Washington State Life Sciences and Global Health Defense Export Market Research

Discussion Draft

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EXECUTIVE SUMMARY

Background and Purpose

The life sciences and global health sector is an important contributor to the Washington state economy. In 2014, the life sciences sector directly employed 34,200 workers and contributed $11.4 billion to Washington's GDP (Washington Biotechnology & Biomedical Association, 2014). The global health sector in 2014 directly employed an estimated 12,600 workers, ranging across nonprofit development organizations, research entities, and universities.

A less known aspect of the life sciences and global health sector is the role of these companies and organizations in defense work. In fiscal year 2015, Washington's life sciences and global health defense contractors sold $68.2 million in equipment and services to the Department of Defense in fiscal year 2015. Unlike other sectors, these companies sold primarily to lesser-known DOD agencies like the Defense Logistics Agency, Defense Threat Reduction Agency, and Defense Health Agency, with $43 million going to the Army, Navy and Air Force.

The Washington State Department of Commerce (Commerce) has requested this study to assess opportunities for life sciences and global health defense contractors to expand their activities overseas, with both defense and civilian clients and partnering organizations. Analytics presented in this report illustrate findings on overseas market opportunities, including key markets, trends, as well as challenges and considerations, culminating in a set of actionable strategies for Commerce to support overseas expansion among these businesses and organizations.

Exporting entails numerous challenges, including regulatory/export controls, economies of scale needed to expand overseas, and important information gaps on where opportunities might exist. This report will help address many of these challenges and provide a strategic framework for Commerce to help defense contractors expand their business into overseas markets. Recommendations address key trends and considerations specific to life sciences and global health businesses in Washington engaged in defense contracting.

Key Findings

Research findings presented in this report include industrywide trends and market conditions shaping life sciences and global health exporting opportunities. These findings are summarized below.

Industry Trends and Baseline Conditions

- Washington state life sciences companies sold $68.2 million in equipment and services to the Department of Defense (DOD) in

fiscal year 2015, mostly to smaller agencies such as the Defense Logistics Agency, Defense Threat Reduction Agency, and Defense Health Agency.

- Within the life sciences and global health industry, the main exportable subsectors among Washington defense contractors are: 1) medical equipment; 2) health IT; 3) safety equipment; 4) pharmaceuticals, biologicals and chemicals; and 5) training and equipment.
- Aging demographics around the world will create additional opportunities for life sciences and medical exports. This is particularly true among several of Washington's major exporting partners, such as China and Japan.
- There are complicated regulations for pharmaceutical and medical equipment in other markets, similar to the FDA's regulatory process in the U.S.
- Washington companies are already large exporters of medical equipment, especially ultrasound.

Markets and Opportunities

The potential leading markets for Washington life sciences and global health defense contractors are Japan, China, South Korea, Canada, and Mexico. These markets are already important export markets for Washington state—these existing trade linkages may offer avenues of growth for defense contractors who are not yet exporting their goods and services. Market-specific findings are summarized below.

- Japan is a large market for medical devices and health IT, and a great opportunity market due to its aging population. At the same time, medical devices are highly regulated in Japan.
- South Korea also has aging demographics and high demand for advanced medical devices. It is important to note that there are requirements to export through South Korean partners.
- China is currently Washington's largest market for medical devices. There is intense domestic competition and IP concerns, but demographic and economic trends, including an ageing population, increasing investments in the healthcare sector, and growing demand for higher-end medical services, make China an important market opportunity.
- The EU market offers great opportunities but complicated barriers. Germany, France and the UK are three of the 10-largest economies in the world but each has rigorous certifications and are trying to constrain costs. But the size of these markets make them valuable opportunities to explore.
- Brazil is a large opportunity market for medical products. However, there are significant market entry barriers, including the fragmented nature of the market and complicated regulations.

Recent social upheavals and economic slowdown further weaken the market opportunity there, especially for higher-end, more expensive healthcare products and equipment.

- Canada's low market barriers, fast approval process and proximity to Washington, make it an attractive opportunity market for Washington state life sciences companies.
- Mexico is a valuable opportunity market that is often overlooked. It is one of the world's largest economies, has close proximity to Washington and has a growing medical device and instrument market.

Strategies for Supporting Life Sciences and Global Health Defense Contractors

Opportunity/Theme	Key Findings/ Considerations	Strategy	Type of Assistance
Industry-wide	Many firms remain unaware of Washington State Department of Commerce services.	**Engage in proactive outreach and marketing of services.** Inform companies in this sector of Washington State Department of Commerce services, especially the ability to vet potential distributors and representatives.	Education and training
		Disseminate information. Create a section of the Washington State Department of Commerce website with regulatory and other information on medical devices for the target markets in these recommendations.	Education and training
	Many current exporters report securing distributors is the most difficult aspect of exporting.	**Technical assistance.** Consider hiring a position to focus on technical outreach in the defense market. This position would act as an ombudsperson for life sciences (and other sectors) by liaising with technical contacts at DOD and related agencies, and by acting as a traffic cop to connect companies to the right resources and contacts.	Technical assistance
		Expand the Washington Military & Defense Economic Impact Tool to include current information on life sciences defense trends. The tool can be broadened to serve the information gathering needs of life sciences defense contractors in Washington by providing regular newsfeeds and content published on the site as well as sent via SMS and email to registered subscribers.	Market research

Opportunity/Theme	Key Findings/ Considerations	Strategy	Type of Assistance
Japan	Japan has an aging population with a growing need for advanced medical devices and therapies. There are already strong economic and cultural linkages with Washington that can be leveraged.	Work with the Japan External Trade Organization and other partners to **help firms navigate the Japanese market**, including attendance at Medical Japan.	Market research/ technical assistance
	Japan will be a member of the Trans-Pacific Partnership if it is ratified.	**Market information.** Create a section on the Washington State Department of Commerce's website with information on Japanese regulations, barriers and contacts for help.	Education and training
South Korea	South Korea has strong existing trade linkages in Washington.	**Develop a list of possible Korean distributors.**	Market research
		Leverage relationship with Samsung to help Washington state companies work with the company, a major producer of medical equipment.	Market research
		Make available info on the Washington State Department of Commerce's website about South Korea's National Health Insurance (NHI) system, including what NHI pays and for what products.	Education and training
Brazil	Brazil's demographic trends favor U.S. exports there, but are tempered by significant market entry barriers, economic downturn, and political instability.	**Develop a list of vetted local distributors.**	Market research
		Actively make available and raise awareness of the above list to Washington companies and **raise awareness of Washington State Department of Commerce services offered.**	Education and training

Opportunity/Theme	Key Findings/Considerations	Strategy	Type of Assistance
Mexico	Nearby large market, part of NAFTA.	**Develop a list of potential distributors** and **representatives** in Mexico.	Market research
		Actively inform Washington companies of Commerce's ability to vet distributors and representatives in Mexico.	Market research/ education and training
European Union (Germany, France, UK, and Austria)	Some of largest healthcare markets in world, measured by total healthcare expenditures and on per capita basis.	**Inform** Washington companies on **how to enter these markets** and include this information on the Washington State Department of Commerce website.	Education and training
		Vet distributors and representatives for companies in these markets.	Market research
		Consider organizing a trip to **medical trade shows in the EU**, such as MEDICA in Dusseldorf.	Market research/ education and training

CONTENTS

INTRODUCTION

Background and Purpose

Life sciences and global health covers a broad range of activities and organizations, spanning health sciences research institutions, nonprofits, health service providers, pharmaceutical companies, and many more. Globally, the sector's diversity of activities means it doesn't have a single supply chain, the way some other sectors do. Instead, each major component has its own unique supplier structure.

The sector is experiencing two major trends: increased interest in health IT for mature health markets and developing countries alike, and the implications of aging populations in some of the world's mature life sciences markets. Health IT solutions offer expanded and improved care to people in mature health markets.

At the same time, developing countries are looking to health IT to deliver cost-effective information and health services to their people. Telehealth, for example, reduces the cost burden of getting healthcare by eliminating patient travel time. Countries like Germany, the UK and France are beginning to see their demographic composition shift, with sustained low birth rates resulting in an older population on average.

According to the United Nations, the world's population aged 60 and over is forecasted to increase from 12.3% of the population in 2015 to 21.5% of the population in 2050. This represents a fundamental, global shift that will impacts the life sciences and global health industry. In particular, this shift will involve increased demand for diagnostic and medical equipment, especially equipment involved in late-in-life care.

The Washington State Department of Commerce (Commerce) has requested this study to assess opportunities for life sciences and global health defense contractors to expand their activities overseas, with both defense and civilian clients and partnering organizations. Analytics presented in this report present findings on overseas market opportunities, including key markets, trends, as well as challenges and considerations, culminating in a set of actionable strategies for Commerce execute on to support overseas expansion among these businesses and organizations.

Methods

This project has required a hybrid research methodology, leveraging a wide spectrum sources and materials. These include:

- Existing federal and private sector research reports
- News articles
- Exporting and defense contractor data

- Industry forecasts
- Military spending data, sourced from national government budget reports and the Stockholm International Peace Research Institute, among other sources
- Interviews with: 1) existing exporters in the life sciences and global health sector; 2) defense life sciences and global health contractors; 3) government and policy officials, including in the Department of Defense and U.S. Foreign Commercial Service; and 4) industry experts

Method for developing recommendations

Recommendations are focused on addressing market opportunities specific to defense life sciences and global health activities and contractors in Washington. Variables considered include: 1) characteristics unique to defense contractors, including size and ability to scale to foreign sales; domestic factors, such as regulatory considerations and pull of the domestic U.S. market over international markets; 3) foreign government factors, including state policies biased to indigenous industries; 4) industry and technology factors, such as the exportability of certain products and services; 5) macroeconomic conditions; 6) regional and geopolitical factors, such as the strengthening of U.S. military alliances in East and Southeast Asia; and 7) considerations specific to defense versus civilian opportunities.

Recommendations were further synthesized according to existing resources at Commerce. These include education and training, technical and regulatory assistance, market research, and advocacy support. A more detailed discussion of how recommendations were developed can be found in the **Appendix**.

Organization of Report

- **Life Sciences and Global Health Defense Spending in Washington**. An overview of leading life sciences and global health subsectors and contractors in Washington.
- **Key Industry Trends and Global Considerations**. Factors and trends shaping opportunities and challenges for life sciences and global health defense contractors, including domestic and overseas barriers.
- **Exporting and Competitiveness Factors**. Strengths and weaknesses of Washington life sciences and global health defense contractors in overseas markets.
- **Market Opportunities**. Country and region-specific opportunities for defense contractors, based on the matching of current, resident capabilities and overseas demand and market conditions.

- **Recommended Strategies**. Actionable strategies Commerce can undertake to support life sciences and global health defense contractor exports.

DEFENSE SPENDING IN WASHINGTON

Washington's life sciences and global health defense contractors sold $68.2 million in equipment and services to the Department of Defense in fiscal year 2015. Unlike other sectors, these companies sold primarily to smaller DOD agencies like the Defense Logistics Agency, Defense Threat Reduction Agency, and Defense Health Agency, with $43 million going to the Army, Navy and Air Force.

The main subsectors are: a) Medical Equipment; b) Research and Development; c) Medical Services; d) Health IT; e) Safety Equipment; f) Pharmaceuticals, Biologicals and Chemicals; g) Training and Equipment; and h) Support, Maintenance, Repair and Inspection.

Medical Equipment

Medical equipment is one of the largest life sciences and global health categories purchased by the Department of Defense and Coast Guard. In fiscal year 2015, an estimated $29.6 in contracts were awarded to Washington firms engaged in these activities. While the military has some specific requirements for products it buys, much of the medical equipment Washington manufacturers sell to the DOD is largely the same as commercial medical products.

- **Sonosite, Inc.** regularly sells medical imaging equipment to the Defense Logistics Agency. (Office of Management and Budget, 2016)
- **Sterlitech Corporation**, a Kent-based laboratory product manufacturer, sells water purification equipment to the Army. The company's offerings cover filtration systems, vacuum pumps, centrifuges for sample preparation, and laboratory sterilization equipment like autoclaves. Much of the laboratory equipment is manufactured with small research and analytical laboratories in mind. (Sterlitech Corporation, 2016; Office of Management and Budget, 2016)

Support, Maintenance, Repair, and Inspection

This category covers support activities related to life sciences and global health. Medical equipment and facility testing, maintenance, repair, and inspection are the major services covered in this category. This is another relatively small contracting category, with $500,000 in contracts in 2015.

A large number of medical device manufacturers also offer maintenance, repair, and inspection services to the Department of Defense.

- **Sonosite**, one of the leading ultrasound producers, for example, has a five-year warranty services and regularly repairs and maintains these devices.
- **Cadwell Industries** also offers service contracts—both on-site and remote, depending on customer needs—for its medical devices, which include electroencephalograms and sleep monitoring equipment, among others.

Research and Development

Research and development includes medical, biomedical, and environmental quality research and development. The Infectious Disease Research Institute, Institute for Systems Biology, and Fred Hutchinson Cancer Research Center are examples of life sciences research organizations in Washington. In fiscal year 2015, an estimated $3.2 million in contracts were awarded to Washington firms engaged in these activities.

The Institute for Systems Biology, Geneva Foundation, and Healionics Corporation were all contracted for medical, biomedical, and other applied research and development in the life sciences.

- **The Geneva Foundation**, a nonprofit organization dedicated to improving medicine in the military, is headquartered in Washington and has received more than $100 million in grants and contracts from the Department of Defense since fiscal year 2008. The group has research locations throughout the United States, and engages in research on numerous health topics, from IBS and Crohn's disease to PTSD. (Geneva Foundation, 2016; Office of Management and Budget, 2016)
- The Defense Threat Reduction Agency contracted the **Institute for Systems Biology** for applied biotechnology research services. The research will cover the identification of early stage sepsis biomarkers, which would help health professionals begin treating sepsis before symptoms first appear. Sepsis is a medical condition where the body's response to an infection results in widespread inflammation. Such inflammation can damage organ systems and can even result in death. This research, though funded by the Department of Defense, would have implications outside of the field of defense. (Global Biodefense, 2013)
- **Healionics** was awarded a Small Business Innovation Research (SBIR) grant from the Department of Defense in 2014 for research on a new vascular graft design. Presently, the standard approach to repairing damaged arteries is to bypass the damaged area with a vein surgically removed from another part of the body. However, not all patients have suitable, healthy veins in other parts of their body, and this research would benefit them.

(Healionics, 2015; Healionics, 2014; Office of Management and Budget, 2016)

- **Micronics Inc.**, a disease diagnostic research and development company in Washington, is also a defense contractor. In 2012, the company was hired by the Department of Defense U.S. Special Operations Command to develop field kits for blood type testing. The small platforms offer human diagnostic testing that can be done rapidly in the field, in addition to the valuable service this kind of tool can provide for the Department of Defense, it is also valuable for emergency responders and healthcare providers. (Micronics, 2016)
- **SightLife** is a Washington-based nonprofit global health organization that focuses on eliminating corneal blindness in the U.S. and around the globe. The organization is accredited with the Eye Bank Association of America and the Food and Drug Administration. SightLife is the largest provider of corneas for transplants in the nation. The organization assesses and transports donor eye tissue as well as works with eye banks in surgeons in 25 countries. On average, SightLife is able to provide corneal transplants to 50 people every day. The organization's work for the Department of Defense falls in line with its regular activities: it regularly provides corneal transplants. SightLife provides the same service to the Department of Veterans Affairs. (SightLife, 2016)

Medical Services

Medical services cover laboratory testing, pharmacology, and pathology services. There are a number of contractors engaged in these activities across the state. These organizations provide laboratory testing, medical and dental care, and water safety testing services to the Department of Defense and Coast Guard (Office of Management and Budget, 2016). Examples of medical services defense contractors include:

- The **Puget Sound Blood Center** provides medical testing services to the Department of Defense.
- The **Seattle Cancer Care Alliance** is a cancer treatment facility in Seattle that provides medical services to the Department of Defense.
- **Centric Analytical Labs** provides laboratory testing services. In particular, the company focuses on water safety testing.
- **Incyte Pathology** is a Spokane Valley-based disease diagnostics company. The company's expertise lies in anatomic pathology, diagnosing diseases based on tissue testing.
- **Antek Dental Lab** provides dental laboratory services to the Department of Defense, including porcelain, ceramic, and metal dental products. The company is located in Bremerton, close to Naval Base Kitsap.

Health IT

Health IT is a growing field within life sciences and global health, and covers software and related equipment. This category includes automatic data processing software and hardware and communication systems used in the life sciences. Medical device producers often develop software-reliant equipment like heart rate monitors and automatic external defibrillators that make use of health IT software and systems. Healthcare software companies and consultants like Healthcare Resource Group are also part of this subsector.

A number of companies in Washington sell automatic data processing software and equipment for life sciences applications to the Department of Defense, including Philips Healthcare, Cadwell Laboratories, Physio-Control, and Fujifilm Sonosite.

- **Philips Healthcare** primarily sells biomedical equipment, which increasingly involves automatic data processing units and software.
- **Medpacs LLC** provides Picture Archiving and Communication System (PACS) services to the Department of Defense. PACS allow efficient storage of and access to medical images from different machine sources. Magnetic Resonance Imaging output, X-Ray plain film, and Computed Tomography images, for example, can be stored in the same system. This specialized product and associated services are usually developed and performed in-house by hospitals and other large healthcare providers.

Safety Equipment

Safety equipment is essential to laboratory and hospital work in life sciences and global health. Products like lifesaving equipment and hazardous material spill containment and cleanup equipment help reduce safety threats in research and development laboratories as well as facilities. Examples of safety equipment defense contractors include:

- Fife-based **Excel Gloves and Safety Supplies**, for example, sells common medical and industrial safety supplies to the Department of Defense. The company also contracts with King County and other local government entities.
- **MesoSystems Technology** is an example of a defense contractor that provides specialty safety equipment. The company manufacturer products for bio-threat surveillance, detection, and response. MesoSystems' AirSentinel is a building protection sensor that combines a smoke alarm with a portable air sample that enables collection of samples for detailed laboratory analysis. (Bloomberg, 2016)

Pharmaceuticals, Biologicals, and Chemicals

This subsector includes drugs and biologicals, whether for human or veterinary use, along with pharmaceuticals and chemicals. This category represents a smaller area of defense contracts in Washington. Total contracts in this space summed to $300,000 in 2015. Most of the largest contracts in this category are with blood banks, including the **Puget Sound Blood Center** and the **Tacoma-Pierce County Blood Bank**.

Several Washington pharmaceutical companies contract with the DOD, including:

- **S R Helix Group** has a number of recurring sales of chemicals and pharmaceuticals to the Defense Logistics Agency. Most of these contracts are in the $200-$600 range.
- **Alder BioPharmaceuticals**
- **OncoGenex Pharmaceuticals**
- **Sound Pharmaceuticals**
- **Bayer Healthcare**
- **Genzyme**

Training and Equipment

This category covers certification and accreditation services as well as actual training aids used for medical training purposes. Examples of training and equipment defense contractors include:

- **Medical Training Consultant Inc.**, a Tacoma-based company that provides consulting and education to government professionals, is one example. In particular, the center specializes in intravenous therapy.
- **Simulab Corporation** is a training equipment manufacturer. The company's goal is to design and deliver realistic training devices that simulate soft tissue. The company's TraumaMan product is the most widely used surgical trainer in the world, and the product has been used by more than 375,000 students in its 15-year history. In 2015 alone, more than 35,000 students trained on TraumaMan devices. Simulab also manufactures suturing simulation products. More than 70% of U.S. medical schools train with Simulab's suturing products. (Simulab Corporation, 2016)

KEY INDUSTRY TRENDS AND CONSIDERATIONS

Several key factors will shape global opportunities for life sciences and global health defense contractors. These include trends in healthcare expenditures overseas, demographic trends, subsector-specific considerations, existing global clusters for comparable technologies, and

existing trade ties between U.S. and Washington firms and overseas markets. Each of these considerations is discussed in turn below.

Life Sciences and Global Health in Washington

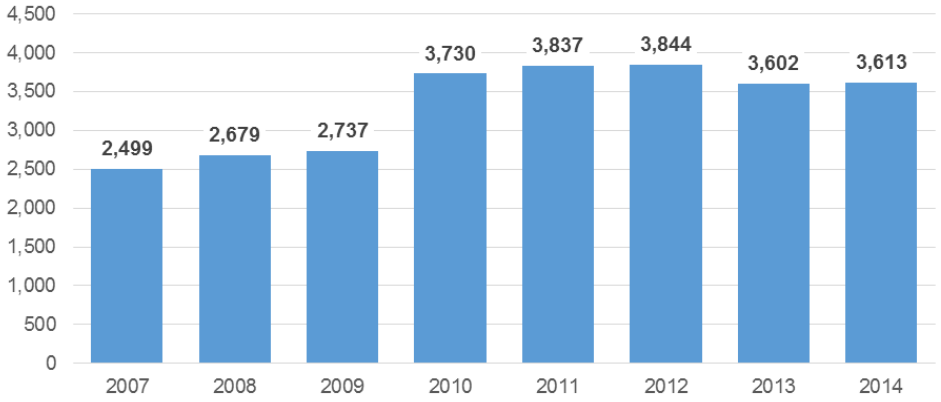
Washington has a large life sciences and global health industry. The Seattle region is home to one of the five largest life sciences clusters in the nation, with more than 500 organizations. In 2014, the sector had 34,200 jobs. **Philips** is the second-largest global producer of ultrasound equipment and the largest producer of ultrasound machines in Washington. The company's Bothell location has 2,000 employees. Other ultrasound producers in Washington include Siemens, Ekos, and Mirabilis. (Life Sciences in the Greater Seattle Region, 2016)

Top sectors by number of employers, 2015:

- Medical Technology: 301
- Biotechnology/Pharmaceuticals: 240
- Digital Health/Health IT: 126
- Other: 115
- Academic, Nonprofit, Research, and Support: 106 (Washington State Life Sciences Economic Impact Report, 2015)

Washington companies specializing in biotechnology research and development include the Institute for Systems Biology, the Fred Hutchinson Cancer Research Institute, the Allen Institute for Brain Science, and the University of Washington among many others. The subsector increased from just under 2,500 jobs in 2007 to more than 3,600 in 2014 (a compound annual growth rate of 5.4%); by comparison, total employment in the state grew at a compound annual growth rate of 0.6% over this same period. In 2014, the subsector paid wages of $465.4 million, an average wage of $128,400 per worker excluding benefits, up from $86,300 in 2007.

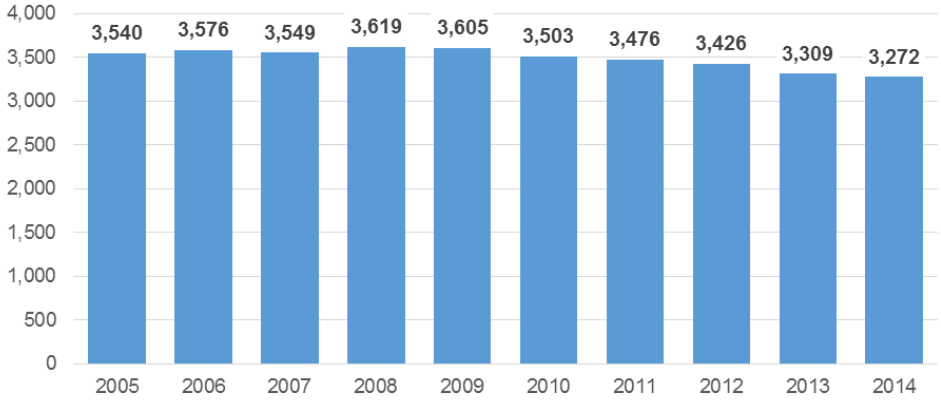
Exhibit 1. Biotechnology Research and Development Jobs, Washington State, 2007-2014



Sources: Washington State Department of Revenue, 2014; U.S. Bureau of Labor Statistics, 2015.

Medical device manufacturing employment in the state has declined in recent years. Covered jobs in this subsector totaled 3,300 in 2014, and are highly concentrated in Redmond and Bothell. In particular, the industry is composed of a few large manufacturers, like Sonosite, with a large number of smaller manufacturers spread across the region.

Exhibit 2. Medical Device Manufacturing Jobs, Washington State, 2007-2014



Sources: Washington State Department of Revenue, 2014; U.S. Bureau of Labor Statistics, 2015.

Washington Life Sciences and Global Health Supply Chain Analysis

The United States Benchmark Input-Output table describes how different industries purchase from one another, making it a valuable tool for assessing supply chain linkages and cross-industry exporting opportunities. Medical device manufacturing covers: surgical and medical

instrument manufacturing, surgical appliance and supplies manufacturing, dental equipment and supplies manufacturing, ophthalmic goods manufacturing, and electro-medical and electrotherapeutic apparatus manufacturing.

The bulk of medical device manufacturers' inter-industry purchases are for components, such as rolled and extruded copper, semiconductors, bolts, adhesives, and plastics (**Exhibit 3**). These manufacturers also sell within their industry. For example, a surgical appliance manufacturer could purchase an appliance component from another surgical appliance manufacturer.

Medical device manufacturers sell the bulk of their goods (by value) to healthcare practitioners like hospitals, nursing facilities, offices of physicians, and medical laboratories. This suggests hospitals as possible overseas markets for defense contractors in this space.

Washington's medical device producers are primarily original equipment manufacturers (OEMs). With this in mind, the key export strategy for Washington's medical device manufacturers centers on exporting finished products.

Exhibit 3. Direct Purchasers of Medical Devices, U.S., 2012

Industry	Share
Hospitals	25%
Offices of physicians	10%
Offices of dentists	10%
Outpatient care centers	8%
Surgical and medical instrument manufacturing	7%
Surgical appliance and supplies manufacturing	5%
Services to buildings and dwellings	3%
Nursing and community care facilities	2%
Waste management and remediation services	2%
Veterinary services	2%
Dental laboratories	1%
Medical and diagnostic laboratories	1%
Electromedical and electrotherapeutic apparatus manufacturing	1%
Other	22%

Sources: Bureau of Economic Analysis, 2012.

Healthcare Expenditures Globally

The U.S., owing to its size and economic position, remains the largest market for healthcare services and products. In 2014, total healthcare expenditures in the U.S. amounted to nearly $3 trillion; by comparison, the next largest market, China, spent roughly one-fifth of U.S. outlays (**Exhibit 4**). The difference between major markets converges slightly on a per capita basis, with the U.S. still leading at $9,400 per resident

compared with more than $6,000 in Australia and $5,400 in Germany. Overall, according to the World Health Organization (2016), global healthcare expenditures totaled nearly $7.6 trillion, of which $5.8 trillion were from the ten largest markets.

Exhibit 4. Leading Countries by Total Healthcare Expenditures, 2014

Rank	Country	Total Expenditures (bils US $)	Per capita Spending
1	U.S.	$2,985.7	$9,400
2	China	$574.8	$420
3	Japan	$470.7	$3,700
4	Germany	$437.0	$5,410
5	France	$326.5	$4,960
6	United Kingdom	$253.0	$3,930
7	Italy	$198.0	$3,260
8	Brazil	$195.2	$950
9	Canada	$186.6	$5,290
10	Australia	$140.0	$6,030
	Subtotal, top ten	*$5,767.6*	*$2,450*
	Worldwide	**$7,593.4**	**$1,060**

Source: World Health Organization, 2016.

Measures as a percentage of GDP, the highest healthcare spending in 2014 was the Americas, at 14.2% (**Exhibit 5**). The European Region made healthcare expenditures equal to 9.5% of GDP, while South and East Asia, including China, India, and Japan, totaled 4.3%.

Exhibit 5. Total Healthcare Spending, 2014

Country Group	Total Healthcare Expenditures as % GDP	Per capita spending (US $)
African Region	5.5%	$107
Region of the Americas	14.2%	$3,730
South-East Asia Region	4.3%	$84
European Region	9.5%	$2,426
Eastern Mediterranean Region	4.8%	$243
Western Pacific Region	7.1%	$746
Total	**9.9%**	**$1,057**

Source: World Health Organization, 2016.

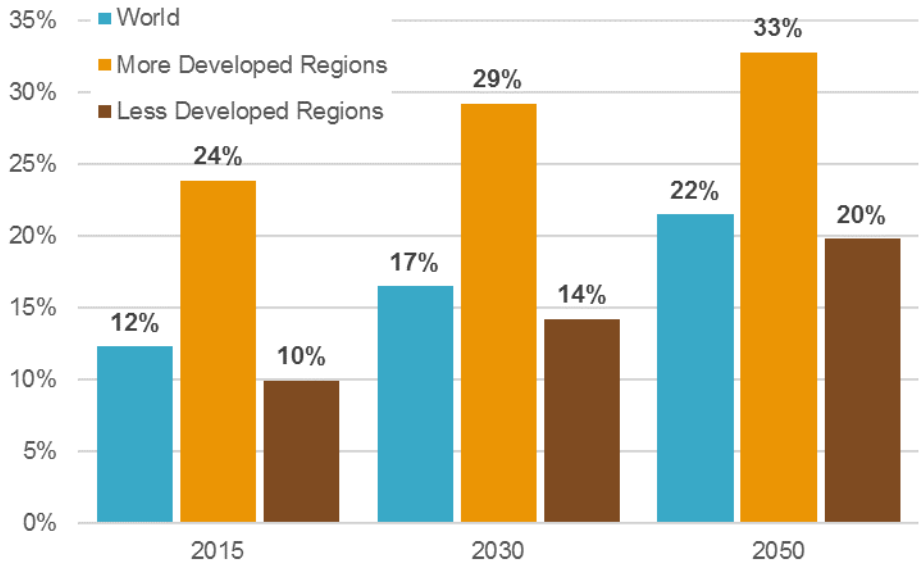
Aging Populations

A common phenomenon among more affluent countries and some developing economies around the globe is the ageing of populations. This is due in part to a relative decline in population growth, as couples choose to have fewer children relative to their own parents.

Countries with aging populations often have higher medical needs than other countries, and their medical needs are different. In countries with aging populations, there is often increased demand for diagnostic equipment like imaging machinery, as well as demand for long-term care services. In this way, population aging is simultaneously driven by, and a driver for, advancements in medical technology availability. By 2050, the United Nations forecasts that 22% of the global population will be 60 or older, up from an estimated 12% in 2015.

Countries the UN has identified as "less developed nations" are expected to experience an increase in population aged 60 and older from 10% in 2015 to 20% in 2050. For countries the UN has identified as 'more developed nations,' the increase in population aged 60 and older is more gradual. This is because these nations have already experienced a rapid increase over the past two decades, a rate that the UN forecasts to slow significantly. (**Exhibit 6**)

Exhibit 6. Population Aged 60 and Older, 2015 Estimate and 2030 and 2050 Forecasts



Source: United Nations, 2016.

Health IT

Health IT is still a relatively new field, with a growing commercial sector in the U.S. Health IT products and services are designed to improve patient care and health outcomes, increase coordination capabilities, and reduce health costs. Today, two of the fastest-growing fields in health IT include telehealth and mobile health. The widespread, low-cost adoption of health IT solutions could have major impacts on health outcomes for decades to come. (International Trade Administration, 2016)

Health IT has the potential to significantly alter the healthcare sector. Both advanced countries with high health spending per capita like Japan, Germany, and Sweden, and low- and middle-income countries represent growing opportunities for health IT. For low- and middle-income countries, the higher burden of disease makes implementing health IT solutions like telehealth and mobile health attractive, cost-effective tools. In countries with high health spending per capita, new health IT solutions can help limit costs and improve care delivery. (International Trade Administration, 2016)

Due in part to how young the field of health IT is today, exporters may run into antiquated, outdated, or inadequate country policies regarding health IT. Many countries have not had the chance to respond to the rapidly-changing health IT landscape. Additionally, companies may find that medical liability concerns will vary by country and product; in some countries, health IT solutions like remote diagnoses and remote care are not legal. In other countries, inaccurate or faulty treatment using mobile

health or telehealth may involve different liability laws than others. (International Trade Administration, 2016)

As in many IT subsectors, the concern for data privacy and security is highly important to health IT. Due to the sensitive nature of medical information, health IT may be even more sensitive to information security issues. Some countries may require that patient data be stored in-country, adding another level of complexity for aspiring exporters of health IT. (International Trade Administration, 2016)

Medical Devices

Advanced healthcare markets, like countries in the EU and East Asia, have high demand for cutting-edge medical technology products. U.S. exporters may find export opportunities in areas that import high-end technological products.

According to the U.S. International Trade Administration, demand for medical devices will be strong globally between now and 2020 (**Exhibit 7**). The Americas, predominately the U.S., will remain the largest geographic market, but demand in the Asia Pacific region will increase at an annual rate nearly a percentage point faster (6.6% per year); much of this growth can be attributed to China and growing demand from a growing middle class. Western Europe, the second largest major geographic market in 2016, will experience the fastest-projected growth in medical device demand (7.5%), due in part to the ageing of affluent societies in the UK, Germany, France, and elsewhere. (U.S. International Trade Administration, 2016)

Exhibit 7. Worldwide Medical Devices Market Forecast, 2016-2020, Billions of Dollars

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 Europe	14.6	15.7	17.0	18.1	19.1
Middle East and Africa	10.0	10.8	11.6	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: U.S. International Trade Administration, 2016.

Increasing trend to more mergers of health systems, resulting in market consolidation in the US. Large, integrated systems are becoming larger and even more integrated due to acquisitions. Some manufacturers made recent acquisitions of key customers or vice-versa. (Healthcare Supply Chain Top 25, 2013)

In 2015, the largest markets for U.S. medical devices and pharmaceutical products were Belgium, Netherlands, Japan, Canada, and Germany (**Exhibit 8**). Total U.S. exports of these products summed to $83.0 billion in 2015; the top ten export markets equaled 69% of all U.S. exports of these products.

Exhibit 8. U.S. Top Global Markets for Pharmaceutical and Medical Device Exports, 2015, Millions of Dollars

Rank	Country	Exports (mils $)
1	Belgium	10,238.1
2	Netherlands	9,148.4
3	Japan	7,203.1
4	Canada	6,501.3
5	Germany	4,997.0
6	United Kingdom	4,424.4
7	China	4,411.7
8	Mexico	4,045.5
9	Switzerland	3,146.8
10	Ireland	2,974.7
	Other Countries	*25,886.2*
	Total	**82,977.2**

Sources: U.S. Census Bureau, 2016; Community Attributes Inc., 2016.

Global Clusters

There are three significant clusters of medical device manufacturers: Japan, South Korea, and Germany. Companies in these clusters compete with Washington's life sciences and global health companies, and some have subsidiaries in Washington.

Japan

Japan has a cluster of medical device producers, including: Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Koden, and Fukuda Denshi. The country also has a large number of medical IT companies: Hitachi, Sony, Fujitsu, Ricoh, Toshiba, Samsung. (Japan Healthcare Resource Guide, 2015)

South Korea

The South Korean government has supported high-tech research and development through establishment of High-Tech Medical Clusters, one of which (Daegu-Gyeongbuk) has an ICT focus. (Health IT Top Markets Report, 2015)

Germany

Germany has a few large producers, including Siemens, B. Braun and Fresenius. 95% of the German medical technology industry is made up of small and mid-sized companies or subsidiaries of larger companies. As a result of a low-growth domestic market, the German medical technology industry has to rely heavily on export markets for continued growth. (Germany Healthcare Resource Guide, 2015)

EXPORTING AND COMPETITIVENESS FACTORS

Certifications

In some cases, countries will not import certain goods without a specific certification. Some international certifications also signal quality to potential importers. One such example is ISO 9001. This certification refers to manufacturing process practices. It is a quality management system certification that spans recordkeeping, checking for defects, implementing a continuous improvement program, and others. This certification covers all manufacturing fields, including those in the life sciences and global health sector.

There are a number of major quality management systems specifically designed for medical products and software. While these vary by product, there are several major certifications. ISO/TR 27809 is a quality management system for health software producers designed to ensure patient safety. ISO 13485 is a quality management system created particularly for medical devices. ISO 23640 describes quality management practices for in vitro diagnostic medical devices. It includes evaluation of stability of in vitro diagnostic reagents. ISO 12417 is a set of quality management techniques for cardiovascular implants and vascular device-drug combinations. CE Certification is available for medical supplies, medical diagnostic tests, and other life sciences products that meet EU safety requirements. This is required for entry into the EU, but is also regarded as an international mark of quality.

The Certificate of Pharmaceutical Product is a certificate issued in accordance with World Health Organization (WHO) standards by a certifying authority within a country. This international standard was designed to help importers and exporters by providing a common standard and reducing the burden of navigating foreign certification processes. This is a voluntary international system used by WHO member states, and implementation varies from member to member.

Export Controls

Life sciences and global health defense exports are often subject to export controls. These regulations on the overseas sales of life sciences and global health products and services help shape potential markets for

Washington defense contractors. Details on the rules and specific implications for life sciences and global health defense firms are discussed below.

International Traffic in Arms Regulations

The International Traffic in Arms Regulations (ITAR) control the import and export of defense articles and defense services. The U.S. Munitions List (USML) is a list of defense articles and services controlled under ITAR. The USML is divided into 21 categories. USML Category XIII (Materials and Miscellaneous Articles) and USML Category XIV (Toxicological Agents) are the most relevant to the life sciences industry. For example, intelligence cryptographic software that a defense contractor may want to reuse for protecting sensitive medical information may fall under USML Category XIII and biological assays that include bacteria, viruses, or other hazardous reagents may fall under USML Category XIV.

ITAR has strict licensing requirements and exports of defense articles and defense services to most all countries and in most all circumstances require an export license from the U.S. State Department's Directorate of Defense Trade Controls (DDTC). Certain articles and services may, however, be exported to Australia, Canada, and the United Kingdom, without DDTC licensing if certain requirements are met. Nevertheless, Washington defense contractors must carefully review ITAR's licensing requirements and exceptions to avoid inadvertently violating ITAR.

Export Administration Regulations

The U.S. Commerce Department's Bureau of Industry and Security (BIS) administers and enforces EAR. Maritime companies must consider compliance with EAR when providing non-military use products to, or technology with, customers outside of the United States.

The CCL is divided into ten categories. CCL Category 1 (Materials, Chemicals, Microorganisms, and Toxins), CCL Category 3 (Electronics Design Development and Production), and CCL Category 4 (Computers) are the most relevant to the life sciences industry. For example, certain piezoelectric materials fall under CCL Category 1, high resolution analog-to-digital converters fall under CCL Category 3, and high powered computers for processing biometrics or image enhancement fall under CCL Category 4. In some cases, a product for export including all of these items may be subject to the licensing requirements under each of the categories.

Unlike ITAR, which requires DDTC licensing for nearly all exports, a potential maritime industry exporter with items controlled on the CCL first would review the CCL to determine the precise Export Control Classification Number (ECCN) that controls the item for export. It is important to note EAR controls products, design/testing/production

equipment, materials, software and technology. **Accordingly, the email of detailed blueprints or technical data controlled under a specific ECCN might require an export license from the BIS just as an export of the end-item produced using those blueprints**.

Many items previously listed on the USML that are now listed on the CCL are assigned ECCNs in the 600 series. Items in the ECCN 600 series are generally subject to a policy of denial by the BIS for export to China, Cuba, Iran, North Korea, Sudan, and Syria.

Each ECCN includes a list of the reasons for control. Once the exporter has located the ECCN and the reasons for control, the exporter can then refer to EAR's Commerce Country Chart (Country Chart). The Country Chart provides rows listing all countries of the world and columns listing the various reasons for control.

By reviewing the reasons for control and the country, an exporter can determine if a BIS export license is needed. If the reason for control column includes an "X" next to a country, then the exporter must apply to the BIS for an export license to export the item to that particular country unless a license exception is applicable. Each ECCN includes information on special license requirements and any licensing exceptions that apply. When an export license is required, the exporter can apply using the BIS's online system known as "SNAP-R."

Export Control Reforms

Through the Obama Administration's export control reform effort, the USML has undergone major revisions that have greatly reduced the number of products that fall under ITAR controls. As a result, Washington's life sciences and global health industry may see new market opportunities available because DDTC licensing may no longer be required for certain items that previously were under ITAR controls.

Although certain systems and major components have been removed from ITAR controls, the products affected generally have been parts, components, attachments and accessories that were only nominally adapted for military use and that have both military and civilian uses, so called "dual-use items."

A detailed example of an export compliance review came be found in the **Appendix**.

Food and Drug Administration Regulations

The Food and Drug Administration regulates pharmaceutical product and medical device sales in and through the U.S. This includes those that are manufactured for export only without approval for sale within the U.S., and those manufactured within the U.S. with approval for both export

and use within the U.S. Products made outside the U.S. that pass through the U.S. on the way to their final destination are also regulated and certified by the FDA. The FDA has this regulatory power under the Federal Food, Drug, and Cosmetic Act.

Export Assessment

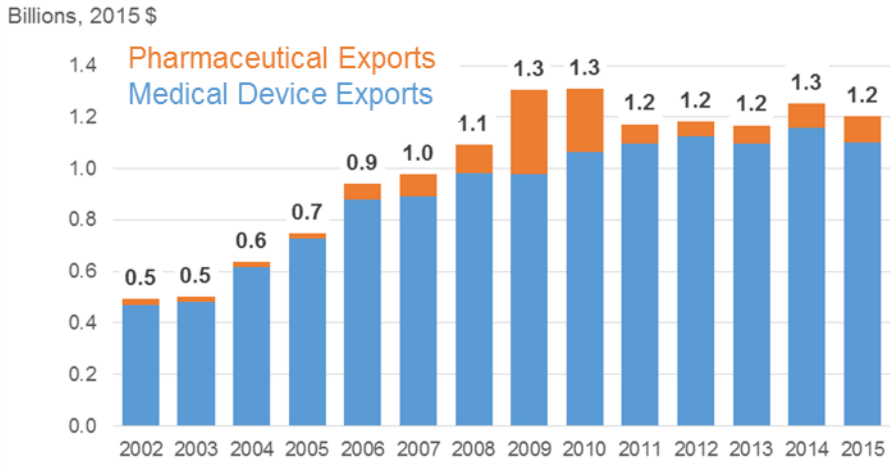
Washington exports a variety of life sciences and global health goods and services. Medication, biologics, bandages, medical and surgical equipment, and electronic medical devices are some major categories. Ultrasound equipment, one of the state's largest exports in this sector, is included among electronic medical devices.

Historic Exports

Pharmaceutical exports in 2015 totaled $101.4 million. Medicines and vitamins were the two largest pharmaceutical exports from Washington in 2015, generating $48.5 million and $33.3 million in sales, respectively.

Medical and surgical instrument exports totaled $1.1 billion in 2015, slightly down from $1.2 billion in 2014. Ultrasound equipment constituted the largest share of sales in this category. Philips, a medical device exporter, produces ultrasound machines in Washington at its Bothell facility. Other large medical and surgical instrument exports in 2015 included electro-diagnostic instruments ($164 million) and surgery and dental equipment ($205 million).

Exhibit 9. Washington State Pharmaceutical and Medical Device Goods Exports, Billions of 2015 Dollars, 2002-2015



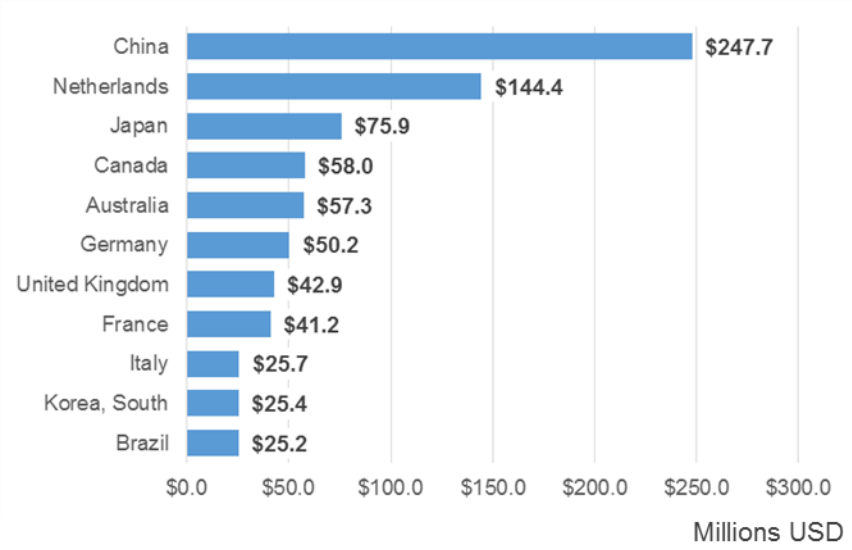
Sources: U.S. Census Bureau, 2016; Community Attributes Inc., 2016.

Key Markets

Washington companies export medical devices around the world. In 2015, the state sold $248 million in medical devices to China, an additional $144

million to the Netherlands, and $76 million to Japan. Canada, a country with which the U.S. has low trade barriers, imported $58 million in medical devices from Washington.

Exhibit 10. Washington State Top Global Markets for Medical Devices, 2015, Millions of Dollars



Sources: U.S. Census Bureau, 2016; Community Attributes Inc., 2016.

MARKET OPPORTUNITIES

Identifying and understanding market opportunities relies on analysis of key global trends, sources of demand, and the core competencies of Washington's life sciences and global health defense contractors. Market research reports, news articles, and stakeholder feedback were leveraged to identify specific opportunities.

The U.S. still retains a dominant share of the overall global market for many healthcare technologies. According to IMS Health (2015), in 2014 total pharmaceutical sales in the U.S. were greater than the combined sales of the next nine largest pharmaceutical markets in the world (**Exhibit 11**).

Exhibit 11. Top 10 Pharmaceutical Markets Worldwide, 2014

Rank	Country	Sales, 2014 (bils $)	% Growth over 2013
1	United States	376.3	12.5%
2	Japan	78.9	1.5%
3	China	75.9	11.3%
4	Germany	45.7	4.9%
5	France	38.1	1.6%
6	Italy	28.5	2.9%
7	United Kingdom	25.2	8.2%
8	Brazil	23.8	13.3%
9	Spain	21	2.1%
10	Canada	20.9	4.2%
	Top 10 markets combined	**734.2**	**9.1%**

Source: IMS Health, December 2015.

Japan

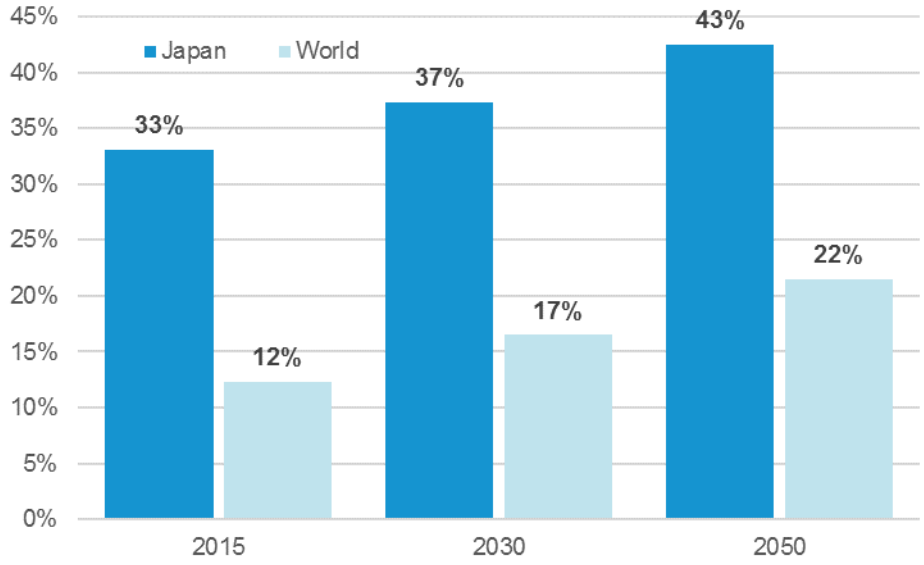
Market Overview

Japan is the third-largest economy in the world with $4.7 trillion in GDP in 2015. The country has a population of 126.9 million and is currently experiencing two important demographic phenomena: first, its birth rate has slowed dramatically in recent decades. Second, and largely as a result of the first trend, Japan has an aging population. In 2015, an estimated 33% of Japan's population was age 60 or older, the highest rate of any country. The Japanese population has been shrinking since 2014. (CIA, 2016)

Market Opportunities

Japan's market for medical devices and materials is among the world's largest. In 2013, the country's market for medical devices was $33.6 billion, up 3.2% from 2012. Japan imported $7.7 billion in 2013 from U.S. companies. In the near term, the market is expected to increase due to Japan's aging population and demands for advanced medical technologies. The market is heavily dependent on imports, especially advanced medical technologies. U.S. exports to Japan have a 23% total market share according to the official figures. U.S. medical device companies are strong producers of pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Japan's aging population, continued demand for advanced medical technologies and the Government of Japan's measures to promote the healthcare industry will sustain growth. (Japan Healthcare Resource Guide, 2015)

Exhibit 12. Population Aged 60 and Older, Japan and World, 2015 Estimate and 2030 and 2050 Forecasts



Source: United Nations, 2016.

Japan has the third-highest GDP (after the U.S. and China), a health IT market exceeding $1 billion in value, an aging population, a high concentration of its population in urban areas, a tech-friendly society, and good health IT infrastructure. This indicates that health IT has a good foundation in the nation with the potential for more growth. Despite the government's best attempts, the financial burden of providing healthcare benefits for the population is proving unsustainable (this is largely because Japan is a slow-growth, developed market). This means that private healthcare solutions will likely become a greater portion of total healthcare provision in the coming years. ACCJ identified five possible areas of cooperation with the U.S: healthcare data standardization, healthcare big data and data utilization, privacy and security, IT in national health insurance, and preventative care and IT. (Health IT Top Markets Report, 2015)

Market Barriers

Regulatory Complexity

Japan does not levy customs duties on medical devices, however it does highly regulate medical devices. Japanese companies that want to export to the U.S. need a license. U.S. companies that want to export to Japan need a license and register with the Pharmaceutical and Medical Device Agency as a "Registered Foreign Manufacturer." The U.S. firm needs to either have a subsidiary in Japan or designate a Japanese company that has marketing approval. This could be a regulatory consulting company or an importer or distributor. (Japan Healthcare Resource Guide, 2015)

The following industries have a hand in health IT: the Ministry of Economy, Trade and Industry (METI) has the lead in health IT services and commercial engagement; the Ministry of Health, Labor and Welfare (MHLW) leads on pharmaceuticals, medical devices, promotion of health products, and home healthcare; the Ministry of Information and Communication (MIC) leads on telecom policy, privacy and open data; the Consumer Affairs Agency leads on protection of personal information, with the above agencies and the Ministry of Internal Affairs and Communications providing guidance on regulations; and Ministry of Education, Culture, Sports, Science and Technology (MEXT) oversees university hospitals. There are many overlapping responsibilities, resulting in complex engagement for foreign companies. The regulatory environment is, however, expected to improve with continuing collaboration between the U.S. and Japan. (Health IT Top Markets Report, 2015)

Competition

Japan's domestic medical device industry focuses on diagnostic imaging equipment; therapeutic and surgical equipment; biometrics measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Top companies include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Koden, and Fukuda Denshi. (Japan Healthcare Resource Guide, 2015)

Japanese companies are at the forefront of health IT, including **Hitachi**, focused on the development of healthcare infrastructure and medical care. Other competitors include Toshiba, Sony, Fujitsu, and Ricoh. (Health IT Top Markets Report, 2015)

Market Assessment

The country is made more attractive by low barriers to trade, but competition from established domestic manufacturers temper the available opportunities. In addition, the nation's regulatory system can be complex and difficult for foreigners to navigate. As such, a company that wishes to export to Japan may need to be prepared to dedicate significant resources to doing to—including potentially hiring an expert on the nation's health product regulations.

The barriers to trade are not insurmountable, however, and the significant opportunities represented by an aging population and increasing demand for health IT solutions make the nation a middling-to-high opportunity for Washington's life sciences and global health defense contractors.

South Korea

Market Overview

Korea has a three-tier medical system: 1) private hospitals and public health centers that have limited services and are for early intervention; 2) inpatient and outpatient care and emergency services; and 3) general hospitals or medical school hospitals which are the largest, have more services, but are very expensive. (Health IT Top Markets Report, 2015)

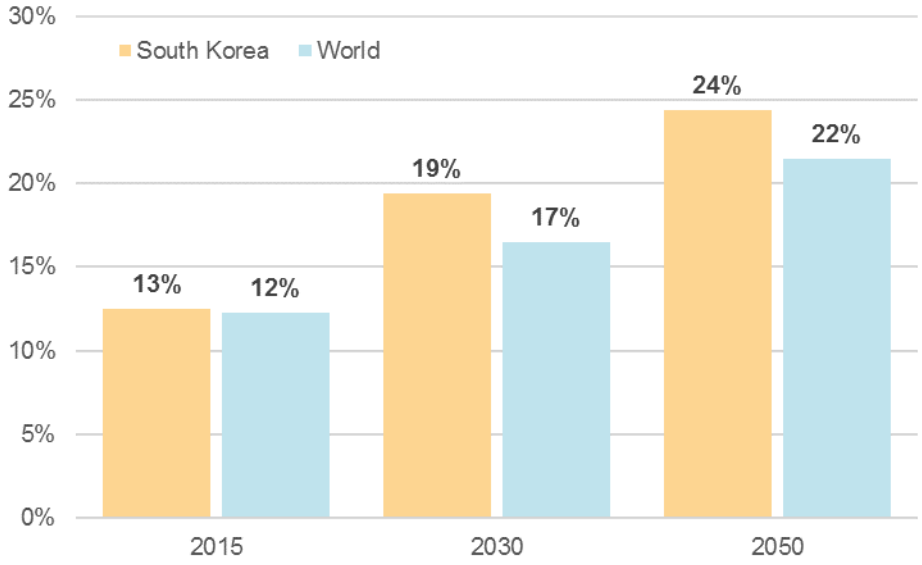
Market Opportunities

Korea depends on high-end medical devices from the U.S., EU, and Japan, to supply about 60% of total market demand. Currently, the United States has largest import market share in Korea, followed by the EU and Japan. Korean companies manufacture comparatively lower-end (mid-technology) medical devices. In 2015, total imports of medical devices were estimated at $3.2 billion, with U.S. imports totaling more than $1.4 billion. (South Korea Healthcare Resource Gide, 2015)

The top ten medical device imports in 2014 were: stents, soft contact lenses, sight corrective ophthalmic lenses, Dialyzers for hemodialysis, Knee joint prostheses, MRI devices, analyzing products, chemiluminescence immunoassays, intravascular catheters, CT systems, and IVD reagents for clinical immunochemistry. (South Korea Healthcare Resource Gide, 2015)

South Korea has well established infrastructure for IT, making it a good target for health IT. It also has an aging population and very high research and development spending (4% of GDP, the highest in 2015). At the same time, the country's medical system is very strained. (Health IT Top Markets Report, 2015)

Exhibit 13. Population Aged 60 and Older, South Korea and World, 2015 Estimate and 2030 and 2050 Forecasts



Source: United Nations, 2016.

Collaboration with **Samsung** (also the region's top competitor) is possible. (Health IT Top Markets Report, 2015)

Due to the Korea-US Free Trade Agreement (KORUS FTA) implemented on March 15, 2012, approximately 85-90% of imported medical devices in Korea received duty-free treatment within one year, and tariffs on the rest will be eliminated by 2018. (South Korea Healthcare Resource Gide, 2015)

Market Barriers

Regulatory Complexity

All medical devices are required to obtain marketing clearance from the **Ministry of Food and Drug Safety** (MFDS) before they are manufactured in or imported into Korea. Medical devices are classified into four categories in Korea depending upon product use. MFDS requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Class III and IV devices must pass the most stringent technical review by authorized labs to prove their safety and effectiveness. Since MFDS issues product licenses only to locally based firms, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers, or U.S. supplier's corporation located in Korea. Lead time for approval ranges from six to 12 months. (South Korea Healthcare Resource Gide, 2015)

Government policies and regulations currently exist for data privacy and security, medical devices, public health, and ICT, but not specifically for health IT. The government has published an e-Health roadmap. Five agencies have jurisdiction over aspects of Health IT, making coordination between agencies and updating current ICT regulations challenging. (Health IT Top Markets Report, 2015)

Competition

All three telecommunications operators and other large Korean companies are entering into the Health IT market. **Samsung** is particularly interested in the healthcare sector and has also shown interest in purchasing health IT products and services from other companies, proving possible opportunities for small- and medium-sized U.S. companies to enter the market. (Health IT Top Markets Report, 2015)

National Health Insurance Program and Reimbursement Pricing

The Korean government determines funding, coverage, coding, payment and, most importantly, pricing. Korea has compulsory National Health Insurance (NHI) system for 50 million citizens. The NHI system was introduced in 1977 and covered entire population by 1989. This is simultaneously a stabilizing element, making it clear to potential exporters what they can expect to be paid for certain products, and a barrier to trade, effectively causing exporters to rely on a single buyer in the country. (Health IT Top Markets Report, 2015)

Market Assessment

South Korea has two major factors that make it an attractive export market: it has an aging population, and has high demand for advanced diagnostic products and medical devices. Similar to Japan, Washington companies that want to export to South Korea will experience competition from domestic producers. Regulatory complexity is another barrier. Weighing the barriers against the opportunities, South Korea is a middle-to-high opportunity for Washington's life sciences and global health defense contractors.

China

Market Overview

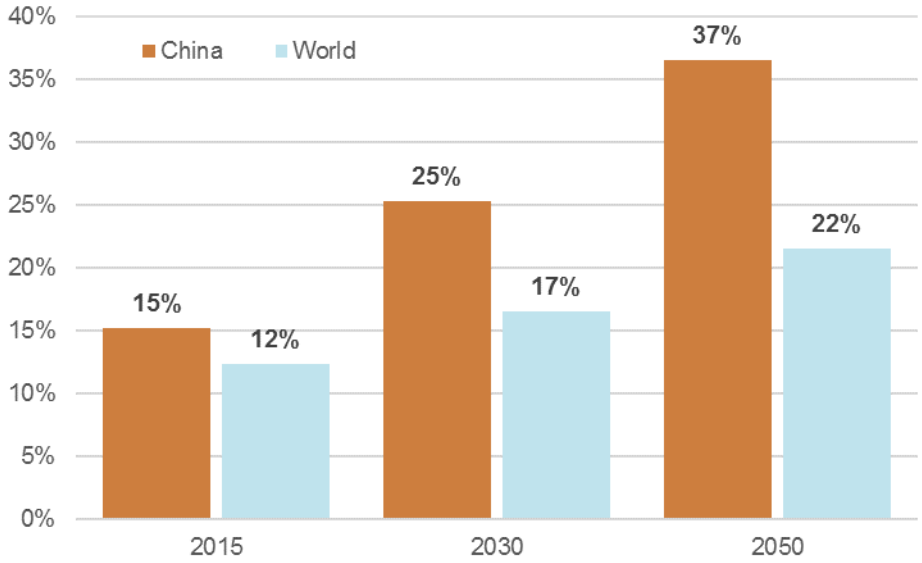
China is one of Washington's largest trade partners. In 2015, Washington exported just under $20 billion in merchandise and commodities to China. The country is one of the largest global markets for medical devices and health IT, with a growing population and increasing demand for health products. In 2015, China had a population of 1.4 billion people and an economy that generated $19.5 trillion. (CIA, 2016)

Market Opportunities

China has been among the fastest-growing economies in the world, growing 7.4% (GDP) in 2014. The Chinese medical device market is one of the fastest growing sectors in China. In 2013, China became the second-largest medical device market in the world (surpassing Japan). In 2014, the medical device market in China totaled RMB 255.6 billion, up 20.5% from 2013. Three quarters of demand is generated by hospitals. Based on China's Health and Family Planning Commission, 70-75% of medical devices in Tier-3 hospitals and 66% in Tier-2 hospitals will be imported from foreign countries. In particular, medical diagnostic and imaging equipment is in high demand (including ultrasound, MRI, digital X-ray, and supersonic diagnostic units). (Healthcare Technologies Resource Guide, 2016)

China's population breakdown by age is also shifting. From 2015 to 2050, the United Nations forecasts an increase in China's population aged 60 and older from 15% of the country's total population to 37%. This is one of the most rapid increases forecasted for any country by the UN Additionally, china's large base population means that the total number of people aged 60 and older is expected to increase from approximately 209.2 million people to 491.5 million people. This represents a significant and growing market for medical products that cater to an aging population, such as diagnostic equipment. Recently, the Chinese government has lifted its one-child policy, partly due to the high ratio of older population to working-age population. (**Exhibit 14**)

Exhibit 14. Population Aged 60 and Older, China and World, 2015 Estimate and 2030 and 2050 Forecasts



Source: United Nations, 2016.

Market Barriers

Overall, the Chinese market is dominated by domestic producers. The high-end medical device market is dominated by foreign producers. Imported products must be registered with the China Food and Drug Administration (CFDA) through a representative office or subsidiary in China. U.S. importers will find that a single distributor is insufficient and may need regional distributors. (Healthcare Technologies Resource Guide, 2016)

An important concern for the medical device industry is risk of intellectual property rights infringement. Counterfeit medicine and medical products have long been significant problems for manufacturers. Key IPR concerns include using medical device manufactures' patented technology to develop and sell competing products and unauthorized trademark use. (United States Department of State, 2005; International Trade Administration, 2016)

Market Assessment

China's reliance on domestic production combined with the emphasis on the country's cost effectiveness advantage in the life sciences and global health industry make exporting to the country a careful proposition for Washington's defense contractors. At the same time, the country has a significant and growing market for high quality diagnostic products and medical technology, a market segment that Washington life sciences and global health defense contractors can take advantage of.

European Union

Germany

Market Overview

Germany is Europe's largest economy and second most populous nation (after Russia), making it an important element in the region's economy. In 2015, the country was home to 80.9 million people and was the fifth largest economy globally. Its 2015 GDP was $3.8 trillion. (CIA, 2016)

Market Opportunities

Germany has a history of producing medical equipment, with an emphasis on diagnostic imaging, dental products, and optical technologies. Germany is the third largest market in the world after the United States and Japan and is also the largest European market. 76.8% of healthcare spending is sourced from the public sector. In 2014, local production of medical equipment totaled 30.6 billion euros in a market of 31 billion euros. Imports totaled 21.6 billion euros, 6.2 billion of which was from the US. There is a stable demand for high-quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive

equipment, in vascular surgery, urology, gastroenterology, dermatology, and neuro-surgery. (Germany Healthcare Resource Guide, 2015)

Firms exporting medical devices to Germany will not encounter any direct trade quotas or barriers. (Germany Healthcare Resource Guide, 2015)

Germany has one of the world's highest GDPs, above average healthcare spending per capita, a large healthcare market (more than $300 billion in 2012) and an aging population (second only to Japan). Surveys indicate that patients and physicians are interested in improvements to the medical system, including electronic storage of emergency data; electronic letters of referral; and EHRs, so commercial prospects for those areas are promising. (Health IT Top Markets Report, 2015)

Market Barriers

Competition

The German medical technology market grew by 2.3% in 2014. Germany has a few large producers, including Siemens, B. Braun and Fresenius. 95% of the German medical technology industry is made up of small and mid-sized companies or subsidiaries of larger companies. As a result of a low-growth domestic market, the German medical technology industry has to rely heavily on export markets for continued growth. (Germany Healthcare Resource Guide, 2015)

90% of Germany's population has public health insurance, most of the remaining 9 million Germans have private health insurance from 130 companies. Current health laws do not permit all health IT applications. There are roughly 200 health IT companies in Germany, with just over half targeting clinical or hospital practices. Germany has a well-established health IT association. (Health IT Top Markets Report, 2015)

Supply Chain Concerns

Market equipment imported to Germany is usually sold through a local subsidiary, through medical distributors with an established distribution network, or through appointed agents. Finding a mid-size distributor covering all of the German market has become harder since large manufacturers have increasingly purchased distributors off the market to gain access to established distribution channels, rather than developing those themselves. Thus, GE Healthcare bought Medicalis and Idel, and Donjoy bought Ormed, amongst others. (Germany Healthcare Resource Guide, 2015)

Regulatory Complexity

The German market for medical devices is regulated by both Germany and the European Union. The requirements are based on environmental, consumer health, safety and social concerns. Not all standards and

regulations are mandatory, but compliance greatly enhances a product's marketability. The **German Medical Products Law** (MPG) applies to all equipment, instruments, devices, and materials, for use on or in the human body and is relevant when trying to get permission to enter the German market. Roughly 400,000 products are regulated by this law. The CE Mark, signifying a product fulfills all necessary EU requirements, is necessary for many imported products. (Germany Healthcare Resource Guide, 2015)

There is no import duty on medical devices. There is a 19% import turnover tax payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import turnover tax is usually offset by ultimately passing it on to the end user in the form of a Value-Added-Tax (VAT), known in Germany as Mehrwertsteuer (MwSt). (Germany Healthcare Resource Guide, 2015)

Market Assessment

Competition, the need to find an experienced local distributor, and regulatory complexity represent significant barriers for Washington defense contractors. However, the opportunity represented by the German market is significant, too. Relative to other markets, the German market is a middling opportunity; the costs associated with market barriers need to be assessed on a company-by-company basis.

Austria

Market Overview

In 2014, Austria imported $2 billion in medical equipment, with expected growth of 10% in 2015. Re-exporting is common in Austria, often to Germany. The country offers universal or nearly universal healthcare to its population. U.S. companies can view Austria as a pilot market for the rest of Europe and an entryway to the larger German market. Austrians expect hospitals to have up-to-date technology, an opportunity for advanced U.S. manufacturers. In particular, new, high-tech ultrasounds are in high demand in Austria. (Healthcare Technologies Resource Guide, 2016)

Market Opportunities

The best strategy is to select a qualified local distributor (many of whom speak English and are familiar with U.S. sellers) and remain with the same distributor for several years. Market entry can take several years due to a conservative market attitude in Austria around medical equipment. (Healthcare Technologies Resource Guide, 2016)

Market Barriers

The trend is towards making hospitals smaller in Austria, which may impact demand. Austria already relies on imported medical equipment and U.S. manufacturers are the second-largest importers after Germany. Germany is closer, shares a language, produces equipment under the same regulatory framework, and has duty-free access to Austria. (Healthcare Technologies Resource Guide, 2016)

Market Assessment

Austria may be an easier market to enter than Germany. Overall, the country has a smaller market for the types of goods produced by Washington's life sciences and global health defense contractors. Contractors may view Austria is a pilot market for broader European ambitions, and the market can be an especially valuable test market for Germany.

UK

Market Overview

The United Kingdom is a global economic and trading center. The UK is the third-largest economy in Europe and the fifth-largest economy in the world measured by nominal GDP. The UK has traditionally been an entry point into European markets. The recent Brexit vote has created large uncertainty for the UK's economy and its role in European markets.

The UK spends significantly on health research. In 2009, the UK spent the fourth-highest amount on health research at $12 billion, after the USA ($119 billion), Japan ($18 billion) and Germany ($13 billion). Additionally, the UK is home to 4,400 life sciences and global health companies. (Biotechnology and Money, 2016)

Market Opportunities

The UK ranks 5th among OECD countries for overall spending on healthcare. The UK ranks only behind the U.S., Japan, Germany and France for overall healthcare spending. However, the UK spends less per capita than most other developed countries, potentially due to the country's universal healthcare system. In some quarters this is praised as evidence of an efficient National Health Service (NHS) and in others the NHS is criticized for spending too little. (OECD, 2016)

A recent article in the Independent notes that "the UK came first in the latest Commonwealth Fund assessment of healthcare systems around the rich world." But other surveys, such as one by the Euro Health Consumer Index, ranks the UK much lower, stating that "UK Healthcare spending as a proportion of GDP is falling behind international averages. In addition, aging demographics, obesity problems and a high rate of alcohol consumption are affecting UK health outcome statistics." The UK also

has the worst cancer outcomes of any rich country. These healthcare trends may also offer opportunities for life sciences and global health companies to improve healthcare outcomes. (The Independent, 2014)

The U.S. Department of Commerce notes that "UK imports of U.S. medical devices totaled $1.2 billion in 2015, accounting for 19% of the market. U.S. companies are leading suppliers of diagnostic, dental, orthopedic equipment and high quality wound care products to the UK." In addition, in the UK, it is now mandatory for all public sector organizations to advertise their procurement opportunities worth over £10,000 ($15,663) on Contracts Finder. (International Trade Administration, 2016)

In addition to the public sector, there is a smaller private sector market which offers niche opportunities for exporters. However, the relative size of the public sector in the UK may make it a significantly more attractive opportunity. (International Trade Administration, 2016)

Market Barriers

Approximately 85% of the NHS budget is distributed to Primary Care Trusts (PCTs) that are responsible for providing healthcare and health improvements within a local area. These PCTs report into regional Strategic Health Authorities (SHAs); these authorities assist in developing local NHS strategy and providing a link between PCTs and the national Department of Health.

PCTs maintain their own budgets and they set their own priorities, based on the overarching priorities and budgets set by the relevant SHAs and nationally-set health policy. PCTs are key stakeholders in healthcare funding, and preside over a range services provided by hospitals, primary care networks and clinics.

The UK's National Health Service elicits many views, both praise and criticism. It was famously featured in a dance sequence during the opening ceremonies of the London Olympics and is often praised by both outside and internal healthcare experts. The UK is part of the European Committee for Standardization (CEN). Currently, medical devices are approved through the CEN process. However, NHS assesses and buys the vast majority of medical devices in the UK. The NHS has a slow adoption rate of new, expensive devices. In addition, according to Decision Resources Group, the volume of medical procedures in the UK is low compared to other European markets (Medical Devices Online, 2016).

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) uses quality-adjusted life years (QALYs) to evaluate the cost-effectiveness of treatments. The process leads to a high degree of

rejection of expensive treatments of orphan diseases and rare forms of cancers. (Deloitte, 2016)

Market Assessment

The UK represents one of the largest healthcare markets in the world. The country faces a variety of healthcare challenges which provide opportunities for Washington state life science contractors. At the same time, the NHS offers challenges for approval and its focus on cost containment may constrict certain opportunities. Trying to navigate the system for an inexperienced company will be challenging. With a UK Trade Counsel located in Seattle and with many support firms in the state with experience and expertise in the UK, navigation help is readily available. (Biotechnology and Money, 2016)

France

Market Overview

France is the sixth-largest economy in the world with a GDP of $2.8 trillion. It also has the 12th-highest expenditure on healthcare per capita. The market for medical equipment in 2015 was $7.3 billion with just over half ($3.8 billion) coming from imports. The U.S. accounts for about one-third of those imports. France has an aging population. Like other European countries, France has been attempting to contain a rise in healthcare costs in recent years. (OECD, 2016)

Market Opportunities

France is the second-largest market for medical devices in Europe. Imports have been growing at a faster rate than the overall market. The U.S. Department of Commerce ranks medical equipment as a "best prospect for export" and notes the subsectors of imaging and radiotherapy equipment as especially promising.

Market Barriers

The French government has an objective of reducing health expenditures which currently are above the OECD average (though far below the U.S.). This could lead to lower demand for medical equipment, though the U.S. Department of Commerce notes that it could also boost demand for medical equipment designed to facilitate fewer and shorter hospital stays. This could also lead to opportunities for health IT services that reduce costs. Being a part of the EU, medical devices must obtain a CE mark. The Haute Autorité de Santé (HAS) has authority for assessing drugs, procedures and medical devices.

Deloitte asserts that in recent years, the French government "has focused on cutting the rate of reimbursement on many drugs, removing a number from health insurance system coverage, and promoting the use of

generics." Medical devices are often purchased by hospitals or procurement organizations set up for groups of hospitals. Some new or expensive devices are negotiated by the national government with hospitals to attempt to have cost containment.

Market Assessment

France is a good opportunity for medical device exports. As always, finding the right distributor is key to success as is acquiring the EU CE mark and approval from HAS.

Brazil

Market Overview

Brazil, the largest and most populous country in South America, has grown to be a regional leader. In the early 200s, the country drew from its significant natural resources and domestic labor pool to drive economic growth. Economic growth in the early 2000s has foundered in recent years: national GDP dropped from $3.26 trillion in 2014 to $3.17 trillion in 2015, a decrease of 3%. At the same time, the country is beset by domestic political scandals resulting in large public demonstrations. (CIA, 2016; Time, 2015)

Market Opportunities

Brazil is the largest medical equipment market in South America and should continue to expand through the next years. Brazilian medical equipment revenues in 2014 reached an estimated US$ 7.0 billion, which represents an increase of 9.4% from the previous year. The U.S. is the largest importer, accounting for 30% of the import market. U.S. companies work through local agents or distributors. (Brazil Healthcare Resource Guide, 2015)

New opportunities for U.S. exporters include: clinical chemistry, laboratory equipment (including investments in RandD), disposables and surgical (high demand from public and private hospitals), diagnostic equipment, orthopedics and implants, health IT, dental, and pharmaceuticals. (Brazil Healthcare Resource Guide, 2015)

Brazil has few regulations related to health IT at present, and the government is in the earliest stages of developing a sector strategy. The healthcare market is extremely large: valued at $210 billion in 2014 and forecasted to more than double by 2024, reaching $446 billion. (Health IT Top Markets Report, 2015)

There are few Brazilian manufacturers of advanced medical products so Brazil's reliance on imports is slated to continue into the near future. Brazilian buyers view U.S. and other foreign products (mainly Canadian and European) as having comparable quality and reliability. Thus,

financing terms often become the differentiating criteria in making a sale. (Brazil Healthcare Resource Guide, 2015)

In addition to the attractive size of the Brazilian medical market, U.S. exporters can consider the opportunities offered by the Mercosur bloc, and use Brazil as an entry into other South American markets, including Argentina, Uruguay and Paraguay. (Brazil Healthcare Resource Guide, 2015)

Market Barriers

Brazil's current economic condition limits its attractiveness to would-be exporters. Additionally, recent political events in the country, including the revelation of $4 billion in bribes to governing Worker's Party leaders, make it appear less stable than other markets. (Time, 2015)

Because of regional economic disparities and varying states of infrastructure, importers can have trouble finding one distributor that has complete national coverage. As a result, importers may need to use multiple distributors or focus on a single region. This can limit an exporter's growth potential after they have entered a market, and may be seen as a barrier to entry. (Brazil Healthcare Resource Guide, 2015)

Setting up new companies in Brazil is relatively complex, although the Ministry of Development has signaled a desire to simplify the process. This means that companies that wish to improve their market access by opening a subsidiary in Brazil may by stymied by the regulatory process. (Brazil Healthcare Resource Guide, 2015)

Brazil's government is expected to take on a higher share of health expenditures over the next ten years, increasing from 48% to 52%. This means that, in the coming years, exporters to Brazil can expect to do business with the government more often. While this increase can indicate stability in the market through the potential for standardized prices and a single large buyer, it also makes the market more centralized. (Health IT Top Markets Report, 2015)

Medical products in Brazil are highly regulated by Anvisa. All products must be registered in order to be sold. For products with higher risk, it may be necessary to have additional local certifications, international market data, and inspections in manufacturing plants. (Health IT Top Markets Report, 2015)

Market Assessment

Barriers to exporting to the Brazilian market are not high from a regulatory standpoint. However, other considerations surrounding economic and political concerns in the nation as well as internal

transportation inefficiencies make it important to carefully consider the market before pursuing any export opportunities.

Canada

Market Overview

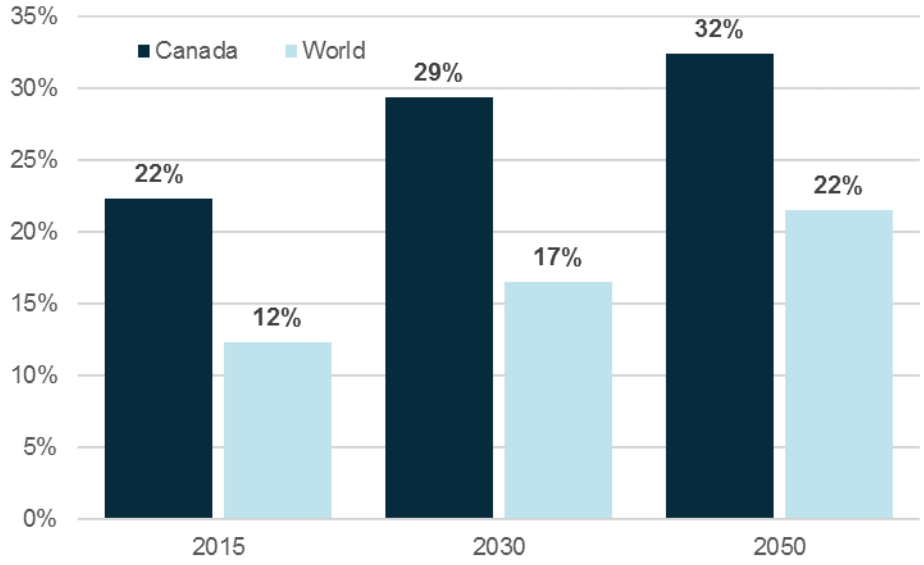
Canada has worked to harmonize regulations with the U.S. and the EU. Under the Canadian Food and Drugs Act, devices are categorized as Class I, II, III, or IV (just like in other harmonized countries). All devices require an establishment license, with all but Class I devices also requiring a device license. (Canada Healthcare Resource Guide, 2015)

Market Opportunities

Hospitals and other public health institutions are the main buyers of medical equipment (70% of market demand in Canada). They use group purchasing and distribution. Canada currently relies on imports for roughly 80% of its consumption. The U.S. is the largest single exporter (45%) followed by Switzerland (13%), Germany (8.6%), and the UK (5.3%). Canada's import market is expected to grow at a 4.4% rate through 2016. (Canada Healthcare Resource Guide, 2015)

Canada's population aged 60 and over continues to grow. In 2015, an estimated 22% of the country's population was 60 years old or older. By 2050, that number is forecasted to increase to 32%. An aging population presents opportunities for medical device manufacturers and health IT companies to help improve health outcomes for this segment of the population, areas that Washington defense contractors are experts in. (**Exhibit 16**)

Exhibit 16. Population Aged 60 and Older, Canada and World, 2015 Estimate and 2030 and 2050 Forecasts



Source: United Nations, 2016.

U.S. and Canadian regulations regarding the safety of medical devices are similar, meaning that U.S. exporters have an advantage. Combined with the geographic proximity of Canada and the country's growing demand, Canada is an excellent export opportunity. (Canada Healthcare Resource Guide, 2015)

Canada has one of the fastest drug approval systems: it halved its approval time from 1994 to 2009. Canada is considered a global leader in its regulatory approach, and its system is used as a model for new systems in other countries. Intellectual property protection is also among the strongest in the world. (Biotechnology & Pharmaceuticals in Canada, 2009)

Market Barriers

Health Canada has regulatory authority over the sale of medical devices in Canada. Health Canada is similar to the U.S. Food and Drug Administration (FDA). Medical equipment imports must comply with marking, labeling, and packaging requirements as described in the Food and Drug Act. (Canada Healthcare Resource Guide, 2015)

Market Assessment

Canada's low market barriers, fast drug and medical device approval times, and significant opportunities make it a valuable market for medical device manufacturers, especially diagnostic equipment, and health IT companies.

Mexico

Market Overview

Mexico's economy is the 15th largest in the world measured in nominal GDP and 11th when measured by purchasing power parity. It is the second-largest economy in Latin America. With 114 million people, Mexico is the 11th most populous country in the world. Mexico is also the United States second-largest market for exports. According to the U.S. Department of Commerce, "Mexico's imports of medical equipment, instruments, disposable and dental products totaled $4.1 billion in 2014." Those imports represent 80% of Mexico's medical equipment market and just over half of those imports come from the United States.

Ten years, ago, Mexico introduced a publicly-funded universal health insurance program. Today, public healthcare institutions account for more than 70% of medical services provided in Mexico. Workers have access to the Instituto Mexicano del Seguro Social (IMSS) which is funded equally by the employee, employer, and the federal government. Approximately 58 million people are covered through the IMSS. Government employees are all covered through the Institute for Social Security and Services for State Workers. Seguro Popular covers those who do not have formal employment. According to the World Bank, the number of individual beneficiaries of Seguro Popular grew from 31.1 million to 55.6 million from 2009 to 2013. (OECD, 2016)

Market Opportunities

Mexico's aging population, growing middle class, and better access to healthcare services provides great opportunity for Washington state companies. In addition, Mexico is transitioning into developed country healthcare problems, changing from communicable diseases to chronic degenerative diseases. The OECD notes that obesity has become a growing concern in Mexico, with Mexican obesity rates even higher than in the U.S. In addition, heart disease and cancer rates have increased, partly because of longer lifespans and improved quality of life. (OECD, 2016)

With developed country health issues, many of the medical devices and pharma products Washington state companies sell domestically now make for a great market in Mexico. Mexico's pharmaceutical market is Latin America's second largest. (OECD, 2016)

Additionally, the country's proximity to the U.S. make it more attractive. With lower shipping costs than exporters from other countries, Washington life sciences and global health contractors may be able to achieve better cost efficiencies, making them more attractive.

Market Barriers

Bulk purchasing may represent challenges for Washington life sciences and global health defense contractors who wish to export their goods to Mexico. The U.S. Department of Commerce notes that "In order to reduce cost for medical devices, public healthcare institutions are consolidating big purchases to buy for several institutions in one public tender. This methodology forces suppliers to reduce prices in order to be more competitive." As a result, smaller companies may not be able to achieve the economies of scale desired by Mexico's public healthcare institution. (OECD, 2016)

Medical and healthcare products must be registered with the Federal Commission for the Projection against Sanitary Risk (COFEPRIS). The agency is in charge of providing market approval for all medical products prior to sale or use in Mexico. In addition, foreign medical device manufacturers require a legally-appointed distributor or representative in Mexico. This can prove challenging for smaller companies that may not be able to dedicate the necessary resources to a single export market. (OECD, 2016)

Market Assessment

Mexico is an important and often-overlooked market for the life sciences and global health sector. Medical devices are listed as a "best prospect for exports" to Mexico by the U.S. Department of Commerce. The size, growth and proximity of Mexico make it a good opportunity market for Washington state companies. At the same time, companies will need help to navigate the regulatory environment, including finding the right legally appointed distributor or representative in Mexico.

RECOMMENDATIONS AND ACTION STEPS

Cross-Market and Sector Recommendations

There are several broad, industry-wide strategies Commerce can carry out to support contractors that apply across many different markets. In many cases, life sciences and global health defense contractors are simply not aware of existing resources that can help them export. Specific recommendations are:

- **Proactive outreach and marketing of services**. Proactively inform companies in this sector of Commerce services, especially the ability to vet potential distributors and representatives. Consider new innovative methods to disseminate this information such as using the business licensing or tax process.
- **Disseminate information**. Build out and update a life sciences and global health sector section of the Commerce website with information and data on target markets, regulations, financing

information, trends, and contact information for the life sciences and global health sector lead. A shared knowledge database for life sciences and global health defense contractors can also include basic information on exporting, logistics, shipping, customs and more.

- **Consider hiring a position to focus on technical outreach in the defense market.** This position would act as an ombudsperson for life sciences and global health (and other sectors) by liaising with technical contacts at DOD and related agencies to connect companies to the right resources and contacts.
- **Expand the Washington Military and Defense Economic Impact Tool to include current information on life sciences and global health defense trends**. The tool can be broadened to serve the information gathering needs of life sciences and global health defense contractors in Washington by providing regular newsfeeds and content published on the site as well as sent via SMS and email to registered subscribers.

Market-Specific Recommendations

Commerce should target Japan, South Korea, Brazil, Mexico and the European Union for helping life science companies export.

Japan

As noted in the Market Opportunities section, Japan is a large opportunity market for Washington state companies. At the same time, it is a complicated market with a variety of challenges. To take advantage of this opportunity and overcome these challenges, Commerce should pursue the following:

- Work with Japanese partners such as the Japan External Trade Organization to help firms navigate the Japanese market by: 1) developing a list of possible Japanese distributors and partners (especially in light of the requirement that foreign companies "designate a Japanese company that has marketing approval"); and 2) examine bringing a group of companies to the **Medical Japan** trade show.
- Include information on Japanese regulations, barriers and contacts for help in the life sciences and global health section of Commerce's website.

South Korea

Similar to Japan, South Korea offers both opportunities and challenges. Commerce should:

- Develop list of possible Korean distributors.

- Leverage the state's relationship with Samsung to help Washington state companies work with the company. Samsung is a major producer of medical equipment.
- Make available info in the life sciences and global health section on Washington State Department of Commerce's website about South Korea's National Health Insurance (NHI) system, including NHI's standardized payment system.

Brazil

Although Brazil is a large market with significant medical device and pharma needs, it is also a country with challenges and barriers. Interviews with existing exporters have revealed both the lure of the Brazilian market and frustrations due to regulatory and market access barriers.

To be successful in Brazil, a company needs to have a trusted partner in-country. Commerce should:

- Develop a list of vetted local distributors and make it available to contractors and
- Raise awareness of the list and of other Commerce services to Washington life science and global health defense contractor companies.

Mexico

Mexico is a largely overlooked world market with close proximity to Washington state. Because companies must work with legally-appointed distributors or representatives in Mexico, Commerce should:

- Develop a list of potential distributors and representatives in Mexico; and
- Actively inform Washington companies of their ability to help vet distributors and representatives in Mexico.

European Union (EU)

Target Germany, France, the UK and Austria in the EU. The first three are the largest economies in Europe and the largest markets for medical equipment and other healthcare products and services. The latter has relatively few barriers and is a good test market for entering other EU countries. Commerce should:

- Provide information to Washington companies on how to enter these markets (and include this information in the life sciences and global health section on the Commerce website);
- Vet distributors and representatives for companies in these markets; and

- Consider organizing a trip to medical trade shows in the EU, such as MEDICA in Dusseldorf.

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APPENDIX

Methodology for Developing Recommendations

The table below delineates key considerations that help shape strategy development for the life sciences and global health sector.

Exhibit A-1. Framework for Developing Strategies for Supporting Life Sciences and Global Health Defense Contractors

Strategic Considerations	Description	Examples
Firm characteristics	• Firm size • Experience exporting	• Small firm vs. large firm economies of scale • Ability and/or desire to export • Resources to invest in exporting effort
Domestic conditions	• Health of U.S. economy • Regulatory issues • U.S. government programs supporting exporting	• Strength of U.S. market versus overseas opportunities • ITAR, EAR, FCPA, compliance challenges and access to necessary information • U.S. Foreign Military Sales Program and U.S. foreign military aid (e.g., Egypt, Israel) • Excess Defense Articles program • ITAR exemption status among certain allies, including Australia
Foreign market/ government conditions	• State policies supporting local industries • Weak/limited IPR enforcement • Cultural barriers	• Taiwan's recent plan to support more domestic production of maritime vessels • China's weak record on IPR protection • Offset requirements • Relationship building • Finding overseas distributors • Foreign governments often demand for same hardware as U.S. military.
Firm characteristics	• Firm size • Experience exporting	• Small firm vs. large firm economies of scale • Ability and/or desire to export • Resources to invest in exporting effort
Domestic conditions	• Health of U.S. economy • Regulatory issues • U.S. government programs supporting exporting	• Strength of U.S. market versus overseas opportunities • ITAR, EAR, FCPA, compliance challenges and access to necessary information • U.S. Foreign Military Sales Program and U.S. foreign military aid (e.g., Egypt, Israel) • Excess Defense Articles program • ITAR exemption status among certain allies, including Australia
Foreign market/ government conditions	• State policies supporting local industries • Weak/limited IPR enforcement • Cultural barriers	• Taiwan's recent plan to support more domestic production of maritime vessels • China's weak record on IPR protection • Offset requirements • Relationship building • Finding overseas distributors • Foreign governments often demand for same hardware as U.S. military.

A-2. Categories of Assistance and Support from the Washington State Department of Commerce

Type of Assistance	Examples
Education and Training	• Seminars on exporting opportunities, how to find market opportunities • Seminars on legal and trade barriers and issues • Trade delegations to learn about new markets, including trips to DC to meet with embassy officials. • Add info and links to existing website on resources
Technical and Legal Assistance	• Proper paperwork • Export finance • Export control compliance
Market Research	• Identifying overseas opportunities (defense and civilian) • Finding distributors and/or overseas representatives • Helping develop connections with the Foreign Military Sales program
Advocacy	• Helping firms dealing with trade disputes and IPR infringement cases and other barriers • Commerce as a first point of contact for defense contractors

Example of Maritime Defense Export Controls Compliance Example

As an example, suppose that Company A is interested in selling a diagnostic kit that includes substance X to Company B in the Netherlands and also to Company C in China. Company A would search the CCL Category 1 to determine that such diagnostic kits are listed under ECCN 1C991. More specifically, diagnostic kits that do not include ricin or saxitoxin or Schedule 2 or 3 substances are listed under ECCN 1C991.e. ECCN 1C991.e notes that such kits are controlled for reasons of chemical and biological weapons (CB) and anti-terrorism (AT). However, CB only applies to 1C991.d. The ECCN indicates that on the Country Chart, for AT, column 1 applies. *See* **Exhibit A-3**.

Exhibit A-3. ECCN Reasons for Control Entry for 1C991

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738).*
CB applies to 1C991.d	CB Column 3
AT applies to entire entry	AT Column 1

Company A can then look at the country entries for Companies B and C on the Country Chart. The Netherlands does not have an "X" in the AT columns. *See* **Exhibit A-4**. Accordingly, Company A likely does not need a BIS license to export the diagnostic kit to the Netherlands. (EAR contains a list of ten general prohibitions that must be reviewed in connection with any international transaction. If one of those prohibitions applies, then a BIS license is required regardless of the determination under the Country Chart analysis.)

China also does not have an "X" under AT. *See* **Exhibit A-5**. According to the Country Chart, a BIS license is not required to send the diagnostic kit to Company C either. However, China does have an "X" under CB, so if the diagnostic kit had fallen under ECCN 1C991.d, a BIS license may have been required.

Exhibit A-4. Commerce Country Chart for the Netherlands

Countries	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
Mexico	X					X		X	X		X	X		X		
Micronesia (Federated States of)	X	X		X		X	X	X	X	X		X		X		
Moldova	X	X	X	X		X	X	X	X	X		X	X			
Monaco	X	X		X		X	X	X	X	X		X		X		
Mongolia	X	X	X	X		X	X	X	X	X		X	X			
Montenegro	X	X		X		X	X	X	X	X		X	X	X		
Morocco	X	X		X		X	X	X	X	X		X		X		
Mozambique	X	X		X		X	X	X	X	X		X		X		
Namibia	X	X		X		X	X	X	X	X		X		X		
Nauru	X	X		X		X	X	X	X	X		X		X		
Nepal	X	X		X		X	X	X	X	X		X		X		
Netherlands[3]	X					X		X	X							

Exhibit A-5. Commerce Country Chart for China

Countries	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
Bulgaria[3]	X					X		X	X							
Burkina Faso	X	X		X		X	X	X	X	X		X		X		
Burma	X	X	X	X		X	X	X	X	X		X		X		
Burundi	X	X		X		X	X	X	X	X		X		X		
Cambodia	X	X		X		X	X	X	X	X		X	X			
Cameroon	X	X		X		X	X	X	X	X		X		X		
Canada	X										X					
Cape Verde	X	X		X		X	X	X	X	X		X		X		
Central African Republic	X	X		X		X	X	X	X	X		X		X		
Chad	X	X		X		X	X	X	X	X		X		X		
Chile	X	X		X		X	X	X	X	X	X	X		X		
China	X	X	X	X		X	X	X	X	X		X		X		
Colombia	X	X		X		X	X	X	X	X	X	X		X		

The ECCN also provides information on license exceptions. However, for this particular product, no exceptions apply. *See* **Exhibit A-6**.

Exhibit A-6. ECCN License Exceptions Entry for ECCN 1C991

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

There also are a number of country-specific export regulations under EAR that may apply to other products. For example, many medical products such as certain protective equipment for medical personnel and vaccines may be exempt from license requirements or other EAR restrictions.

As referenced above, EAR also has ten general prohibitions. Exports of most items to countries currently embargoed by the U.S. are generally prohibited. In addition to restrictions on the destination country, U.S. companies exporting controlled products must ensure their products do not pass through certain countries during transit to the final destination. These countries include Armenia, Azerbaijan, Belarus, Cambodia, Cuba, Georgia, Kazakhstan, Kyrgyzstan, Laos, Mongolia, North Korea, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan, and Vietnam. If a product must pass through one of these countries during transit, a company must apply for a BIS license.

Additionally, U.S. companies that import products may need a BIS license to re-export the products if they are modified to have more than a *de minimis* amount of controlled content. For example, if a Washington ultrasound manufacturer upgrades a foreign ultrasound machine to include upgraded software or ultrasonic materials, the ultrasound manufacturer may need to apply for a BIS license to re-export the ultrasound machine.

In addition to the CCL, the BIS also maintains lists that designate certain persons, companies, or organizations that are restricted from receiving certain exports. Companies that receive export requests from unfamiliar organizations or individuals should consult these resources as part of their due diligence.

ITAR and EAR are not the only export control regulations that life science companies need to know. The U.S. Food and Drug Administration (FDA) regulates pharmaceutical product and medical device sales in and through the United States. This includes those that are manufactured for export only without approval for sale within the United States, and those manufactured within the United States with approval for both export and use within the United States Products made outside the United States that pass through the United States on the way to their final destination are also regulated and certified by the FDA. The FDA has this regulatory power under the Federal Food, Drug, and Cosmetic Act.