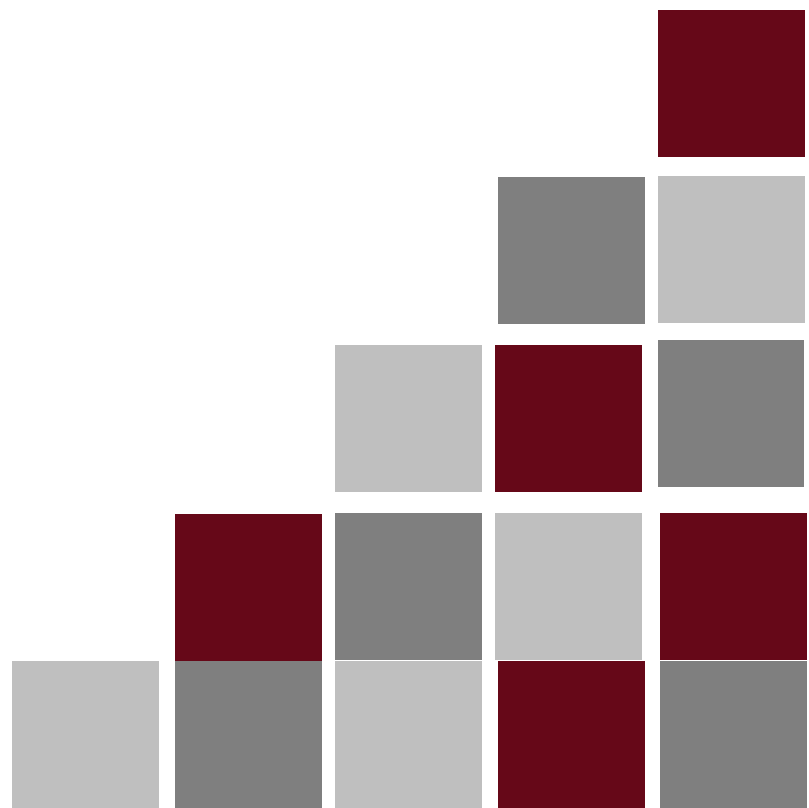


Principles by IUCG:

Medical Manufacturing: Global Perspective and Future Outlooks



INTRODUCTION

Medical Manufacturing

The medical manufacturing industry has enjoyed immense growth over the years largely due to continuous product innovation and longer life expectancy. Its global market size is valued at \$423.8 billion as of 2018. The industry covers a wide range of products, from advanced cardiovascular implants to basic surgical needles. Most medical products are not considered a service by themselves, but rather aid in the delivery of health services. In general, medical manufacturing includes the design, production, sterilization and packaging of all medical devices and equipment. Such medical products can be broken down into four main segments: disposables (bandages, surgical gloves, and plastic syringes); surgical and medical instruments (used in surgeries and cosmetic procedures); therapeutics (includes implantable and non-implantable devices); and diagnostics (includes x-rays and other complex equipment).

Overview

Parameters such as cost of production, profit margins and competition vary from one medical device to another. For example, the implantable device sector is difficult to enter, pricing is ambiguous, and competition is low. Higher prices and substantial profit margins can be attained, as larger companies typically realize 20 to 30 percent profit margins. Conversely, lower end sectors such as the routine surgical supplies product line is much more competitive, with lower profit margins and higher sales volume.

However, federal and international regulation transcends across all medical devices. The regulation and quality assurance of such medical instruments are both important and necessary in ensuring consumer trust and patient health. With international trade being crucial to the medical device industry, countries have had to agree on international standards for a wide array of products. While countries have currently agreed to measures under the International Organization for

Standardization section 13485, there are ongoing conversations to tighten these standards. The International Medical Device Regulators Forum is a group of the top ten medical device manufacturing countries, in which they discuss quality assurance measures and requirements that the international community should agree to.

Industry Breakdown

United States Industry Breakdown

The United States comprises the largest share of the global medical device market. It has a market share of 40 percent, \$156 billion in market value, and is expected to grow to \$208 billion by 2023. The United States exports the most medtech in the world, about \$43 billion worth of medical equipment, playing a key role in the industry. Medical devices are developed to address human health needs and as such, health complications can pose anywhere between a minor and critical risk, with each complication having the ability to be unique. Critical risks, for example, consist of rare diseases, such as cystic fibrosis, that affect about 70,000 people worldwide. The wide spectrum of health issues that people can have yields an industry that is made up of expansive product lines, with the top segments being orthopedics, spinal instruments, neurologic, cardiovascular devices, and general medical instruments.

The United States is known for rapid innovation and has a competitive advantage in medical device manufacturing within sub sectors such as microelectronics, telecommunications, instrumentation, biotechnology, and software development. Spending about 7 percent of sales revenue on research and development (R&D) initiatives has led to great product advancement especially in neuro-stimulators, biomarkers, robotic assistance, and implantable electronic devices.

Mergers and Acquisitions

Large companies and small startups have an interdependent relationship to meet market demand. Due to the growing nature of the healthcare market, fast-paced technological progress and niche market segments, the U.S. medical device industry consists mainly of small businesses and startups that can handle constant change. In

fact, more than 80 percent of medical device businesses in the U.S. consist of less than 50 employees. Most medical device manufacturers are small-tiered firms with 73 percent of businesses having fewer than 20 employees. These smaller firms are engaged primarily with research, development, and production.

The medical field is constantly evolving as new research and technology becomes available. Therefore, startup companies are easily able to penetrate new markets and adapt to product improvements. Actual production of equipment is also administered through small businesses that specialize in specific product lines. However, it can be difficult for these startups and small-tiered companies to scale. This is where the dominant medical device firms come into play.

While large, conglomerate companies account for a substantial part of the industry's revenue, they only represent a small amount of all medical device firms. These companies try to consolidate and monopolize market share by engaging in multiple mergers and acquisitions (M&As) of startups. This allows them to service a wide spectrum of medical device production with global reach. More than 60 percent of the growth of the largest medtech players is due to M&As. While startups contribute physical production, R&D flexibility, and market share expansion, they lack marketing, resources, capital, and wide scale strategy that only large companies can provide. They offer administrative overhead and support that is otherwise inaccessible. These dominant companies also offer distribution services to consumers, such as hospitals, pharmacies, and other healthcare facilities. They handle government regulation and supply chain management. Medical conglomerates often take on high risk by investing hefty sums of sales revenue into startup R&D initiatives, without seeing profit for years.

Top Medical Manufacturing Firms

In 2015, the top one percent of medical device companies represented 82 percent of the total industry assets and the top 0.2 percent of companies represented 56 percent of overall assets. Some of the major players within the industry are outlined below.

Medtronic

With headquarters in Ireland, the company had \$29.7 billion in revenue in 2017 and made up 8 percent of the medical device market share in 2015. The company's businesses are mainly operated through four major categories, including the cardiac and vascular group (CVG), restorative therapies group (RTG), diabetes group, and the minimally invasive therapies group (MITG). However, Medtronic is looking to diversify its portfolio and expand its reach. In an announcement in February 2020, Medtronic stated that it would be acquiring Digital Surgery, a leader in the surgical artificial intelligence (AI) realm. As the company targets the AI space, Medtronic will hope to scale Digital Surgery's work and become a global leader in this new market segment.

Johnson & Johnson Medical Device Companies

With main offices in the United States, Johnson and Johnson had \$25.1 billion in revenue in 2017 and a 6 percent market share in 2015. The company operates three distinct sectors: medical devices, pharmaceuticals, and consumer health. The medical device segment accounts for about 35 percent of Johnson and Johnson's total value. While the company's revenue composition from its diabetes and cardiovascular divisions have and are projected to decrease, growth is expected in the orthopedics and surgical segments. These predictions are supported by the company's recent acquisitions of Emerging Implant Technologies, Orthotaxy, Auris Health, and assets of Medical Enterprises Distribution. The acquisitions represent major players in the digital surgery and orthopedic space and demonstrate Johnson and Johnson's goal to expand their market share in these segments.

Siemens Healthineers

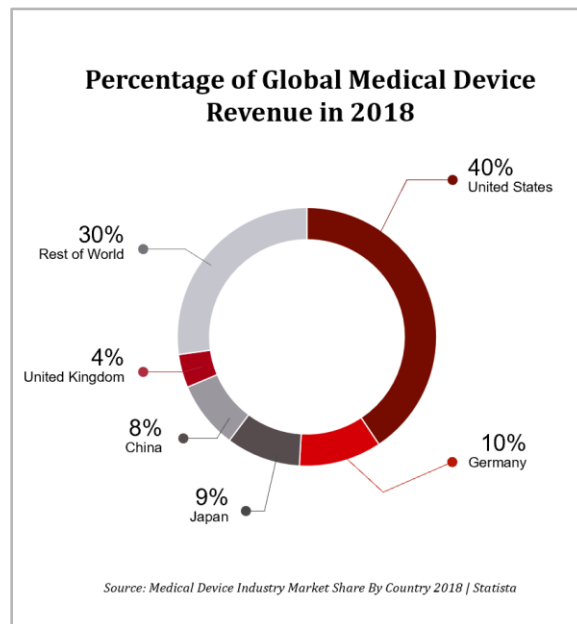
Based out of Germany, Siemens saw \$14.9 billion in revenue in 2017 and a 3 percent market share in 2015. Siemens is focused on enhancing the patient experience with goals of digitizing healthcare, enhancing diagnostic treatments, and improving precision medicine. In order to carry out their goals, Siemens plans on expanding its advanced therapeutic division by developing minimally invasive technology and tailoring health treatments to patients. With its 2019 acquisition of Corindus, a

pioneer in minimally invasive technology, Siemens has positioned itself to become a leader in the therapeutics market segment.

GLOBAL MARKETS

Established Markets

Continuous improvement, lean manufacturing, and innovative technologies are pillars of the medical device industry, with the United States, Germany, and Japan representing the established medical device markets. These three countries monopolize the majority combined global market share, at about 59 percent. They also export the most medical equipment in the world and have high import competitiveness.

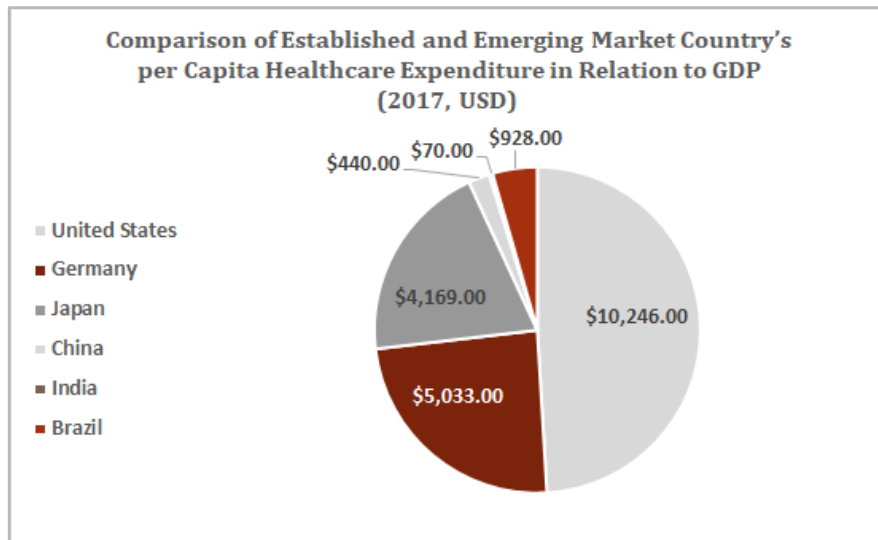


In the United States, the medical manufacturing industry invests a greater percentage than that of the telecommunications, automotive and defense industries. The heavy investments into R&D demonstrate the level of importance companies place in developing new and improved products. Through these continuous improvement efforts, medical devices have shorter life cycles (18-24 months) than other non-medical manufactured products, and the period of returns on investment is typically shorter than expected. Due to shorter product life cycles, U.S.

manufacturers mainly export to foreign countries that have lower times to market and moderate regulations. Using this strategy, the product can reach consumers before R&D makes the device obsolete.

While Germany and Japan are also established markets for medical devices, they produce in a mature market. Germany and Japan have mature markets because they spend less in R&D, about 5 percent of sales revenue, and have stable growth. Germany and Japan's medical manufacturing industry is made up of small and midsize companies, which is a contrast from the United States' small and large sized companies. Germany is the largest medical device producer in Europe and second largest exporter in the world, about 10.2 percent of global medical tech production after the US (39.6 percent) and China (11.1 percent). Germany's medical device market is valued at \$35.1 billion as of 2018. It produces all types of medical devices, but specializes in diagnostic imaging, precision medical and dental instruments, and optical technologies. Japan is the largest medical device market in Asia. Japan's medical device market value in 2018 was \$29.3 billion with a compound annual growth rate of 6.9 percent. Its medtech market heavily relies on sophisticated product imports (especially from the U.S.), with typically unsophisticated exports.

In all three established markets, the sale of medical devices is lucrative. There is a great deal of import competitiveness due to more manageable government regulations and high per capita healthcare spending in these countries. Government regulations in the U.S., Germany, and Japan are less stringent than in emerging markets and lead to lower times to market. Products are able to reach consumers quickly and sales are higher. In addition, per capita healthcare spending in established markets is more than ten times that in emerging markets. Factors such as income, wealth, population size, and healthcare structures contribute to the disproportionate healthcare expenditure. The United States has high income, a private healthcare system, and a mid-size population, leading to extremely high healthcare spending per individual. India, a low income, mixed healthcare system, and large population size has extremely low healthcare spending per individual. Higher healthcare spending indicates a higher demand for medtech products. If per capita healthcare expenditure continues to increase, while government regulations remain permeable, established markets are poised for long term growth.



Source: World Health Organization, Global Health Expenditure Database

Emerging Markets

China, India, and Brazil represent future emerging markets for medical devices. Demand for medtech has been greatly influenced by longer life expectancy and massive populations in India and China. There are also immense areas of urbanization, which increases the spread of infectious disease and lifestyle calamities. Currently, demand for medtech devices is low in emerging markets, but as public health concerns grow exponentially, opportunity to penetrate the market becomes available for large medtech exporters. However, it is significantly more difficult to export to these areas due to convoluted regulatory standards and a preference for domestic manufacturers. China, India, and Brazil have government policies and red tape procedures that would prolong the time it takes the product to reach healthcare facilities. Such policies include excessive data submission requirements, stringent safety regulations, and an increase in documentation and transparency. In addition, these countries prioritize domestic medical device manufacturers and would prefer not to import. These obstacles become especially problematic for the United States because of its tendency for product modification and short product life cycles. By the time a U.S. product passes all technical standards in a foreign market, its profit potential is limited as a superior substitute is developed.

Comparison of Regulatory Factors, Demand, and Barriers Between Emerging and Established Medical Manufacturing Markets

Regulatory Factors	Emerging Markets			Established Markets		
	China	India	Brazil	U.S.	Germany	Japan
Maximum time to market	High	High	High	Low	Low	Moderate
Regulatory Complexity	High	Moderate	High	Moderate	Moderate	Moderate
Regulatory Cost	High	Moderate	High	Moderate	Moderate	High
Demand Factors						
Medical Device Density	Low	Low	Low	High	High	High
Per Capita Healthcare Expenditure	Low	Low	Moderate	High	High	High
Overall Barriers						
Import Competitiveness	Low	Low	Moderate	High	High	High

Source: U.S. International Trade Commission, Competitive Conditions Affecting U.S. Exports of Medical Technology to Key Emerging Markets

When penetrating emerging markets, Germany and Japan have a competitive advantage over the United States. Germany and Japan are both mature medical device producers and offer stability and longer product life cycles. They can afford to endure protracted government regulations and longer times to market without sacrificing substantial losses to their sales. In this regard, Germany and Japan's lack of R&D is favorable. However, it is important to acknowledge efforts to standardize global medtech regulations. The International Medical Device Regulators Forum (IMDRF) is a global initiative to create harmonization of medical device regulations and standards. IMDRF involves representatives from the top ten medical manufacturing countries. Already, China, India, and Brazil have adopted aspects of IMDRF guidelines to their regulations. While no groundbreaking progress has been made, if the forum is successful, the stringent foreign government policy will no longer be a problem, and the United States will have the opportunity to gain market share. Research suggests Germany and Japan will expand their territory in the future and increase exports to emerging markets, as long as foreign government regulation remains a challenge for U.S. medical conglomerates.

Global Industry Interdependence

International trade is integral to the medical manufacturing industry as countries rely on each other for certain medical equipment and supplies. In Japan, the aging population is growing and so is the medical device market. In terms of yen, the Japanese currency, the country's medical device market grew by 6.9 percent from 2017 to 2018. However, the Japanese medical device market heavily depends on imports, specifically advanced medical equipment such as pacemakers and orthopedic equipment. In the United States, about 35 percent of domestic production is exported, and a comparable share is imported.

INDUSTRY DISRUPTION

COVID-19

On April 15, 2020, the total number of confirmed cases reached nearly 2 million and deaths surpassed the 120,000 mark. Spain, the Netherlands, and Turkey are just some of the countries that have expressed dissatisfaction with Chinese made medical equipment. The Dutch health ministry had to recall 600,000 face masks and Spain stated that 60,000 testing kits purchased from China were defective. Despite high regulation standards for imports in China, there are lower quality standards for exports. With distrust for Chinese products, calls for stronger regulations surrounding manufacturing practices and standard assurance protocols may take place in the future. This could mean higher production costs as more has to go into ensuring the product has met a high enough level of quality.

As the Coronavirus sweeps throughout the globe, global supply chains have crippled, and governments are declaring critical shortages of medical equipment. In order to ensure countries meet and maintain an acceptable level of quality, the International Standardization Organization (ISO) has developed agreed upon medical device manufacturing protocols, practices, and requirements. The ISO group is an international, non-governmental body with a membership of 164 national standards bodies. Medical device firms around the world agree to maintain certain quality management systems and manufacturing principles under ISO 13485. When

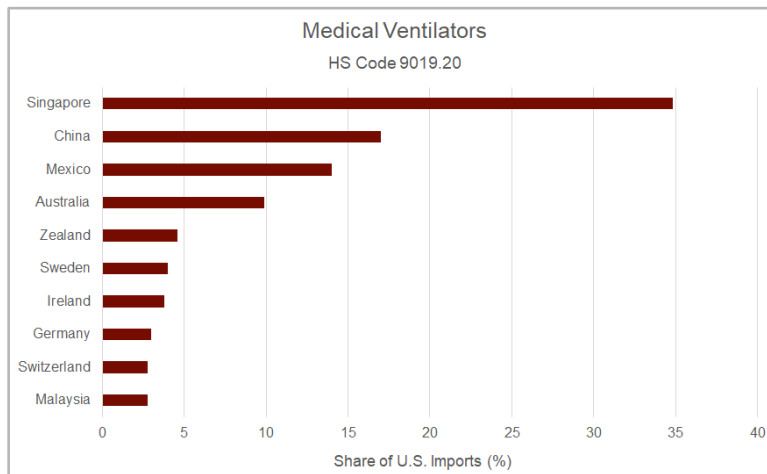
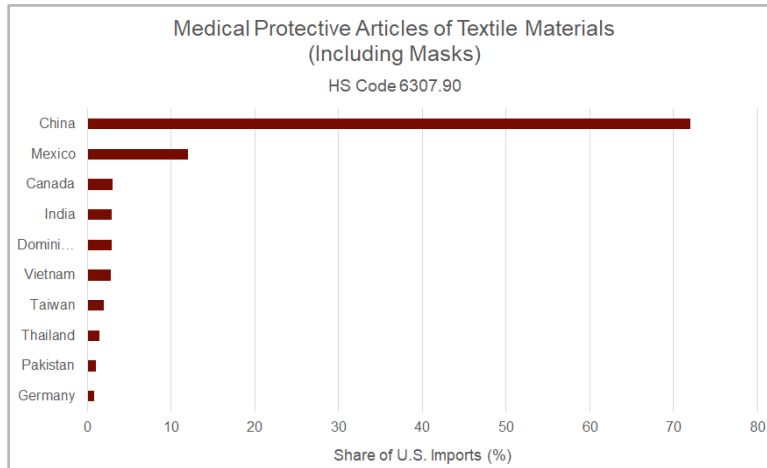
countries do not meet these international standards, relations can become strained and with the recent COVID-19 pandemic, just that has happened.

Regulation, however, is not the only issue. As of April 6, 2020, more than 25 countries including China, India and the European Union have imposed limits or bans on certain exports. These measures can delay or even obstruct countries' necessary medical imports, including ventilators and protective equipment, to fight the silent killer of COVID-19. With the unknown possibility of future pandemics, countries may push to manufacture certain product lines they deem of national security interest, such as medical devices, within their own borders. This could disrupt global supply chains and change the dynamics that trade plays within the medical device industry.

United States Impact of COVID-19

Like many other nations, the COVID-19 outbreak has created a high demand for ventilators and personal protective equipment. As of March 28, 2020, the Federal Emergency Management Agency had, “shipped or delivered 11.6 million N95 respirator masks, 26 million surgical masks, 5.2 million face shields, 4.3 million surgical gowns, 22 million gloves and 8,100 ventilators,” according to the Washington Post. Yet, as the United States continues to have the largest number of cases, the demand keeps growing. On April 1, 2020, it was reported that the U.S. Department of Homeland Security announced the national safety stock for personal protective equipment was nearly depleted. While the United States has been able to drastically increase its own production of necessary medical equipment through the Defense Production Act, it does not take away from the country's reliance on foreign manufacturers. According to a recent report by the Congressional Research Service, the pandemic has highlighted the United States' dependence on China for much needed medical supplies. With N95 masks and ventilators largely in demand, the CRS points to the fact that China accounts for 72 percent of medical protective equipment (including masks) imports, 36 percent of digital and infrared thermometer imports, and 17 percent of medical ventilator imports.

Select U.S. Imports in 2019



Source: Congressional Research Service using data from the U.S. International Trade Commission DataWeb and Global Trade Atlas

Even before COVID-19, the United States had issues with China's industrial policies surrounding the medical device industry, specifically regulatory standards and content requirements. With the exacerbation of global supply chains and calls from Members within Congress and executive branch officials to act on Chinese dependence, we foresee two changes regarding the supply chains of the medical device industry.

Implication of COVID-19

The Coronavirus could cause the United States to begin talks, if they have not done so already, with friendly nations to increase their medical device imports and

exports. Countries such as Germany, Ireland, and Mexico could increase exports to the U.S. by expanding the production of medical devices that China currently accounts for. While the U.S. wants to decrease its dependence on China for medical products, China plans on making strategic plays within the health sectors to meet its Made in China 2025 (MIC 2025) plans and increase influence around the globe. With biotechnology, pharmaceuticals, and medical devices being integral parts of the MIC 2025 health plan, the United States will likely take action to diversify medical equipment imports within the next five years. Because the United States has the largest market share of the medical device industry, their charge to restructure global supply chains and reduce Chinese dependence could set off a domino effect for how other countries receive their medical devices.

INNOVATIVE OPPORTUNITY

Future Trends

New technology development encompasses a wide array of product lines and is conducted by both small start-ups and large conglomerates. However, small medical device start-ups are primarily engaged with R&D and developing new medical technologies, typically in the therapeutic segment. Because small firms tend to have lower revenue streams, these companies are typically funded by venture capital firms that believe the new technology will reap significant profits. Three new technological areas, minimal invasiveness, additive manufacturing, and artificial intelligence have attracted a notable amount of attention.

Minimal Invasiveness

The idea of minimal invasiveness is to develop and upgrade products that are less intrusive during surgeries. This technology makes equipment more effective for healthcare workers to use, as well as improves patient experience. For example, research can focus on equipment involved in catheter-based and laparoscopic procedures. Research can also focus on how to ascertain the same diagnosis through less intrusive technologies that may not need to enter the body. With current

market size projections at \$29.9 billion by 2024, medical device manufacturers hope to stay ahead of the curve.

One leading company in the R&D of minimally invasive technology is Siemens Healthineers. This corporation recognizes the arduous task faced by surgeons and is actively developing tools to support this trend. For instance, lumbar spine surgery is a common medical procedure but requires a highly intrusive operation to be performed. With minimally invasive apparatus, such as advanced 3D imaging, smaller incisions are becoming more prevalent. This results in more efficient, accurate procedures, and faster patient recovery.

Additive Manufacturing

Additive manufacturing, more commonly known as 3D printing, has become a recent trend within the device industry. Medical manufacturing firms highlight additive manufacturing's unique ability to customize devices to the patient's specific need and its ability to more closely resemble the human bone structure. In 2017, the United States' Food and Drug Administration set guidance on 3D printed medical devices, a significant step for the additive manufacturing market. As the United States continues to support the new innovation through regulatory standards, it is projected that North America will be the largest market for 3D printed medical devices.

With the ability to readily develop prototypes, large medical device conglomerates have made substantial investments into the new market segment. A notable company leading the additive manufacturing march is Stryker Corporation. In 2019, the company announced its plan to invest over \$200 million for expansion of its R&D efforts at its 3D printing facilities in Cork, Ireland. However, Stryker is also facing competitions from Medtronic and Johnson and Johnson, both major players in the industry. Merger and acquisitions within the additive manufacturing space in the future are extremely likely as large conglomerates compete to differentiate themselves by gaining a technological edge over one another.

Artificial Intelligence

R&D investment in the digital realm such as artificial intelligence (AI) will revolutionize the medical manufacturing industry. As researchers shift their focus to preventative health strategy, diagnostic technology is becoming a greater interest to health companies. Artificial intelligence is especially beneficial in healthcare because of its ability to analyze and draw risk conclusions based on data. Programming AI with data on various diseases will allow it to diagnose illnesses and conditions, making patient care more efficient, less costly, and relieving some of the burden on healthcare providers. AI can also be used in physical medical procedures, such as surgeries, to eliminate the risk of damage caused by human error. This groundbreaking technology had a market size of \$1.4 billion as of 2016, but is expected to grow to \$22.8 billion by 2023, with an extraordinary compound annual growth rate of about 48 percent.

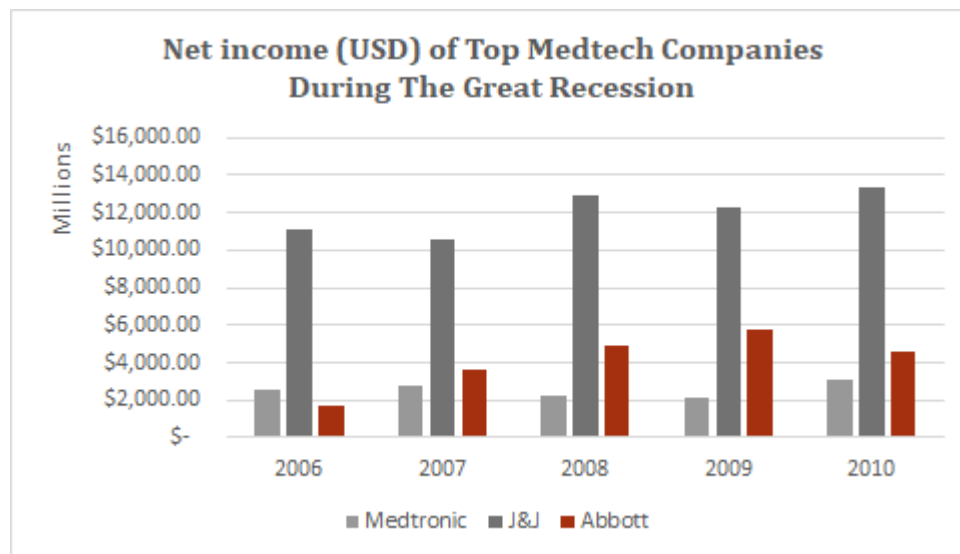
Every top medical conglomerate in the world has invested in AI R&D and this trend will undoubtedly continue. For example, the leading medtech manufacturer, Medtronic, released the first artificial intelligence system for colonoscopy in 2019, which detects colorectal polyps. Based on AI's innovative nature, we can predict that the United States will be the first to capitalize on this new venture and gain the most market share. This is already beginning to take shape as U.S. based medical manufacturers take the lead on AI R&D. China will also be a major player in health AI technology because of its Made In China 2025 plan, which heavily emphasizes greater global influence in health sectors. China is currently allocating more resources to healthcare R&D in order to make sure their healthcare influence is materialized. Established markets like Germany and Japan are likely to follow, not lead, in the development of AI due to its lower R&D expenditure and reputation of stable medical manufacturing markets. Such drastic growth is better suited for countries prepared to handle radical innovation.

OUTLOOK

Economics

Unsurprisingly, the largest medtech manufacturing companies with the most market share in fast growing market segments (electrophysiology, neurovascular) are predicted to grow the most in the upcoming years. It is extremely difficult for new entrants to gain substantial market share due to the consolidation of businesses (M&As), high investment needs for startups, and intense competitiveness within market segments. 70 percent of sales are already in the hands of the top three companies in high growth segments (over 6 percent annual growth rate), most of which are top 30 medical-device companies by revenue.

Typically, during economic turmoil, medical manufacturing is shielded by innovation and necessary health demand. In comparison with other industries, medtech is considered “safe”. During the Great Recession, top medical device companies faced lower loss compared to other industries. For example, Medtronic faced a 22.6 percent decline to its net income between 2007 and 2009 but recovered by 2010. Other medtech companies saw little to no damage to their bottom line between 2007-2009.



Source: Financial Income Statements using data from Yahoo Finance

As we currently enter a recession, we can predict the same kind of disturbance for the upcoming years. On March 27th, 2020, The Trump administration released the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Due to the unprecedented global pandemic, the historic two trillion-dollar stimulus will be allocating \$16 billion to producing personal protective equipment, including masks and ventilators. Demand for personal protective equipment will strongly increase, while unnecessary medical device demand will decrease as avoidable medical

procedures are put on hold. Medtech companies may face stagnation but will not see immense loss during the recession. Medical equipment is considered indispensable regardless of the economic state.

Summary

The medical manufacturing industry is predicted to have stable growth in the foreseeable future, with the United States and China leading the way for innovation. While the United States plans on investing in more R&D initiatives, China hopes to follow through with its MIC 2025 health plans, expanding its global medical influence. Mergers and acquisitions continue to be the predominant way to gain market share, as startups and companies work conjointly with bigger companies to develop, produce, market, and distribute medical supplies.

The United States, Germany and Japan are established markets for medtech. There is high import competitiveness due to moderate government regulations and high per capita healthcare spending compared to emerging markets such as China and Brazil. Because the United States invests more in R&D, its products are highly innovative and have short life cycles. Japan and Germany, on the other hand, have less innovation, longer life cycles, and operate in a mature market. This gives Japan and Germany an advantage over the United States when trying to gain market share in emerging markets.

China, India, and Brazil are emerging markets with increasing demand for medtech but tend to have stringent government regulations. This increases the product time to market. The United States has continuous product improvement and cannot afford longer times to market, because devices quickly become obsolete. Germany and Japan, however, can afford to go through the government processes and will have the competitive advantage in emerging markets, unless more international regulations come to fruition.

With the recent COVID-19 pandemic, weaknesses in global supply chains and regulations have been exposed. As countries witness the difficulty in obtaining medical supplies, calls for investing more in domestic manufacturing may rise. The United States federal government has already begun talks to shift some medical

manufacturing back home and countries around the globe may follow America's lead.

Future opportunities within the medical device space include minimally invasive technology, additive manufacturing, and artificial intelligence. These technologies aim to develop a greater accuracy in diagnostic testing, improve a patient's experience by tailoring health needs, and increase the effectiveness of surgeries and medical devices. The United States and China are expected to lead the way and in these advanced and upcoming technology segments.

As the global economy faces turmoil catalyzed by COVID-19, the medtech industry will not face enormous losses. Today, there is a greater view of importance for medical equipment due to the pandemic and it is protected by continuous health demand and innovation. During the 2008 global recession, top medtech companies had little to no loss to their net income and recovered quickly. The same can be expected for this upcoming recession; medical manufacturing may stagnate but will not face extensive loss.

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