, Made in America Movement at www.themadeinamericamovement.com/reshoring/u-s-medical-device-industry/ sourced from Expansion Solutions Magazine, by SelectUSA at http://www.expansionsolutionsmagazine.com/industry_articles/view/9210/the_u_s__medical_device_industry