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The State of the U.S. Medtech Industry

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The United States is the global leader in medtech innovation, but can it continue to maintain that position?

As the medical device industry enters 2015, the United States remains the world leader by market size, with total revenue of around $110 billion— around one-third of the $350 billion global pie. But the U.S. medical device industry also faces multifaceted challenges that are hampering growth. In recent years, the furious pace of growth the U.S. medtech industry had grown accustomed to has slowed. Through 2020, the U.S. medtech market is expected to expand by only 5%, according to Evaluate. That's down significantly from its 15% growth rate a decade ago, according to Accenture. To improve its prospects, the industry will need to capitalize on its strengths, overcome its weaknesses, seize opportunities for growth, and address threats that could hamper its progress.

Strengths

Market Position and Size. The United States continues to command a leadership role in the global medical device space. As of October 2014, U.S. companies held four of the top five rankings for medical device companies with the most revenue and represent 22 of the top 40 spots. Overall, U.S. companies account for almost two-thirds of the total revenue for the top 40 medical device companies, followed by Germany with 14% and Japan with 7%. An aging population and increased availability of healthcare as a result of the Affordable Care Act (ACA) should continue to keep the United States well positioned in the medtech space. U.S. medical device exports grew at a compound annual growth rate of 4.5% from 2008 to 2013 and are expected to increase at similar rates in the future, according to Bloomberg. Growing economies in Asia and Africa, where gross domestic product is predicted to rise by more than 5.5%, also bode well for U.S. companies, which enjoy good brand recognition and reputations there.

R&D Investment. While the United States is expected to continue to play a leading role in medical device research and development (R&D) for many years to come, its dominance is eroding. After declining in 2009 for only the second time since the 1950s, according to the National Science Board, R&D spending across all U.S. industries has rebounded—although gains of $2.9 billion in 2010 and $7.3 billion in 2011 were unimpressive. Larger medical device manufacturers, in particular, have been slow to dedicate more dollars to R&D. From 2013 through 2020, large corporations in the industry with projected spend of $1 billion or more are expected to grow their R&D budgets by approximately 3%, while the rest of the industry is expected to increase R&D spending by more than 5%, according to Evaluate.

Academic Institutions. The United States is home to 141 accredited medical schools and approximately 400 major teaching hospitals and health systems—many of which consistently rank among the best in the world—according to the Association of American Medical Colleges. Many of these academic institutions partner with medical device companies to collaborate on research and development of new technologies.

Strong Finance Metrics. While growth in the industry has slowed over the past decade, revenues still grew at a faster pace than GDP. Renewed confidence in the medtech sector was evidenced by strong improvement in market capitalizations, which surged 37% in 2013, compared with 4% growth in 2012. More than 70% of U.S. medtech companies saw their market cap increase, and nearly a quarter saw their share prices grow 100% or more, according to Ernst & Young. In addition, there has been a strong market for mergers and acquisitions (M&As) in the medtech sector. The total deal value during the first three quarters of 2014 was considerably higher than in the same period in 2013, while the number of M&A deals rose 20%. The period from mid-2013 through mid- 2014 was also promising for small and midsize companies, with 31 U.S. and European medtech IPOs raising $1.5 billion in funding. This illustrates investors' faith and confidence in the industry's future prospects.

Weaknesses

Innovation Plateau. A major reason for slowing growth in the medtech industry has been a gradual shift from risky blue-sky research to more evolutionary research. Large, established corporations, especially, have turned to more predictable research with a more easily measured return on investment. Unfortunately, low-risk or incremental improvements in medical device products do not justify price increases in the eyes of payers. In contrast, smaller companies outside the United States can accept a larger magnitude of risk due to their more nimble nature and less burdensome regulatory environment, which could lead to greater innovation.

Medical Device Tax. The medical device sector has been negatively impacted by a 2.3% excise tax on sales of medical devices in United States implemented in 2013. According to a February 2014 status report from AdvaMed, as many as 165,000 U.S. jobs have been lost due to the tax, and nearly one-third of respondents to a survey by the trade group said they had reduced R&D investment because of the tax. The device tax also places U.S. companies at a disadvantage against foreign competitors by raising the U.S. companies' effective tax rate. Furthermore, it often forces U.S. companies to lower the price of their products in order to remain competitive in the global marketplace. Additionally, the higher tax rate reduces companies' resources for capital investments, R&D, clinical trials, manufacturing improvements, and investments in startups.

Regulatory Environment. Increased regulatory scrutiny by FDA has lead to increased costs for development of new products. For example, U.S. regulations such as unique device identification, which went into effect in September 2013, add to the growing cost of compliance for companies looking to do business in the United States. U.S. medical device manufacturers should also be concerned about foreign regulations, particularly in China, which is pursuing policies that favor domestic manufacturers. This may force U.S. medical device manufacturers that want to sell in China to manufacture there. This creates a predicament because companies will need to rely on China's intellectual property laws and enforcement, which have been major concerns to date. In addition, companies will have to carefully scrutinize and evaluate new Chinese business partners. Foreign regulations are also an issue in the EU, where new laws will soon replace the EU's Medical Device Directives. Areas of concern for medtech companies in the proposed legislation include enhanced competence requirements for notified bodies, approaches toward clinical evaluations, and the definition of single-use devices. While there is still ambiguity as to when the final version of the legislation will go into effect and what it will look like, companies will eventually have to comply with the new regulations.

Inferior Government Subsidies for R&D. The R&D tax credit has been vital to sustaining U.S. innovation, but the temporary credit has often been allowed to lapse since its enactment in 1981. Without permanent status, businesses can't fully rely on the R&D tax credit in financial budgeting and forecasting. A permanent credit would give companies the confidence to invest in R&D, knowing that a certain amount of their expenses would be offset come tax time. The U.S. R&D tax credit is also inferior to others around the globe. The United States currently ranks 22nd in the world for federal R&D tax subsidies, with countries in Europe, Asia, and South America providing greater incentives for businesses to move there.

Venture Capital. Venture capital firms allocated just 7% of their funding to healthcare in 2013, down from 13% in 2009. Due to long times to market and stringent FDA regulations, early-stage companies have had an especially hard time attracting venture capital. Angel investors have stepped in to provide essential capital to startup medtech companies, but more funding is needed to keep the industry's innovation pipeline flowing.

Opportunities

Demographics. From 2000 to 2011, the U.S. population over the age of 65 increased 18%, a rate that is expected to continue for at least 20 years. This trend is significant for medtech because the elderly use more health resources compared with their younger counterparts. Despite its inclusion of the medical device tax, the ACA has provided another tailwind for the medical device industry. The law has been credited with reducing the number of Americans without health insurance by 8 million. In particular, it has extended coverage to people with preexisting conditions and low incomes, groups that tend to need more health treatments that require medical devices.

Service and Business Model Innovations. Due to lower reimbursement rates, many medtech companies are enhancing their products with service offerings that offer additional value for their customers, such as increasing operating room efficiency or reducing hospital visits. By having a suite of offerings designed to address the continuum of care in a given disease area, medical device companies can help provider groups meet important care metrics necessary for reimbursement and simplify the contracting complexity healthcare buyers face.

Innovation in Product Development. One way medical device companies are combating higher development and commercialization costs is through use of data technologies to increase productivity at each stage of product development. Companies are now mining information from tools in service, clinical trials, genetics, and demographics to perform analyses that provide insights into trials and generate new ideas, while reducing costs by drawing conclusions faster. With the recent explosion in mobile platforms, interactive graphical user interfaces (GUIs) have become commonplace in medical devices. But research into recent patient incidents and product recalls has found GUI design most often the primary culprit. GUI development is therefore a critical element in most present day medical device efforts. Considerations of how systems can be designed for integration with medical platforms and end users are essential for the safety, efficacy, and ultimate success of new devices.

Application of New Technologies. Some segments of medical device manufacturing are being transformed by the use of 3-D printing, with medical applications accounting for 16.4% of the $2.2-billion additive manufacturing market in 2012, according to a study published by Deloitte University Press. Relatively small medical devices, such as hearing aids or dental retainer molds, are currently best suited for additive manufacturing, but future medical applications include grafting skin onto burn victims, printing blood vessels and heart tissue, making prostheses that resemble the original missing limb, studying cancer with printed cells, and even creating replacement organs for the human body. Another technology with niche applications in medical device manufacturing is flexible automation. The robotics incorporated into these systems can provide the capability to process different products through the same system and are reconfigurable for new products, thereby reducing costs, improving production flexibility, and shortening product development life cycles. As a result, robots are being used increasingly in various areas of medical device manufacturing, including assembly, dispensing, quality control, and packaging.

Software development will also continue to play a major role in medtech innovation as the shift to mobile platforms allows personal electronic devices to transmit patient data to doctors, manage documentation and records, and provide identification and traceability of medical devices.

Threats

Cybersecurity. Cybersecurity threats have become a growing concern, with numerous hacking attempts aimed at medical device companies over the past year. As a result, the U.S. government has taken notice. The U.S. Department of Homeland Security has more than 20 open investigations into cybersecurity flaws in medical devices and hospital equipment, according to an October 2014 report by Reuters. FDA issued its final guidance on cybersecurity in 2014, providing examples of what reviewers expect to see during premarket review. Product Commoditization. Medtech companies have been pressured by payers to lower prices on widely available devices. A report by AdvaMed found that prices for artificial knees, pacemakers, and drug-eluting stents dropped by 17%, 26%, and 34%, respectively, in real dollars adjusted by the consumer price index for medical care from 2007 to 2011. Many other device categories also faced price declines of significant magnitude. As medical devices become more portable— and thus more prevalent—it will be easier for offshore competitors to bring similar products to market faster and at lower prices. U.S. companies need to ensure their devices can be differentiated and demand premium pricing based on their capabilities. One way to accomplish this is through software downloads, which can keep device features and functionality updated without the need for hardware replacement. Companies must also focus on process improvements and lean manufacturing to become more efficient.

Competition from Consumer Tech. Seeing traditional medtech players slow to adopt mobile, analytics, and cloud solutions, consumer technology firms have sensed an opportunity and are starting to enter the medtech space. Google is investing in smart contact lenses, and other consumer tech competitors include Apple, AT&T, Canon, Intel, Motorola, Reebok, Qualcomm, Samsung, Sony, and Verizon. Many of these firms are focusing on functionalities such as wireless communication, portability, and seamless integration with other devices to enable more personalized care. Moreover, they have a head start on the medtech industry given their brand recognition and familiarity among consumers.

Better Business Environments Abroad. The United States' 35% corporate tax rate is not competitive with that of many countries in Europe, including Germany, Switzerland, and Ireland. The higher tax rate has caused several large-profile corporations, including Medtronic, to switch to offshore domiciles. The United States is also declining in its relative attractiveness in areas including property rights, difficulty and length of time of the approval process, and economic freedom.

Foreign Markets. In Japan, the world's second-largest medical device market, the government is making an effort to increase the availability and accessibility of foreign products and technologies through initiatives such as a new Pharmaceutical and Medical Device Law (PMDL), which went into effect last year. Although implementation of the PMDL won't necessarily make Japanese registration easy, it should at least make the process less challenging and more transparent, which should benefit U.S. companies wanting to do business in Japan. China, the world's third-largest medical device market, is also one of the world's fastest-growing. The United States is China's leading supplier of medical devices, and slow growth in U.S. healthcare spending may encourage U.S. firms to further penetrate the Chinese market. But barriers including challenging regulatory procedures, inconsistent reimbursement policies, complex tendering for purchasing medical devices, and tariffs on China's most commonly imported devices may continue to hamper expansion in China by U.S. companies. Israel is also becoming a significant player in medtech innovation thanks to its technological know-how; infrastructure; tax credits, incentives, and grants; and culture of innovation and entrepreneurship. Israel also enjoys a high ranking in ease and speed of regulatory approval. As a result, the acquisition rate of early- to mid-stage Israeli medtech firms has accelerated over the past few years.

Conclusion

While the United States currently holds the largest share of worldwide medtech sales, it cannot afford to rest on its laurels. The coming years will be critical in determining if the U.S. medtech industry can take stave off competition from foreign and consumer technology players while taking advantage of existing strengths. Success will depend in part on how proactive U.S. firms are in embracing a value-added services model combining first class products with complementary services and software to improve healthcare. This will be the major differentiator between high-end products and commodity items, and companies that thrive and those that become extinct.

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