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Industry Spotlight: Medical Devices

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INDUSTRY SPOTLIGHT:

MEDICAL DEVICES

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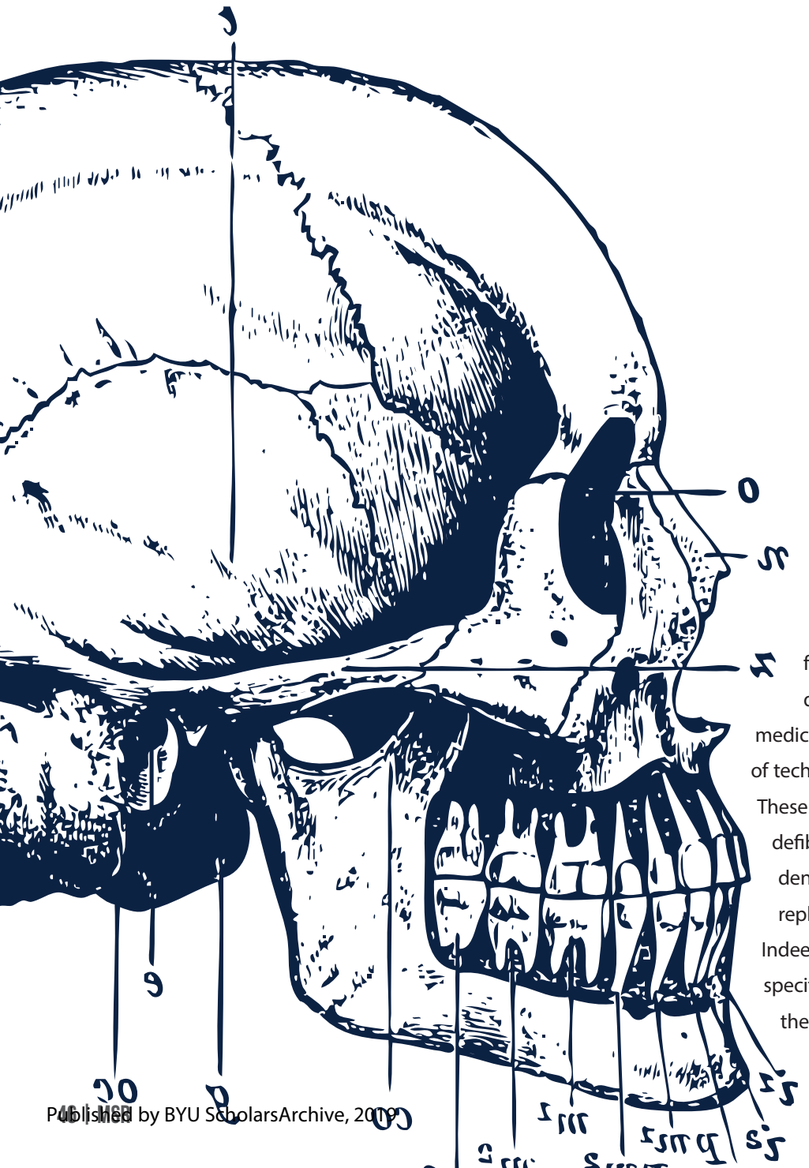

Amid the gamut of human ailments and frailties plaguing the world today, medical devices restore and even redefine health. The medical device industry comprises wide varieties of technologies that repair life and augment living. These range from internal pacemakers to external defibrillators, from full-size wheelchairs to small dental implants, and from individualized knee replacements to institution-wide MRI machines. Indeed, the scope of needs both general and specific supplies an instrumental strength to these companies.

FIGURING OUT HOW TO PRICE AND DISTRIBUTE PRODUCTS WHEN PEOPLE HAVE TO GO THROUGH THIRD PARTIES TO GET THEM BECOMES A CRITICAL PART OF THE BUSINESS MODEL....

Though mortal existence itself would seem to suggest industry stability, the unavoidable nature of illness and injury alone does not guarantee success. In the United States, any aspiring medical device must first clear regulated protocol—mandatory whenever introducing medical devices to the American market or significantly modifying them. This approvals process can be relatively straightforward for simple devices with well-established precedents. A good example of this is bandages, which primarily require only appropriate labeling, registration, and quality standards. However, application stringency quickly rises as devices become more intricately and tightly entwined with our lives. The higher the potential of "risk" a medical device has, the more stipulations are attached. These terms can include the FDA reviewing preliminary clinical data (which itself requires prior approval) before granting pre-market approval or conducting post-market patient surveillance to ensure acceptable outcomes. Specification developers, manufacturers, and exporters are also covered by these procedures, whether they see the device through from start to finish, create replacement parts, or only design products for others to build. Even re-packagers must adhere to these laws (How to Study and Market Your Device).

Once in the market, entrants must deal with a new array of obstacles. This can be as fundamental as how a product can be sold. While our simple example of bandages once again gets an easy, comfortable spot on store shelves everywhere, where do you buy a prosthetic? Which aisle in your local supermarket or even a specialty shop would have implants? In the United States at least, the reality is that many of these medical devices only come to patients by way of medical centers and clinics. That also means insurance. Figuring out how to price and distribute products when people have to go through third parties to get them becomes a critical part of the business model, which is far from a traditional, commercial approach. Managing obstacles like these requires adopting a paradigm different than what many business professionals and students may be used to, but once embraced, the proper mindset sets the stage for navigating this industry's unique challenges.

Successful providers of healthcare solutions fare financially well. Total revenue for the global medical technology market last year was valued at US$405 billion (Evaluate, Global Medtech Revenue), over half of which comes from USA companies (EY, Total Revenues). Chunks to the tune of US$24 billion are passed around for acquisitions like BD's (Becton, Dickinson and Company) of C.R. Bard, Inc. (EY, Major Medtech M&A). The numbers are rising. In 2017, medtech R&D spending experienced 4.7 percent growth worldwide (Evaluate, R&D Spending Growth), an expenditure equivalent to 7.1 percent of these companies' total revenues (Evaluate, R&D as Percent of Revenue) and which is expected to reach US$30 billion

COMPANIES MAY TAKE THE STRATEGY OF POSTPONING ANY PATENT APPLICATION... TO KEEP THOSE RIGHTS OF EXCLUSIVITY FOR THAT MUCH LONGER.

this year (Evaluate, R&D Spending). The top two medical technology companies in the world are Medtronic, Inc., and the Medical Devices & Diagnostics segment of Johnson & Johnson (ProClinical), both based in the US and projected to generate revenues of US$38.9 and US$33.4 billion respectively (Evaluate, Projected Top 10).

Some may wonder whether these large revenues might house hefty profit margins. Remember, though, that such quantities of capital allow for financial security in the face of recalls and lawsuits at worst and for continued R&D at best. Under more typical conditions, a company files a patent to secure the best possible chance for making profits, but all the time spent getting the device approved by the proper agencies whittles away at that short window of opportunity. Assuming there are no problems with the other aspects of commercialization, what may start out as a nominal twenty-year USA patent may drop to only sixteen or ten years of usable time on the market if the innovation is particularly novel (Morton). In such circumstances, companies may take the strategy of postponing any patent application until after a few years of development have proven successful, in effect betting that no one else will file for a similar patent before them in order to keep those rights of exclusivity for that much longer. Looking at the entire process, getting a new device to market from the initial concept averages between three and seven years (Van Norman).

Staying in this lucrative business requires a degree of corporate fitness, maintaining a solid base of dependable products yet also stretching into future developments.

HEALTHCARE IS NO LONGER A GAME OF GETTING HOSPITALS AND CLINICS THE BEST DEVICES AT THE BEST PRICES.

Here, we can expect to find neurally-controlled prosthetics, IoT integrations, and increasing amounts of feedback that provide the data necessary to preemptively repair devices before they fail.

Other devices go so far as to extend beyond natural humanity. The North Sense is one such product, a semi-implanted "exo-sense" offered by Cyborg Nest to grant wearers the sense of magnetic north (The North Sense Experience - Are You In or Out?). The impact of such a device transcends the body's acquisition of additional data, since the brain decides how it functionally interprets the feedback; wearers have reported augmented memory and other heightened sensory experiences (cancerian). And for those who are looking for even more experimental capabilities, a group known as Grinders within the biohacking movement collaborate and explore the unique world of DIY implants. These innovations range from recreational RFID identification chips to echolocation-like proximity detection that can aid blind individuals (Wiltz).

Notwithstanding these new frontiers, the true future of the medical devices industry revolves around people, not technologies. Instead of becoming "the go-to" by amassing a portfolio of top-notch solutions to disparate healthcare problems, the value that medical device suppliers now strive for is a unified, patient-centric experience. Healthcare is no longer a game of getting hospitals and clinics the best devices at the best prices. Rather, success in the field has everything to do with how informed and in-control your typical customer feels. Michael Brown, VP of National Healthcare Systems at Agfa HealthCare, described this distinction while speaking with the peer-reviewed publication *Medical Device and Diagnostic Industry*: "The conversation needs to change away from price and into outcomes. . . . Patient information [should talk to one another] in one common area" (Kane). The implications of such an approach are especially critical for those involved in these companies' business decisions. After all, this "value-based" business model is about establishing user-beneficial systems of interconnected services, not star products.

The destiny of the medical device industry lies not in inventing innovations, but rather in integrating them. In creating holistic profiles and interfacing separate devices' observations into one, perhaps the industry will also bring us, each other, and technology naturally into a healthier symbiosis.

Notes

Cancerian. "Cyborg Nest North Sense? Does It Work?" *Biohack.me Web forum*, Biohack.me, 21 July 2017, forum.biohack.me/index.php?p=%2Fdiscussion%2F2083%2Fcyborg-nest-north-sense-does-it-work

Evaluate. "Projected Top 10 Companies by Medical Technology Revenue in 2024 (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/309291/top-ten-medical-technology-companies-by-revenue-prediction/, Accessed Nov 2018

—. "Total Global Medical Technology Revenue from 2011 to 2024 (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/325809/worldwide-medical-technology-revenue/, Accessed Nov 2018

—. "Worldwide Medtech Research and Development Spending as Percent of Medtech Revenue from 2011 to 2024." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/309305/worldwide-medtech-research-and-development-spending-as-percent-of-revenue/, Accessed Nov 2018

—. "Worldwide Research and Development Spending Growth Rate in Medical Technology from 2012 to 2024." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/329054/worldwide-medtech-research-and-development-spending-growth-rate/, Accessed Nov 2018

—. "Worldwide Research and Development Spending in Medical Technology from 2011 to 2024 (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/309297/worldwide-medtech-research-and-development-spending/, Accessed Nov 2018

EY. "Selected Top Medtech Mergers and Acquisitions Worldwide in 2016-2017, by Value (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/277638/major-medtech-merger-and-acquisitions-by-value/, Accessed Nov 2018

—. "Total Revenues of U.S. and European Medical Technology Companies from 2009 to 2016 (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/276293/total-revenues-of-american-and-european-medical-technology-companies/, Accessed Nov 2018

"How to Study and Market Your Device." *U S Food and Drug Administration Home Page,* Center for Devices and Radiological Health, Mar 2018, www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm2005301.htm

Kane, Corrina. "Prepping for Value-Based Care in the Medtech Space." *MDDI Online,* Medical Device and Diagnostic Industry, 3 Oct 2018, www.mddionline.com/prepping-value-based-care-medtech-space

Morton, Janice. "How to Protect Your Medical Patents Worldwide." *MedTech Engine,* Medeuronet, 14 Apr 2016, medtechengine.com/article/medical-patents/

ProClinical. "Top 10 Medical Technology Companies Worldwide Based on Revenue in 2017 (in Billion U.S. Dollars)." *Statista - The Statistics Portal,* Statista, www.statista.com/statistics/281544/revenue-of-global-top-medical-technology-companies/, Accessed Nov 2018

"The North Sense Experience - Are You In or Out?" *Cyborg Nest*, Cyborg Nest LTD, 2018, cyborgnest.net/pages/steps

Van Norman, Gail A. "Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices." *ScienceDirect,* Elsevier, 27 Jun 2016, www.sciencedirect.com/science/article/pii/S2452302X16300183

Wiltz, Chris. "On the Grind: The World of Do-It-Yourself Implants." *MDDI Online*, Medical Device and Diagnostic Industry, 7 Aug 2017, www.mddionline.com/grind-world-do-it-yourself-implants

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