Challenges and Opportunities for Medical Device Manufacturers

Purolator International

Introduction

To understand current trends in today's medical device industry, consider the growing demand for total knee replacements.

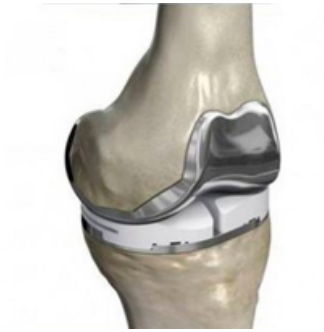
A study by the American Academy of Orthopaedic Surgeons found more than 600,000 knee replacements are performed each year in the United States. That number is projected to exceed three million by 2030, an increase of 400 percent.

This surge in demand is attributed to the aging of the U.S. population, along with advancements in surgical technologies and knee replacement devices that have led to improved results. This in turn has spurred demand among osteoarthritis patients and other long-suffering knee patients.

The U.S. is not alone in this dramatic surge in full knee replacements. Demand is up by almost 20 percent in Canada, 7 percent in Japan, and 16 percent in China. The global market for knee devices was valued at $8.8 billion during 2015 and is projected to grow at an annual rate of 4 percent. United States manufacturers dominate the market, according to Kalorama Information, with the three industry leaders – Zimmer Biomet, DuPuy Synthes (part of the Johnson & Johnson family of companies), and Stryker – accounting for 75 percent of global market share.

And in a sign of where the industry is headed, a new company, Burlington, Massachusetts-based ConforMIS, offers a "patient specific" knee that uses a patient's CT scan for a customized joint manufactured using 3-D additive printing.

Massachusetts-based ConforMIS offers a customized knee implant that is built based on a patient-specific 3-D model.



Although knee replacement devices are but one product in the overall medical device category, they are illustrative of changes and pressures taking place throughout the industry:

- The nation's aging population is driving demand for more medical device products.
- Technology-based innovation will enable manufacturers to develop increasingly patient-centric devices that can be manufactured quickly and often at a lower price point.
- Regulation is a front-burner issue, both in terms of navigating the Food and Drug Administration's (FDA's) application, testing, and approval process, and in meeting the patchwork of international standards.
- Changes within the U.S. healthcare landscape (i.e. consolidation and cost concerns) have strained traditional supply chain practices.
- Industry consolidation is expected to put pressure on small- to medium-size device manufacturers to keep pace with larger global companies.
- Continued fallout in the U.S. following the 2.3 percent excise tax placed on medical devices as part of the Affordable Care Act. The tax required the payment of more than $1 billion by device manufacturers, as reported by *Forbes*. The tax was suspended for two years in 2015, but a cloud of uncertainty hangs over the industry as Congress and President Trump negotiate changes to the Affordable Care Act.
- Uncertainty in both the U.S. and worldwide political landscape, as the U.S. Congress considers overhauls not only of the Affordable Care Act but of the tax code and trade policy. An additional factor is the pending departure of the United Kingdom from the European Union and the possible need for the UK to develop a medical device regulatory scheme.
- Growing concern about cybersecurity, as evidenced by at least one pacemaker manufacturer warned by the FDA that "vulnerabilities" in its devices could leave its devices susceptible to hacking.

At the same time, opportunities abound. As the world's largest supplier – and user – of medical devices, U.S. manufacturers are well positioned to tap into growing worldwide demand. McKinsey & Company consultants, for example, estimate the Asia-Pacific region – home to more than half of the world's population – is poised to overtake the European Union as the world's second-largest market for medical devices. However, manufacturers will need to overcome multiple obstacles – political, geographic, cultural – that have prevented access to this market.

Integral to success will be a retooled supply chain.

Integral to success will be a retooled supply chain that takes into account the evolving needs of the healthcare industry and the tremendous innovations that are changing the way products are manufactured and distributed. The following discussion will focus on the current climate for device manufacturers and offer insight for ensuring maximum efficiency throughout all processes.

The U.S. Medical Device Industry – Overview

The World Health Organization defines a medical device as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose." More than 500,000 different types of medical devices are produced worldwide, ranging from common products such as syringes, bandages, contact lenses, and dentures to more complicated devices, including pacemakers, artificial joints, respiratory ventilators, and cardiac assist devices.

The U.S. medical device industry leads the world in terms of innovation, production, and consumption. The U.S. International Trade Administration (ITA) projects sales during 2017 will reach $155 billion, a value that represents roughly 43 percent of the global market. Much of that production will be exported, with sales to foreign countries exceeding $44 billion in 2015. Top export destinations include Canada, Japan, and the European Union.

More than 500,000 different types of medical devices are produced worldwide.

Demand for U.S. devices is expected to grow worldwide, driven by increasing expenditures and focus on healthcare within several developing markets. This prioritization of healthcare has been marked by construction of new hospitals and clinics, establishment of public health insurance, and greater attention to hygiene and nutrition.

At the same time, the U.S. is a major importer of medical devices. According to the Medical Device Manufacturers Association, more than 50 percent of devices used in the U.S. come from a different country. And the ITA reports medical device imports were valued at $54 billion during 2015, with the majority coming from China and Mexico and falling in the "lower-tech" category of products, including surgical gloves and instruments.

Today more than 6,500 medical device manufacturers operate within the United States, 80 percent of which have fewer than 50 employees. These small- and medium-size enterprises (SMEs) often work in collaboration with one or more of the industry's larger players, providing innovative products or components. Although companies can be found across the U.S., the ITA reports concentrations of device manufacturers in regions with established high-tech industries. The states with the highest number of medical device companies include California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota, and Georgia.

With regard to larger manufacturers, seven of the world's largest manufacturers are U.S.-based:

- Medtronic Inc.
  Dublin, Ireland (until 2014, headquartered in Minnesota)
- Johnson & Johnson
  New Brunswick, New Jersey
- General Electric Co.
  Boston, Massachusetts
- Fresenius Medical Care AG & Co. KGAA
  Hamburg, Germany
- Koninklijke Philips NV
  Amsterdam, Netherlands
- Siemens AG
  Munich, Germany
- Becton, Dickinson and Co.
  Franklin Lakes, New Jersey
- Cardinal Health Inc.
  Dublin, Ohio
- Stryker Corp.
  Kalamazoo, Michigan
- Baxter International Inc.
  Deerfield, Illinois
- Boston Scientific Corp.
  Marlborough, Massachusetts
- Essilor International SA
  Charenton-le-Pont, France

Seven of the world's largest device manufacturers are U.S.-based.

The United States has achieved dominance over the industry largely because of manufacturers' sustained investment in technology and innovation. Research by KPMG affirmed this commitment with a survey in which more than half of participating industry executives prioritized "breakthrough innovation," rather than "enhancing existing product lines and services," as their company's primary strategy.

What exactly is a breakthrough? As KPMG notes, the term can be broadly defined to include new products, new surgical techniques, cost-effective products for emerging markets, and innovations geared toward transforming the way medical devices reach the consumer. Recent examples include:

- 3-D printing, which has already opened the door to unprecedented design and manufacturing flexibility. Already, the report notes, "scientists have successfully replaced a child's vertebrae with a 3D-printed bone."
- Combination of robotics and 3-D visual systems for use in surgical procedures
- New coating for hip implants to prevent premature failures
- Wearable and portable devices that offer real-time monitoring, diagnosis, and treatment of certain conditions, including diabetes and cardiovascular disease
- New teaching methods, including the use of Google glasses by a surgeon at Duke University to stream live feeds to medical students located in India

Without a strong supply chain to ensure efficiency, a company will risk alienating the very consumers it has worked so hard to help.

As manufacturers continue to invest in breakthrough research, the study notes the tendency of some manufacturers to overlook the need for a plan to put those products into consumers' hands. Without a strong supply chain to ensure efficiency, a company will risk alienating the very consumers it has worked so hard to help. In addition, an inefficient supply chain will preclude a manufacturer from expanding its network of partners and suppliers. "We believe that taking the right steps today for 'future proofing' the supply chain can balance risk with reward and turn an operational cost into a true competitive advantage for companies," the report noted.

Industry Challenges and Opportunities

While U.S. device manufacturers are expected to continue to dominate the global industry, several challenges will need to be addressed. Topping the list is the always-present challenge of regulatory scrutiny along with changes taking place within the U.S. healthcare industry, increased competition from international manufacturers, and strong pressure for pricing efficiency. Following is a closer look at each.

First, the challenges:

The Affordable Care Act, which imposed a 2.3 percent tax on medical devices (currently suspended), has had a dramatic impact on the device industry.

The Changing U.S. Healthcare Landscape

According to analysis by Deloitte, four trends are dramatically transforming the U.S. healthcare market, which naturally is impacting the medical device industry.

- **Technology.** From genetic breakthroughs and nanotechnology to 3-D printing, robotics, and electronic patient records, technology is changing all aspects of healthcare.

- **Aging Population.** According to the U.S. Census Bureau, America's 65-and-over population is expected to nearly double over the next three decades, from 48 million to 88 million by 2050. Further, the World Health Organization (WHO) reports that by 2030, U.S. life expectancy is projected to increase by 2.6 years, to 80.1 years. The aging population will mean increased demand for chronic care services, which in turn will drive demand for innovative and consumer-friendly devices. At the same time, the aging population will fuel demand for devices including joint replacements, pacemakers, hearing aids, and other options for improving quality of life.

- **Increased Role of Government.** As Deloitte notes, "the federal government has reshaped the healthcare landscape." Most notably, the 2010 Patient Protection and Affordable Care Act (ACA) resulted in today's health insurance exchanges, Medicaid expansion, and new payment and delivery models. That legislation, which by some estimates extended health insurance coverage to 20 million Americans, also imposed significant new coverage mandates, regulations, and taxes on the healthcare industry, including a 2.3 percent tax on medical devices.

- **Medical Device Tax.** The medical device tax has cost the device industry $1 billion and, not surprisingly, has been the focus of intense opposition from manufacturers. Congress imposed a two-year suspension of the tax in 2015, which is set to expire at the end of 2017. As lawmakers and President Trump consider revisions, or an outright repeal, of the ACA, device manufacturers are pushing for an outright repeal of the tax.

- **Demand for Value.** Millions of Americans – both those enrolled in ACA exchanges and those who receive insurance from their employer – are now enrolled in high-deductible plans. In many instances, the out-of-pocket deductibles are prohibitively expensive, with CNBC reporting an average deductible of almost $12,400 for a family enrolled in an ACA Bronze Plan. As a result, consumers have been forced to become more educated about health costs and savvier in their health-related decisions.

Regulatory Issues

The Food and Drug Administration has responsibility for evaluating all medical devices sold in the United States.

Before any device can be sold in the United States, it must be registered with the Food and Drug Administration (FDA). Devices are categorized by the FDA into three distinct classes, based on associated risks:

- Class I: Low risk and subject to the least regulatory control (i.e., dental floss)
- Class II: Higher risk than Class I and requires greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness (i.e., pregnancy tests)
- Class III: Highest risk devices and subject to the highest levels of regulatory control. Class III devices must typically be approved by FDA before they are marketed. (i.e., replacement heart valves)

Snapshot of the Regulatory Process

The first step in FDA compliance is to determine a product's correct classification. Currently there are more than 1,700 device types that have been classified by the FDA and organized into 16 medical specialties or device panels. Those medical specialties include:

- Anesthesiology
- Hematology/Pathology/Cardiovascular
- Immunology/Microbiology
- Dental
- Neurology
- Ear, Nose, and Throat
- Obstetrical and Gynecological
- Gastroenterology and Urology
- Ophthalmic
- General and Plastic Surgery
- Orthopedic
- General Hospital
- Radiology

A description of each classification panel can be found in Title 21 of the Code of Federal Regulations (CFR). The CFR will also advise which "Class" the device falls within and provide information about the path the device must follow in order to obtain approval for marketing and sale in the United States.

510(k) Filings

In general, most Class I devices can be self-registered and are exempt from having to file a 510(k) submission. Healthcare consultant Emergo Group reports that roughly 92 percent of Class II devices require a 510(k) submission and just 7 percent of Class III devices. The 510(k) – or marketing clearance process – allows the manufacturer to demonstrate that its device is "substantially equivalent" to another legally marketed device.

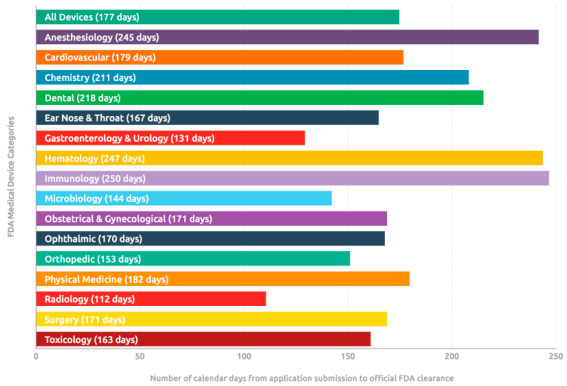
The 510(k) review process has two central areas of concentration: (1) to determine if the device meets scientific requirements and (2) to ensure all administrative filings are complete, including all required documentation and paperwork. To help ensure a smooth and ultimately successful review process, the FDA developed a "Refuse to Accept" (RTA) policy, which features a checklist to guide manufacturers through the filing process.

Premarket Applications (PMAs)

Class III devices, and many Class II devices, will need to undergo a more rigorous "premarket application" (PMA) process. This includes adherence with strict protocols to demonstrate a device's safety and effectiveness. Not surprisingly, the PMA process is highly involved and requires scientific evidence that the benefits to health from the intended use of the device outweigh the possible risks and that the device will significantly help a large portion of the affected population.

While this may appear to be a straightforward process, in fact, obtaining FDA approval – even clearance for a Class I device – can be a frustrating and time-consuming process. On average, Emergo Group reports the FDA took 177 days to clear a 510(k) submission. Not surprisingly, wait times varied based on the complexity of the device, with anesthesiology devices taking an average 245 days, hematology products taking 247 days, and immunology products having to wait an average 250 days.

According to research from Emergo Group, the number of days needed for FDA clearance averages 177, although clearance times can vary based on the category of device.



Among the reasons for the long clearance process:

- **Improper 510(k) submissions.** During 2013, the FDA "refused to accept" almost 60 percent of 510(k) submissions. Submissions were rejected for a variety of reasons, including incomplete or missing information, failure to include required fees, and other reasons such as typos, misprints, and duplicate pages. But since including an updated RTA checklist in 2015, the rejection rate has gotten much smaller. According to MedDevice Online, the 2015 approval rate jumped to 85 percent for 510(k) submissions and 98 percent for PMA filings.

- **Increased volume in international submissions.** Emergo Group reports 510(k) submissions from Asian and European companies nearly doubled in the last two years, with China now accounting for 6.6 percent of all submissions, Germany for 4.5 percent, and South Korea for 4.4 percent. The research cites the strong U.S. dollar along with China's increasing export savviness as key drivers for the increases.

- **Uncertainty surrounding new products.** Research by Dr. Ariel Dora Stern, of the Harvard Business School, found new medical devices spent 34 percent – or 7.2 months – longer undergoing regulatory review than "follow-on entrants." Dr. Stern notes that approval times are largely unrelated to device complexity or "newness," but "rather, we observed many big regulatory delays for devices built on technologies the FDA is already familiar with. That suggests there is something more administrative in the delays – something in the classification process that matters."

  Dr. Stern found these inexplicable – and significant – delays have tremendous adverse effects for small businesses, noting "small firms will be less willing to take on the additional costs of entering new device markets."

International Regulatory Issues

Regulatory concerns exist not just within the U.S., but device makers must also contend with the unique regulations of each country in which they operate. As manufacturers are keenly aware, the current international regulatory landscape is a patchwork of nation-specific, often conflicting, and fast-changing mandates that must be understood and fully complied with.

Device makers face a patchwork of international regulatory and customs mandates, with some developing countries having no regulatory protocols in place for medical devices.

Consider China. According to the International Trade Association, China imposed considerable regulatory changes during 2015 and 2016 that will significantly affect U.S. businesses. "In March 2015, CFDA [China Food and Drug Administration] introduced new requirements for Class II and Class III medical devices. The fee structure requires US$32,446 for initial registration of a Class II imported medical device, US$47,508 for a Class III device, and US$6,277 for a registration renewal. These fees do not include costs for clinical trials, in-country representation, and translation."

In addition, CFDA issued a number of new rules, including "Rules for the Classification of Medical Devices," "Measures for the Supervision and Administration of Use Quality of Medical Devices," "Naming Rules for the Generic Names of Medical Devices," and "Good Clinical Practices for Medical Devices."

These changes represent just a tiny fraction of the overall regulatory process for importing devices into China.

Regulatory compliance can be especially problematic in developing countries, where an established regulatory protocol may still be fluid and where network systems may be lacking to facilitate the compliance process. These countries include Chad, Haiti, the Central African Republic, and Albania, among others.

In 2011, a voluntary group of medical device regulators came together to form the International Medical Device Regulators Forum (IMDRF) with the goal of accelerating regulatory harmonization and convergence. Current members of the group include Australia, Brazil, Canada, China, Europe, Japan, Russia, and the United States.

Uncertainty in Implementing the 21st Century Cures Act

The U.S. Congress attempted to address the delays and bottlenecks inherent to the FDA review process through the 21st Century Cures Act, which was passed in late 2016. The legislation includes a number of provisions intended to improve the regulatory process for medical devices, including:

- Establishment of a Breakthrough Devices program to provide expedited review for devices that offer "more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions." Through the Breakthrough program, innovative devices will be prioritized for conditions that currently have no cleared or approved alternatives. The Breakthrough program builds on the existing "Expedited Access Path C," which prioritizes devices that address rare diseases

- Periodic review of Class I and Class II devices. As reported by *Mass Device*, the law requires a review of Class I and Class II devices every five years to determine whether they may be declared 501(k) exempt

- Classification panels must be evaluated to ensure "adequate staffing expertise" to assess the disease that the panel is designated to address

- Authorization to hire necessary scientific, technical, and professional staff

In the months since the new law was enacted, several glitches have been exposed, which, according to analysis from international law firm Hughes Hubbard & Reed LLP, has caused implementation to come to a standstill. For one thing, hiring restrictions put in place by the Trump administration, may impede the FDA's ability to ensure required staffing levels. Also, the "one-in, two-out" executive order signed by President Trump directs that for every new regulation implemented, two must be tossed out. Since the executive order also extends to guidance documents, which are explicitly called for in the Cures Act, the legal analysis predicts the agency will be severely impacted. "The only certainty," the analysis states,
"is that the act is going to take longer to implement than originally anticipated."

Threat of Increased User Fees

Beginning in 2002 with the Medical Device User Fee and Modernization Act (MDUFMA), medical device companies have been required to pay fees to the FDA to help offset the costs of agency review and administrative processes. According to the FDA, "these fees help the FDA increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to market."

Since then, the FDA and medical device industry representatives have successfully negotiated several user fee renewal agreements, including a recent "agreement in principle" reached on the Medical Device User Fee Amendments IV (MDUFA IV), scheduled to be in place from October 1, 2017 through September 30, 2022.

However, the Trump administration's proposed 2018 federal budget would increase FDA user fees by more than $1 billion beyond what is called for in the agreement in an effort to rely on user fees as the sole source of agency funding. "Industries that directly benefit from FDA's medical product premarket approval and administrative actions can and should pay more to support FDA's continued capacity," the president wrote in the text of the budget.

Not surprisingly, the medical device industry strongly opposes the additional fees and has called on Congress for "immediate extension" of the MDUFA IV reached between the industry and the FDA.

Cybersecurity Threats

As medical devices become increasingly technology-driven, the threat of cybersecurity has become a front-burner issue for manufacturers. An article in *Wired* provided a concise summary of the current threat: "As hackers increasingly take advantage of historically lax security on embedded devices, defending medical instruments has taken on new urgency on two fronts. There's a need to protect patients, so that attackers can't hack an insulin pump to administer a fatal dose. And vulnerable medical devices also connect to a huge array of sensors and monitors, making them potential entry points to larger hospital networks."

The industry has become especially vulnerable to ransomware attacks, whereby hackers infiltrate a large facility or company and demand a quick payment in exchange for releasing the facility's data or restoring a system's functionality.

The FDA has provided detailed guidance for manufacturers with regard to cybersecurity, including a requirement that medical device applications address the need for defensive protocols. However, ultimate responsibility belongs with the manufacturer and not the government. A report by Deloitte found a majority of top medical device executives agree that accountability for cybersecurity is a shared responsibility between businesses and government. However, since that same report found many companies have yet to implement strong protocols to guard against cyberattacks, it is clear that much work remains.

Pricing Concerns

When more than 50 percent of respondents to an Emergo survey of medical device manufacturing managers cited "increased competition" as a key challenge, it was not unexpected that 46 percent of these managers also cited "pricing pressure" as a major concern.

Device makers are not immune from the increased demand for value that is transforming the U.S. healthcare industry. Value-based care is rapidly emerging as a replacement for the traditional fee-for-service approach. Whereas doctors and hospitals were previously paid based on the number of services delivered, including the number of tests or procedures performed, today's trend is toward a more patient-centric approach. Medical care is now value-based and, according to analysis from Aetna, medical professionals are paid for keeping people healthy and for improving the health of patients with chronic conditions in an evidence-based, cost-effective way.

Medical device makers will be affected in several ways:

- **New Reimbursement Process.** The Centers for Medicare and Medicaid Services (CMS) has begun a transition to a "bundled payments" approach to healthcare reimbursements. Under a "bundled" model, a single payment is issued to cover all aspects of a medical procedure. That bundle will then be broken down and divided among all stakeholders. A patient who undergoes a hip replacement, for example, will need a range of services, including a surgeon, anesthesiologist, operating room, x-rays, hospital stay, hip replacement device, additional devices such as a walker and cane, and physical and occupational therapy, among other services. Under the old scenario, each stakeholder would submit a separate claim for reimbursement. But in the new environment, a single "bundled" payment is issued to the hospital, and each stakeholder is paid a negotiated fee from that sum.

  For device manufacturers, the new process means additional pressure to control costs, including an increased awareness of the price of materials used in new designs. "It may make them [device makers] a little more cautious in terms of design and use of materials, staying with those designs that have proven to be effective," Edward Black, president of Reimbursement Strategies LLC, a St. Paul-based healthcare consulting firm, said in an online *MD+DI* article. "If they're customizing devices for individual patients, there will be more pressure on price. Even though they may fit better, they're going to be a lot more expensive."

  Many device makers have made internal adjustments to adapt to the new payment process. At least one, Stryker, made strategic acquisitions of companies that specialize in managing healthcare costs. Another industry leader, Zimmer Biomet, has stated that the reimbursement changes were not unexpected and has made necessary adjustments to its internal practices.

  But the impact could be most severe among smaller device manufacturers that do not have the resources to proactively plan for the payment changes.

- **Demand for Innovation.** The transition to patient-focused care will shine a light on those chronic conditions and diseases for which treatments have yet to be brought to market. While this presents a tremendous opportunity for device makers, it will impose new costs on manufacturers to accelerate development of new products. And, in the new world of negotiated "bundled payments," there is the added concern of reduced reimbursement rates.

- **Speed to Market.** The reality of increased global competition has also heightened the need for U.S. manufacturers to improve speed to market. The *Journal of Neuroinventional Surgery* reports "that the time from concept to market for medical devices is 3-7 years," with the bulk of time spent clearing FDA regulatory requirements. While this estimate includes high-risk Class III devices, it is clear that U.S. device manufacturers face a long and arduous process in bringing a new device to market.

But, while U.S. devices follow a rigorous regulatory process, similar devices manufactured in the European Union, for example, are brought to market much faster. A study by Harvard researchers examined 309 separate devices and found 63 percent were approved first in the European Union. However, that same study found that the devices, approved first by the EU, were three times more likely to require safety alerts and recalls.

- **Global Competition.** Device makers also face increased price pressure from international competitors, as several countries invest in their domestic device industries both as a way to meet the healthcare needs of citizens and tap into growing global demand. Current worldwide leaders include the United States, Japan, and the European Union.

  The competitive landscape is changing, though, as many countries increase investment in their domestic industries. China is one example. That country's device industry has grown at an annual rate of 20 percent since 2009. While not yet able to manufacture the high-tech products that distinguish the world's best companies, China is catching up. Chinese exports have increased at a rate of about 10 percent annually for the past several years, driven mostly by lower-cost devices.

  In addition to China, U.S. manufacturers of high-quality but lower-cost devices are also feeling pressure from Brazil, Korea, Taiwan, Mexico, and India. Each of these countries is investing in their domestic industries and beginning to compete on the global market, as reported by the ITA.

  Worth noting is that most of the world's largest international companies produce goods in the United States. Netherlands-based Philips Electronics, for example, produces more goods in the United States than in its home country.

Threat From Domestic Companies.

As tech giants including Google, Fitbit, and Apple step up investments in consumer health-related products, device manufacturers will be pressured to keep pace. Google, for example, has entered an agreement with Novartis to bring to market its "groundbreaking" smart contact lenses that will reportedly include a glucose monitoring lens for diabetics and one to treat farsightedness. Meanwhile, Apple CEO Tim Cook has publicly stated that his company is interested in entering the device market, although he has yet to confirm precisely in what capacity. Industry watchers have speculated about the company's desire to adapt the Apple Watch to assist diabetes patients with glucose monitoring. The Apple Watch, similar to the Fitbit, already has functionality to capture a wearer's vital information, including heartbeat and exertion level.

The Dapu Therapy Hospital in Hong Kong, China. The Chinese government has made significant investments in healthcare infrastructure, which includes construction of new hospitals and medical clinics.

Industry Opportunities

While the industry must face these challenges head-on, there are also tremendous opportunities for device makers to solidify America's role as the world's leader. These opportunities include:

Increased Global Demand

The global medical device market is expected to exceed $543 billion by 2020, driven by a combination of sustained growth in stable markets and more explosive growth in newer, emerging markets. In many regions of the world, demand for medical devices far outweighs existing supplies.

Much of this "new" demand is due to government investment in national healthcare services within several countries. Citizens who previously had very limited access to healthcare are being introduced to various forms of coverage, including community hospitals, pharmaceuticals, and devices.

Nigeria, for example, is listed by the ITA as a country that offers export potential for U.S. companies. The U.S. government considers the Nigerian healthcare sector to be "grossly underdeveloped" and notes that, since most people exist on roughly $1 per day, adequate healthcare remains largely out of reach for the vast majority of Nigerians. Further, those who can afford quality care tend to leave the country and seek service elsewhere.

However, the country launched a "National Strategic Development Plan," through which the government embarked on a significant infrastructure campaign to build hospitals and clinics, along with procurement of modern medical equipment and drugs. Specifically, Nigeria now has a strong demand for diagnostic-related equipment and technologies such as Magnetic Resonance Imaging (MRI), Computed Tomography scan (CT), digital X-ray, ultrasound, and mammography.

Similar opportunities exist in other countries, of course. China and India are also experiencing surging demand for medical devices, as government investment expands accessibility to millions of people.

Overcoming any of these countries' complicated political landscapes and haphazard regulatory requirements can be a challenge, which is why a U.S. business should consider partnering with a local company or taking advantage of on-the-ground expertise offered through the U.S. Commercial Service.

Technology Continues to Drive Innovation

According to the Advanced Medical Technology Association, advancements in medical technology have helped reduce the duration of hospital stays by 58 percent. Examples of this can be found in virtually all aspects of medicine and patient care:

- Wearable devices allow patients to monitor vital signs from the comfort of their homes, with data seamlessly transmitted to a doctor or medical facility.
- Advances in joint replacement devices and surgical techniques have cleared the way for some doctors to perform the procedure in outpatient centers with some patients sent home the same day, a dramatic change from the norm of a multiday in-patient hospital stay.
- Advances in angioplasty have dramatically reduced the risk of complications so that many patients are allowed to go home the day of their procedure.

Advancements such as these are a tiny representation of the way technology is fueling innovation in the device market. Looking ahead, technology will have an even greater impact, especially with regard to advanced manufacturing, 3-D printing, and the Internet of Things (IoT).

3-D Printing. The medical device industry has embraced 3-D printing both as a way to innovate medical device design and facilitate production as well as improve supply chain efficiency. According to *MD+DI* industry publication, 3-D printing is especially well suited for three key areas:

- Wearable devices, since devices are generally customized for each patient
- Clinical study devices in which small quantities of test products can be built, with design changes easily incorporated
- Implants, including orthopedics and dental devices

3-D printing allowed doctors to successfully produce a hip bone that was successfully implanted in a Croatian patient whose hip had been destroyed by bone cancer.

Source: eos Manufacturing Solutions

As additive printing allows greater flexibility to the manufacturing process, hospitals and medical facilities gain efficiency in their supply chains. As reported by Deloitte, "by streamlining a product's supply chain, companies can reduce production costs, decrease the time it takes for a customer to receive the end product, and simplify multistep production processes." As an example, Deloitte notes that Siemens, one of the world's largest manufacturers of hearing aids, has transitioned to 3-D printing. "Drivers for the change include [3-D printing's] ability to shorten the manufacturing process for customized devices by 50-80 percent, localize the distribution of the end product, and significantly reduce labor costs."

Internet of Things. Gartner, Inc. estimates more than 20.4 billion devices will be connected worldwide by 2020. In the device industry, the value of the IoT is already evident through wearables, implantables, and ingestibles available to certain patients with chronic conditions, including diabetes and heart disease. Beyond patient care, the IoT can help alleviate supply chain issues via better inventory control and recordkeeping. Security will be a top concern as device manufacturers consider expanding the role of IOT-enabled devices. In late 2016, for example, Johnson & Johnson announced that its OneTouch Ping® insulin pump was vulnerable to hacking and possibly susceptible to a perpetrator gaining control of the device. As much as the IoT holds tremendous potential for the device industry, so too are there risks that must be carefully considered.

Technology will continue to have a leading role in keeping U.S. manufacturers at the forefront of the global device industry. But, as global competition keeps up, manufacturers will feel pressure to ensure that their supply chains are keeping pace, able to meet competing demands for cost effectiveness, inventory control, and delivery efficiency.

Adapting Your Supply Chain for Today's Medical Device Needs

Deloitte reported that, using 3-D printing, a manufacturer can produce up to 450 dental crowns and bridges during one 24-hour cycle. Compare this with the 20 dental pieces that can be produced using traditional methods and the capabilities of today's advanced manufacturing processes are evident. This significant difference in output illustrates the need for a manufacturer to ensure that its supply chain has kept pace with this progress. What good is it to dramatically accelerate the rate of production if the devices are going to sit in a manufacturing center waiting to be picked up by a logistics company?

The increasingly global nature of the industry is another area that illustrates the need for supply chain innovation. As U.S. companies expand export opportunities to meet rising demand in countries including China, India, Malaysia, and Nigeria, detailed plans must be in place to ensure shipments meet all customs and regulatory requirements and will arrive undamaged and on time.

Device makers need to ensure their supply chains are performing at a premium level and able to maximize the benefits of new technology-based manufacturing processes.

While advanced manufacturing and increased global demand are certainly positive developments, they come at a time when the medical device supply chain is under enormous pressure for cost efficiency. Concern over increased health spending is causing hospitals and other medical providers to cut costs, leaving medical device manufacturers "caught in the crossfire." Specifically, the new "bundled payments" reimbursement process has put device makers under enormous pressure to cut costs and to prove to hospital administrators and doctors that their devices offer value and belong in their inventory.

As device makers adapt to this changing environment, the need for supply chain modifications becomes essential in key areas, including:

Inventory Management. "There is inventory everywhere," one medical device manager told *Inbound Logistics*, "in the regional distribution center, forward stocking locations, the logistics service provider's warehouse, the sales reps' car trunks, on consignment in the hospital, and at the sterilization point," referring to the urgent need for device makers to get control of their inventory.

Better inventory management will help not just device makers but hospital administrators as well. According to *Modern Healthcare*, since most hospitals do not have the space to store significant amounts of product, including frequently used "physician preferred instruments," or PPIs, they are increasingly looking to manufacturers to maintain inventory nearby. Inventory issues are exacerbated by the need to store multiple sizes of implantable devices such as hips and knees, which take up significant storage space. A device maker could offer hospitals "just-in-time" delivery of the instrument trays and associated items needed for these procedures, thereby helping to alleviate storage issues.

Warehouse Strategy. As device makers accommodate requests from hospitals and medical facilities to hold inventory, an evaluation of existing warehouse space becomes necessary. Does the manufacturer have the resources needed to give customers the ready access to inventory they need? In most cases, this involves having a facility located in close proximity to the end user, which in this case is the hospital. For smaller device makers, this can present a significant cost burden. An experienced logistics provider will often have access to an established network, which a device maker can tap into to meet its storage needs.

Process Visibility. A manufacturer that has invested in automating equipment and production processes must extend that same appreciation for technology to its supply chain. And its most important investment will be in an integrated system that connects every phase of the process – warehouse/inventory, distribution, transportation, and back-office functions – as a way to gain supply chain visibility.

Supply chain visibility provides businesses with real-time – and accurate – information on all components involved in the production process, including manufacture, shipping, storage, and sales. An obvious and immediate benefit of supply chain visibility is awareness of the exact location of any component or finished device. In addition, manufacturers can avoid the high cost of excess inventory and the associated cost and storage issues.

Regulatory/Customs Strategy. Strong worldwide demand for U.S. devices is certainly a positive for manufacturers, but without a good plan in place for managing the patchwork of customs requirements associated with each market, a manufacturer will be doomed to fail. And keep in mind that regulations can vary not only from country to country but within countries too! A manufacturer must understand the unique customs and regulatory protocols in every market and have resources on the ground to ensure full compliance. Most manufacturers turn to an experienced customs broker or logistics provider who will have the resources necessary to handle this highly technical responsibility.

An Innovative Logistics Provider is Integral to Success

To meet the challenges of today's changing healthcare industry, device manufacturers are turning to qualified logistics providers to assume greater responsibility and develop increasingly out-of-the box, innovative solutions. Today more than ever, logistics partners have a seat at the table and a voice in helping businesses address their supply chain challenges.

An experienced logistics provider will help build a strategy that meets the unique needs of the device industry.

The first step is identifying the right provider. Key considerations to keep in mind when choosing a qualified logistics provider include:

Technology-Based. Technology has changed EVERYTHING when it comes to logistics and transportation solutions. As a result, providers are able to offer solutions that were unthinkable a few years ago. Make sure any potential logistics provider has not only invested in technology – and in regular upgrades – but that it has technology-savvy staff who understand the system, and can ensure maximum benefit.

Wide Scope of Solutions. Are you aware that it is possible to have a ground shipment delivered to Canada faster than some transportation providers' air solutions? This is one example of how innovative logistics providers are thinking out of the box and developing innovative solutions. Today, it is possible to have a "customized-like" solution for almost every shipment. Long gone are the days when a transportation company would offer a single take-it or leave-it approach. Choose a carrier with a menu full of options and an anything-is-possible approach to helping address your company's precise needs.

Distribution Network. Make sure your provider has a distribution network in place that meets your entire coverage needs. If your supply chain includes suppliers or customers in Asia, for example, make sure your provider offers the coverage you need. Or if you are in need of warehouses, you will want a provider with a strong warehouse network that you can use.

Flexibility. You will also want a logistics partner that can be flexible and will adjust service to meet your business's specific needs. If your shipment is especially time sensitive, make sure your carrier offers expedited services. In fact, a growing number of businesses are turning to expedited service to handle their "nonurgent" shipments because of the service's guaranteed delivery promise and high levels of customer service.

Continual Improvement. You will want a partner that constantly monitors your account and looks for new and better service options. Too many logistics partners forget about their customers after the contract is signed, and businesses find themselves locked in to certain service levels, even if a better option becomes available. You want a partner that is invested in your success and offers ongoing recommendations for service improvements.

Customs Expertise. With so many U.S. manufacturers dependent on international suppliers and customers, a company cannot afford to have a shipment held at the border because of missing documentation or some other mistake. Make certain your logistics partner has a proven track record managing the international customs process. A truly experienced provider will ensure shipments arrive at the border with all documentation pre-filed, with the correct tariff classification assigned, with all duties and taxes paid, and with a determination of any free trade benefit eligibility.

Customer Service. A good logistics provider will have staff dedicated to your business, who understand your objectives, and who can advise how best to meet those goals. Equally important is that a customer service representative be easily accessible should something go awry or a last-minute change become necessary.

Conclusion

When Boston-based pediatric neurosurgeon Dr. Ed Smith prepares for an especially difficult surgery, such as removing a tumor or gnarled blood vessel from a child's brain, he takes advantage of a technology breakthrough that is rapidly changing the world of medicine: 3-D printing. As reported in *Wired*, Dr. Smith prints a 3-D version of the child's brain, "tumor and all." He will then spend hours examining the sample, plotting out the exact course he will take in the operating room to tackle the problem. "I can rehearse the surgery as many times as I want," he said, noting that he keeps the printed brain nearby in the operating room for quick reference.

Could anyone have predicted the impact of 3-D printing on the healthcare industry? Possibly not, but millions of patients worldwide have already benefited from what this new technology has made possible. And who can possibly know what the next big thing will be?

Whatever it may be, it's a sure bet that U.S. device makers will be at the forefront, bringing increasingly innovative and helpful products to market. Although the industry is not without challenges, including the need to adapt supply chain best practices to align with industry demands, manufacturers will continue to lead the world in innovation and quality.

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