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# The End of NAFTA and a Future for Companies in the Medical Device

## Industry

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In 1994, the North American Free Trade Agreement (NAFTA) created one of the world's largest free trade zones and established the foundation for economic growth and increased prosperity for Canada, the United States, and Mexico. This essay sets out to examine how proposed changes to NAFTA could affect the Medical Device Industry.<sup>1</sup> In recent weeks, U.S. President Donald Trump has threatened to scrap NAFTA or limit the number of economic sectors that "free trade" with Canada and Mexico could encompass. Were this to happen, the medical device industry could be impacted in both positive and negative ways. These possible changes create positive impacts for both Canada and Mexico. Most of the possibly negative changes directly impact the United States. Our research analyzes external environmental factors and the industry as a whole. We look at how the proposed changes could affect three major companies operating in the NAFTA region: GE Healthcare, Johnson & Johnson,

and Medtronic. Through our research, we are able to generate potential strategies for each of these companies should the possible changes to NAFTA occur.

While studying the impact of the potential changes of NAFTA in regard to the Medical Device Industry, we first need to learn about how the industry is currently doing and how potential changes proposed could affect the industry. Our research of the Medical Device Industry uses a strategic audit approach to analyze and make recommendations to the top three companies in the NAFTA region. Were NAFTA to be scrapped or severely limited, there are a number of likely impacts on the Medical Device Industry in the United States. First, Mexico and Canada could retaliate by imposing restrictions on United States products that currently have favorable trade terms and high sales volume. Second, there is the potential for a lower trade deficit between Mexico and Canada. Third, scrapping NAFTA might bring about an end to the Value-added Tax (VAT). The VAT is a type of general consumption tax that is added incrementally throughout each stage of production or distribution. This would increase profit margins for many companies, including those in medical device production. Lastly, there could be more complications involved when American-owned factories stationed in Mexico are moved back to the United States (Varney, 2017).

### *Context*

Our research includes an assessment of the industry as a whole within the NAFTA countries, its top sectors, top trends, and the current performance of GE Healthcare, Johnson & Johnson and Medtronic. We also use Porter's Five Forces, a tool to analyze the competition of businesses, to assess the Medical Device Industry. It

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<sup>1</sup> Editors' note. This essay was written in early Spring 2018, months before the October 2018 conclusion of negotiations resulting in the United States-Mexico-Canada Trade Agreement (USMCA), the successor to the North American Free Trade Agreement (NAFTA). This scholarship provides scholarly insight into the subject that was available at that moment.

**Figure 1: Basic Facts about Healthcare in NAFTA's Three Countries**

	<b>Canada</b>	<b>Mexico</b>	<b>United States</b>
Population	35,099,836	121,736,809	321,368,864
Total Healthcare Spending	\$186 Billion	\$82 Billion	\$3 Trillion
Healthcare expenditures total (% of GDP)	10.4%	6.3%	17.1%
Healthcare expenditures per capita	\$5,292 USD	\$677 USD	\$9,403 USD
Expenditures on healthcare	Gov't 71%, Private 29%	Gov't 52%, Private 48%	Gov't 48%, Private 52%
Size of medical device market	\$6.2 Billion USD	\$5 Billion USD	\$147.7 Billion USD

is a five-force model that determines the competitive intensity or attractiveness of a company in regard to its profitability. Figure 1 details some basic facts about the medical device industry within Canada, Mexico and the United States. The US dollar is very strong and constitutes one of the reasons why the medical device market is on the rise. However, the strong dollar creates challenges for American device manufacturers exporting to markets with weaker currencies (Corpart, 2018). Comparing the NAFTA countries gives a deeper understanding of how each country values healthcare and the medical device industry.

The *Frost & Sullivan* website provides a complete 2017 snapshot of the Medical Device Industry. According to it, the top five sectors of 2017 were: structural heart, robotics and robot assistance, neuro-devices, integrated patient monitoring devices, and diabetes care. Some of the top technology trends relate

directly to the top sectors, such as the revolution of diabetes care, surgical robots, and devices that connect cars and trucks with health sensors. Health sensors placed on the steering wheels of cars can detect heart attacks, seizures and other health conditions that could happen while driving (though this device is still in the early development stage). With innovation in medical devices, though, there are always some unexpected issues that occur. In 2017, some of the concerns raised by innovation in the medical device industry included those concerning a restrictive regulatory environment, the speed of technology, the ability to raise capital to fund innovations and the changes in customer behavior and demands. The medical industry is constantly changing and it is extremely difficult to make sure that products and devices are reliable. In 2017, there was also a transformation in the medical device industry ecosystem. Companies in this sector developed a connected

ecosystem of sensors and devices that are readily available to individuals and that serve the functions of identifying, capturing and measuring health data, stratifying risks, informing patients of conditions, and helping them and their physicians to make decisions and take action. These sensors and devices can be placed on an individual's body, in their homes, in community centers, in clinics and, of course, in hospitals (*Frost & Sullivan*, 2017). These sensors are extremely important for innovation for consumers, such as those with diabetes, who use them multiple times a day to check blood sugar levels. The medical device industry is constantly changing and evolving with new technologies. These changes can be seen in the current performances of the companies Medtronic, Johnson & Johnson, and GE Healthcare.

### ***Medtronic***

Medtronic is a Global Healthcare and Medical Device company located in Mansfield, Massachusetts. Medtronic's mission statement claims that its first priority is "to contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life" (Medtronic). Medtronic is growing innovation in the area of biomedical engineering. In 2017, it invested more than \$2 Billion in research and development, which represented 7.4% of the company's net sales that year. Medtronic also launched labs to bring about new initiatives to deliver financially sustainable businesses that expand access and reduce health inequality in emerging countries (Vivanco, 2017). Medtronic was a very charitable company in 2017. It donated more than \$101 million to charitable causes in corporate cash contributions given through the Medtronic Foundation, in product donations and through employee

volunteering. The four main product and service focuses of Medtronic are cardiac and vascular afflictions, restorative therapies, diabetes, and minimally invasive therapies.

### ***Johnson & Johnson***

Johnson & Johnson is the world's largest independent biotech company with a market cap of \$343.8 Billion. A manufacturer of medical devices, pharmaceutical and consumer packaged goods, it is an American multinational company that was founded in 1886, with its headquarters in New Brunswick, New Jersey. In the third quarter of 2017, Johnson & Johnson's revenue in its medical device section was a little more than \$19,650 Million. In Johnson & Johnson's medical device section, the main products they focus on involve general surgery, energy science, endocutters, biosurgery, infection prevention and wound closure. Medical device sales account for 35% of the company's value. As a company that has been around for more than 100 years, Johnson & Johnson has been and will continue to be a leader of innovation in the medical field. By 2024, the company's forecasting predicts that its revenue will be around \$29 Billion. (Johnson & Johnson - Medical Device). Johnson & Johnson's future growth concerns include changing healthcare needs for an aging population, changing dynamics in the women's health market, price regulation, and developing minimally invasive surgery procedures to reduce infections. Johnson & Johnson continues to be the world's leader of innovation among biotech companies.

### ***GE Healthcare***

GE Healthcare is a sector of GE Capital, whose parent company is General Electric (GE). GE Healthcare offers transformational medical technologies and services that

are shaping a new age of patient care (GE Healthcare). In the third quarter of 2017, GE Healthcare had revenue of \$4.724 Billion, with the medical device segment recording a profit of \$820 Million. The operation profit of the third quarter of 2017 was 17.4%. GE Healthcare's main product categories include accessories and supplies, the GE Health Cloud, bone and metabolic health, advanced visualization, computed tomography, clinical consumables, applied intelligence and anesthesia delivery. The GE Health Cloud is "designed to be a scalable, secure, connected and interoperable platform, delivering the largest application ecosystem for the healthcare industry" (GE Health Cloud). It is capable of being connected to more than 500,000 GE medical imaging machines and more than 1.5 million imaging machines worldwide. GE Healthcare is making strides in cloud technology to make the healthcare and medical world more interconnected.

### ***Porter's Five Forces***

The health of the medical device industry can be gauged using Porter's Five Forces, a common methodology that guides analysis of an industry and the competitors within it. Porter's Five Forces are the threat of new entrants, rivalry among existing firms, the availability of substitutes, bargaining power among buyers, and bargaining power among suppliers. Under the first force, threat of new entrants, we find that it is extremely difficult for new companies to enter this industry due to high barriers from strict government regulations. The industry is also dominated by a few large and top companies who have strong brand images and long-term reputations. Barriers to entry include strict regulations by the U.S. Food and Drug Administration (FDA), such as approvals, requirements, and registrations, as well as copyrights and patents. One scholar explains

the barriers of entry: "There are strict medical device regulations for product approval by the FDA, which include establishment registration, medical device listing, PMA (501) K or premarket approval, investigational device exemption (IDE) for clinical studies, quality system regulation, labeling requirements and medical device reporting (MDR). Couple this with the need for copyrights and patents and the barrier rises even higher to enter this industry" (UKEssays, 2017).

In regard to the second force, rivalry amongst existing firms, there are eight major competitors in this industry. They are Medtronic, Abbott Laboratories, Johnson & Johnson, GE Healthcare, Tyco International, Boston Scientific, Welch Allyn, and Siemens. The medical device industry is rapidly growing and constantly changing as a result of new innovations in healthcare and technology. Products in this industry are typically items found in hospitals, doctors' offices, emergency rooms, and other healthcare facilities. These include items such as X-Ray machines, MRI machines, beds, monitors, cardiac devices such as pacemakers, internal cameras, IV bags, and more. These products also have high fixed costs associated with them. The third force is substitute products. There are no substitutes for these products as they are very specific and cannot conceivably be replaced. The threat of new substitutes, as a result, is very low.

The fourth and fifth forces are the bargaining power of buyers and suppliers, respectively. First, buyers: quite simply, they do not have the ability to force down prices. Hospitals and doctors' offices may be able to get deals or discounts when making bulk/large or frequent purchases. Alternative suppliers exist in competitors outside of the United States in Mexico and Canada. The importance of these products to the

buyers is evident: these medical devices save and improve lives. The bargaining power of suppliers is different; they *can* affect the industry with their ability to raise prices. They can also contribute to making healthcare more expensive. As stated before, the industry is dominated by a few companies. Of the eight competitors, the top ones are GE Healthcare, Johnson & Johnson, Medtronic, Siemens, and Boston Scientific. Their products have unique characteristics and are unique themselves. Some examples of these products are artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves, wheelchairs, anesthesia apparatus, orthopedic instruments, optical diagnostic apparatus, blood transfusion devices, syringes, hypodermic needles, and catheters.

### ***Methodology***

Data on how these companies and products might fare with the end of NAFTA can be organized into two tables. The first of these is our External Factors Analysis Summary (EFAS) table. The second table is our Industry Matrix Analysis. These two tables are crucial for planning strategies for the three companies we focus on here: GE Healthcare, Johnson & Johnson and Medtronic. By utilization of these tables, we can come to some useful conclusions.

The External Factors Analysis table acts as a means to track the external factors within an industry. Prospective changes to NAFTA pose many possible risks and opportunities for the healthcare industry. The EFAS table helps clarify these opportunities and threats. Our research relied on news of the current renegotiations of NAFTA through news sites and online newspapers (Harwood, 2017). During this research, it was difficult

to indicate which possible outcomes could occur because the negotiations changed pace so quickly and often (Heath). The EFAS table lists the opportunities and threats that came with each possible change, and how it would affect the healthcare and medical device industry as a whole.

Opportunities refer to the advantages that would come with specific changes within NAFTA. Here, we found five important advantages that would directly impact the healthcare and medical device industry. Opportunities included lowering the trade deficit between the US and Mexico and getting rid of the VAT (Harwood, 2017). Threats act as negative effects that would hurt the current environment of the healthcare and medical device industry. Here, we found five threats, including the end of the Maquiladora program and the end of resolution panels (Harwood, 2017). These two direct elements could affect the medical device industry, causing devices sold outside the United States to be much more expensive. Given that a large amount of manufacturing for medical devices is done in Mexico, these two threats would increase the cost of manufacturing these products and in turn cause them to be more expensive for leading healthcare companies.

The second table is the industry matrix table, which allows us to organize our findings but also to narrow down specifics to individual companies within the United States, namely Medtronic, Johnson & Johnson, and GE Healthcare. The industry matrix lists the key success factors needed in order for each of these companies to achieve success in the healthcare industry. However, each company takes these success factors and prioritizes them differently. By using the matrix table we are able to show how GE Healthcare, Johnson & Johnson, and Medtronic rank each of these success

**Figure 2: External Factors Analysis**

External Factors	Weights	Rates	Comments
<b>Opportunities:</b>			
Lower trade deficit between US and Mexico	0.05	4	Lowers deficit with Mexico
Get rid of VAT Tax	0.05	3	Gets rid of added tax
Eliminate unfair subsidies	0.1	5	Eliminates extra subsidies for healthcare
Opportunity to impose tariffs without permission to congress	0.05	2	Allows tariffs to be added without the approval of Congress
Mexico develops internal healthcare	0.2	1.5	Mexico to develops their own healthcare
<b>Threats:</b>			
End of Maquiladora program	0.05	1	Ends the permit that allows Mexico to import duty free
Update rule of origin	0.1	3	Ends the advice and discussion between FDA and medical device sponsors
End of resolution panel	0.1	2	Medical devices from Mexico would become more expensive
Medical devices from Mexico more expensive	0.25	3	
Potential loss of jobs/work	0.05	2.5	
<b>Total:</b>	1.00		

**Figure 3: Industry Matrix Table**

Key Success Factors	Weight	Medtronic		Johnson & Johnson		GE Healthcare	
		Weighted Score	Rating	Weighted Score	Rating	Weighted Score	Rating
Innovation	0.2	1	5	0.8	4	1	5
FDA Approval	0.16	0.8	5	0.8	5	0.8	5
Product Development	0.1	0.4	4	0.3	3	0.5	5
Reliable Products	0.15	0.6	4	0.6	4	0.6	4
Top Service Maintenance	0.12	0.36	3	0.6	5	0.48	4
Sales and Marketing Effectiveness	0.08	0.4	5	0.24	3	0.32	4
Product Lifecycle Management	0.13	0.52	4	0.52	4	0.52	4
Reputation	0.06	0.3	5	0.3	5	0.18	3
<b>Total:</b>	<b>1</b>						

factors. This allows an overview of each company and illustrates the main focuses of each leading healthcare company. For example, by looking at the first key success factor it, is clear that Medtronic and GE Healthcare list innovation higher than Johnson & Johnson does (GE Healthcare). At the same time, Johnson & Johnson ranks service maintenance higher than both Medtronic and GE Healthcare (Johnson & Johnson). This shows that each company has different focuses and relies on different key success factors in order to achieve success.

### *Findings*

Based upon the information presented in the external factor analysis summary and industry matrix analysis, we can devise strategies for the three companies mentioned above, both generally and in relation to possible changes in NAFTA. For GE Healthcare, capitalizing on innovation is paramount in importance given the company's goals noted in the industry matrix. It ranked innovation as one of its top success factors and therefore would be focusing on it in the future (GE Healthcare). However, due to possible changes in NAFTA, GE's focus on innovation may prove costly. Mexico manufactures a large amount of medical devices for these three companies and if any of the threats listed in the EFAS table occur, innovative technology will not be cheap. In light of this, making operations more efficient through automation will be useful should the outsourcing of manufacturing result in increased costs. Overall, GE Healthcare should continue to pursue innovation in medical devices, especially in image archiving and cloud visualization tools. Outsourcing and operation of devices could become more expensive for factories in Mexico, and therefore the company should work on ways to make the operation process more efficient by using automated robotics.

In contrast, Medtronic should continue to focus its efforts on charity in order to improve the company's reputation (Medtronic, 2016). By increasing its focus on charity events and building a better reputation, consumers will be more likely to trust and use Medtronic healthcare and services. This type of company strategy will bring more popular favor toward it and set it apart from its competitors. Like GE Healthcare, innovation is also important to Medtronic and, because of that, automation is also a key factor in Medtronic's future success. Building the company's reputation will also cultivate more trust from consumers. This will in the long run build clientele and give the company a competitive edge. Finally, Medtronic should also focus on automated manufacturing and increase research in its diabetes group, since that is its lowest profit group within the company. These key goals will allow Medtronic to continue to flourish, even after the NAFTA negotiations are complete.

Lastly, Johnson & Johnson should focus on its work in the field of minimally invasive surgery (or MIS) procedures (Johnson & Johnson). Evidence from Johnson & Johnson shows that innovation within the medical device field is not as important to the company's focus as it is to GE Healthcare and Medtronic. Instead, Johnson & Johnson shows more interest in alternate forms of innovation, including those that aim to reduce infection rates. Emphasis on these procedures will set the company apart from its competitors. Due to possible changes from the NAFTA negotiations related to manufacturing, Johnson & Johnson's focus on innovative procedures minimizes the need for reconfiguring its business model. These require little need for outsourcing manufacturing which may become more expensive as a result of NAFTA's renegotiation. MIS procedures are also expected to be at a higher demand than they are



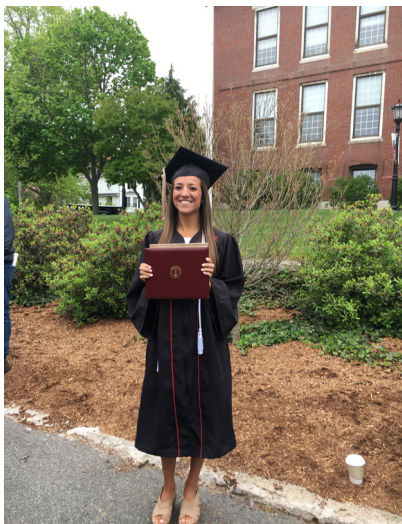
currently, which will mean a competitive advantage for Johnson & Johnson over its leading competitors.

### ***Conclusion***

The goal of this research project has been to analyze the medical device industry and its ties to NAFTA. It describes the context, business focuses and prospects for three top companies in the medical device industry: GE Healthcare, Johnson & Johnson, and Medtronic, and considers how the scenario of the Trump Administration pulling the U.S. out of the trade agreement would affect each one. Our study identifies strategies that each of the companies could implement if the Trump administration were to pull the United States out of the North American Free Trade Agreement. While Medtronic's focus on charity is a great way to improve its reputation, the company should also increase research in its diabetes group since that is its lowest profit group. GE Healthcare should continue to increase innovation in medical devices, especially in image archiving and cloud visualization tools. Outsourcing and operation of devices could become more expensive for factories in Mexico, so the company should work on ways to make the operation process more efficient with automation by using robotics. Finally, Johnson & Johnson should continue to focus its efforts on innovation in minimally invasive surgeries (MIS) as well as other Healthcare services. MIS procedures are expected to be at a higher demand than they are currently, and this strategy would give Johnson & Johnson an advantage over its competitors.



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