A policy analysis to inform options for medical device regulation and post-market surveillance in the Canadian context.

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Executive Summary

With ageing populations and rising rates of chronic diseases, medical devices are increasingly vital components of health care. From tongue depressors and stethoscopes to pacemakers and medical robotics, medical devices are numerous, diverse and constantly evolving, integrating medicine, biomechanics, materials, software, and electronics in their development and application (Chen et al., 2018). However, while innovation is generally beneficial for patients, the complexity and diversity of medical devices poses a challenge for regulatory systems across the globe, which are often slow to adapt to the increasing complexity of medical devices, unpredictable risks, and emerging threats to public health (Curfman and Redberg, 2011; Mishra, 2017; Chen et al., 2018). Consequently, with medical device failures and malfunctions appearing in media and academic journals there is a global push for stricter regulatory reform and harmonization of regulatory frameworks internationally (Curfman and Redberg, 2011; Altenstetter, 2012; Maak & Wylie, 2016; Chen et al., 2018). This capstone will review and compare the regulatory frameworks for three jurisdictions (Canada, the United States and the European Union) with an aim of identifying post-market strategies which could be applicable to the Canadian context. Additionally the current and proposed changes to the Canadian medical device regulations will be discussed and analysed across multiple dimensions (burdens on various actors, innovation vs regulatory oversight and health risk protection) and, the 3-I framework will be used to deepen the understanding behind the shift in regulatory approach that Health Canada is working to implement. Lastly, based on the regulatory approaches compared and analysed it will provide an informed opinion on the approach that Health Canada is taking.

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Introduction

With ageing populations and rising rates of chronic diseases, medical devices are increasingly vital components of health care. From tongue depressors and stethoscopes to pacemakers and medical robotics, medical devices are numerous, diverse and constantly evolving, integrating medicine, biomechanics, materials engineering, software and electronics in their development and application (Chen et al., 2018). These characteristics are essential, particularly for implantable and invasive devices (like artificial joints, pacemakers and defibrillators), to meet the changing and dynamic needs of patients (Curfman and Redberg, 2011). However, while innovation is generally beneficial for patients, the complexity and diversity of medical devices poses a challenge for regulatory systems across the globe which are relatively new and slow to adapt to the increasing complexity of medical devices, unpredictable risks, and emerging threats to public health (Curfman and Redberg, 2011; Mishra, 2017; Chen et al., 2018). Consequently, with medical device malfunctions appearing in media and academic journals there is increasing momentum for stricter regulatory reform and harmonization of regulatory frameworks across jurisdictions to promote the use of medical device across jurisdictions and align regulatory frameworks with each other (Curfman and Redberg, 2011; Altenstetter, 2012; Maak & Wylie, 2016; Chen et al., 2018).

Purpose

In Canada, medical device regulation has become a priority for the Health Minister and policy advisors at Health Canada after mounting reports of injuries and devices being pulled off the market in other jurisdictions (Government of Canada, 2018). This offers an opportunity to consider the current regulations and analyse the proposed future state of the Canadian medical device regulatory framework. Thus, the purpose of this capstone is to compare and critically review regulatory approaches form comparable regulatory frameworks and provide an informed opinion of the approach that Health Canada is taking. Specifically, this capstone will:

1. review the development of medical device regulatory frameworks in Canada, the United States and the European Union,
2. compare medical device regulatory frameworks across the three jurisdictions,
3. review and compare the current and proposed changes that the Canadian Government is making to their regulations,
4. analyse the proposed changes to the Canadian regulations on their burden on industry, the health care system and patients, promotion of innovation, health risk protection and regulatory oversight, and
5. apply the 3-I framework to deepen our understanding the movement underlying the future state of the Canadian *Medical Device Regulations*.

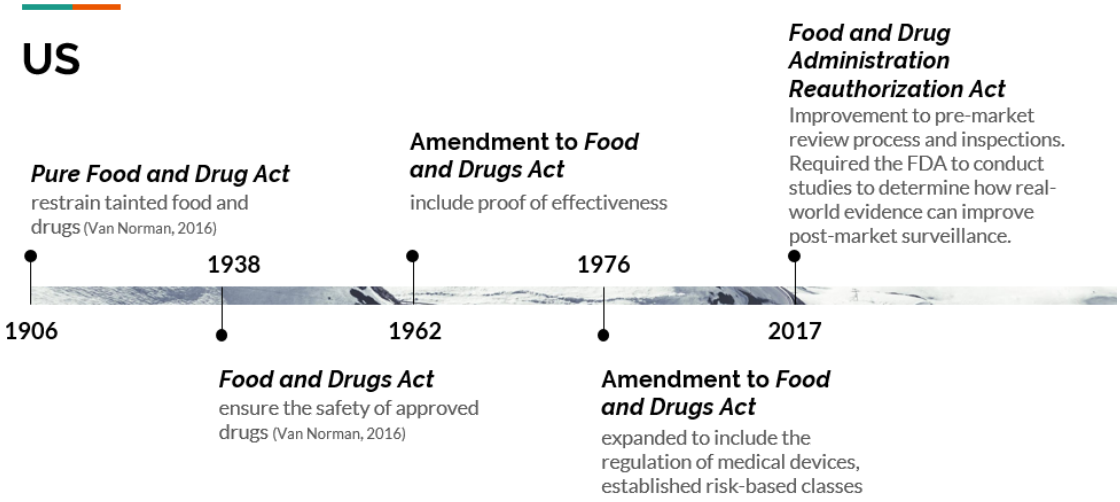
Information on the regulations of the different jurisdictions discussed in this capstone were found online on the respective government websites, regulations, and guidance documents. Internet searches were conducted on each jurisdiction for further information on supporting guidelines and policy interpretation. Grey literature was initially used to identify relevant articles and narrow down the focus of this capstone.

Background

Historical Context of Medical Device Regulations in the US, EU & Canada

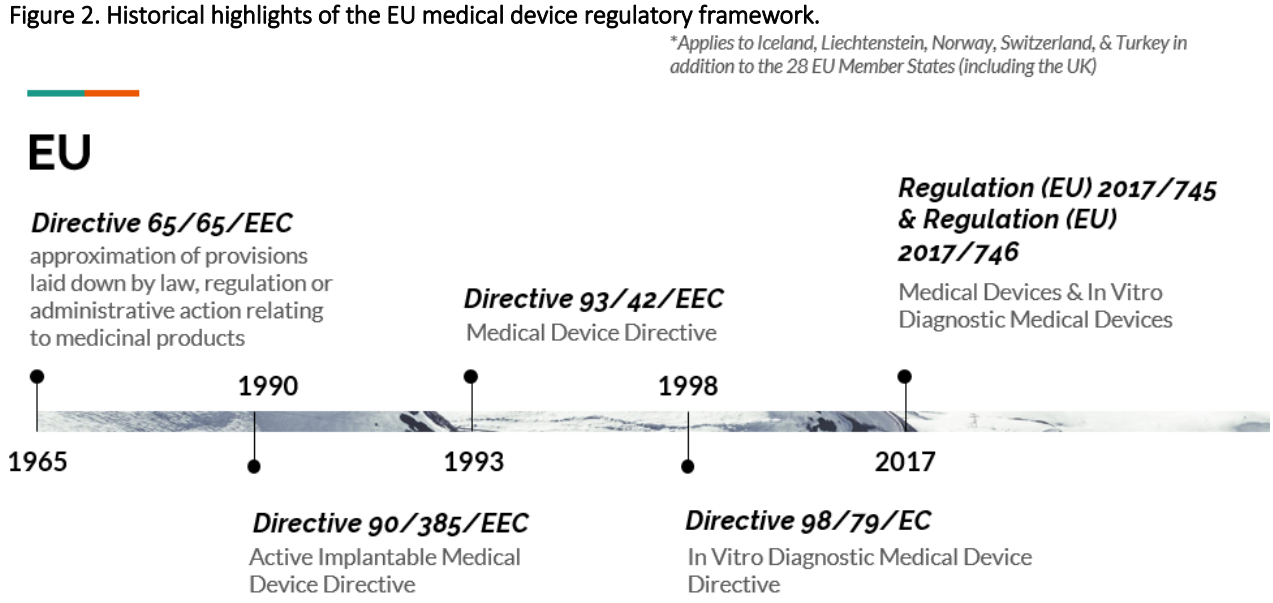
Medical device regulations are a relatively recent development (Mishra, 2017), but build on a longer history of regulation of pharmaceutical products. In the US, the evolution of the current *Food, Drug, and Cosmetics Act* begun with the *Pure Food and Drug Act* in 1906 which was created to restrain tainted food and drugs (Figure 1) (Van Norman, 2016). The *Food and Drugs Act* replaced the *Pure Food and Drug Act* in 1938 to ensure the safety of approved drugs (Van Norman, 2016). Responding to the thalidomide tragedy of the 1960s, regulatory agencies (including Canada, United States and European Union) had to improve the level of oversight and robustness of their regulations (Mishra, 2017). The US *Food and Drugs Act* was amended in 1962 to include proof of effectiveness, and then expanded to include the regulation of medical devices in 1976 and amended with the Medical Device User Fee and Modernization Act in 2002 (Van Norman, 2016; Van Norman, 2016). The Medical Device Amendments of 1976 established the classification system which includes three risk-based classes (based on the extent of regulatory oversight needed for safe and effective devices) ranging from class I (lowest risk) to class III (highest risk) which is still in place today (FDA, 2019).

Figure 1. Historical highlights of the US medical device regulatory framework.



In Europe, standardization of drug regulations preceded the formation of the EU with EC Directive 65/65/EEC in 1965 (Figure 2) (Van Norman, 2016). This is in contrast to medical devices where regulation was in in the hands of the Member States until the mid-1990s, leading to barriers for distribution. The introduction of three Directives (Active Implantable Medical Device Directive, Medical Device Directive, and In Vitro Diagnostic Medical Device Directive) in the 1990s established the Medical Device Directive and initiated the regulation of safety and marketing of medical devices (French-Mowat & Burnett, 2012; Van Norman, 2016; Mishra, 2017). In 2017, major updates to the EU medical device regulations were introduced and will be discussed further in the coming sections (Migliore, 2017).

Figure 2. Historical highlights of the EU medical device regulatory framework.

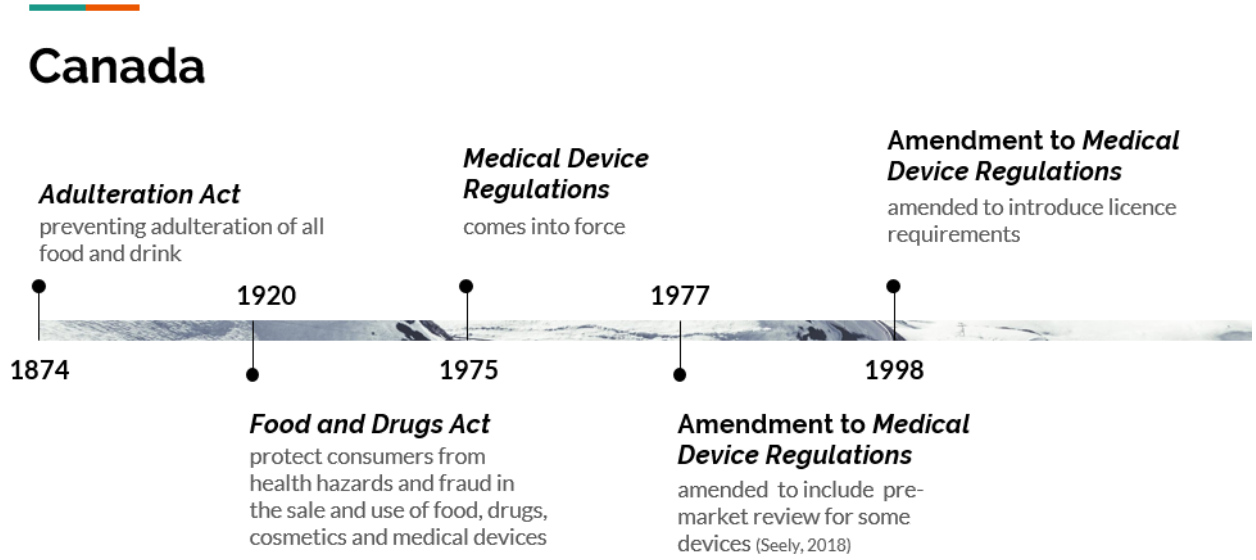


In Canada, succeeding the 1874 *Adulteration Act,* the current *Food and Drugs Act* was first introduced in 1920 with amendments made in 1949, 1951, and 1985 (Figure 3) ("Canada's new food and drugs act", 1953; Mishra, 2017). It is not clear how these amendments affected the regulatory oversight of medical devices but, generally, the amendments organized the legislation in an orderly fashion; allowing for food, cosmetics, drugs and devices to be handled individually ("Canada's new food and drugs act", 1953, Mishra, 2017). Along with the *Food and Drugs Act*, the

Medical Device Regulations were first introduced in 1975 and updated in 1998, expanding pre- and post-market aspects of the Canadian regulatory framework (Boyer, 2015).

Prior to the 1998 amendments, only a small fraction (five per cent) of medical devices were required to undergo pre-market review; the requirements for which remained static and lacked the foresight and adaptability needed to regulate new technology and devices introduced over time (Boyer, 2015). This meant that the large majority of devices (95 per cent) were introduced to the Canadian market without pre-market review. Health Canada required post-market notification within 10 days of the first sale for all new devices (Boyer, 2015). The results of this (lack of) regulatory system was that Health Canada did not have an accurate view of the devices being sold in Canada (Boyer, 2015). It should be noted that requirements for Good Manufacturing Practices and Quality Management Systems were also not put in place (Boyer, 2015). Thus, the 1998 amendments were needed to ensure that Health Canada had improved (both pre- and post-market) regulatory oversight over the sale of medical devices in Canada, their advertising, and sale to Canadians (Boyer, 2015). The 1998 amendment also introduced Good Manufacturing Practices and Quality Management System requirements along with licensing requirements for manufactures (Boyer, 2015).

Figure 3. Historical highlights of the Canadian medical device regulatory framework.



The Medical Device Market

Globally in 2016, the top segments of the global medical device market were diagnostic imaging (e.g. MRI and CT) and consumables (e.g. syringes, needles, sutures, adhesives, etc.) which made up 25 per cent and 16 per cent respectively (Government of Canada, 2017). These were followed by orthopaedic products and patient aids (e.g. hearing aids and pacemakers) (12 per cent each), dental products (seven per cent) and other medical equipment (27 per cent) (Government of Canada, 2017). It is expected that the medical device market will grow globally with rapid growth expected in the Asian market compared to the Americas and Western Europe (Government of Canada, 2017). As mentioned previously, a contributing factor to explain the growth in the coming years will be due to aging populations in addition to new forms and uses of technology, software and data (Government of Canada, 2017).

In Canada, the market share was estimated to be around two per cent of the global market ($6.7 billion USD) in 2016 (Government of Canada, 2017). The top segments of the Canadian medical device market (as a percentage of the total sales in 2016) were diagnostic imaging, consumables, and patient aids which accounted for 21 per cent, 18 per cent, and 15 per cent respectively (Government of Canada, 2017). These were followed by orthopaedic and prosthetic products (12 per cent), dental products (eight per cent) and other medical devices (27 per cent) (Government of Canada, 2017).

Global Landscape of Medical Device Regulations

Before considering the Canadian regulatory framework, it is important to understand the players and differing levels of influence on the global landscape of medical device regulations. Globally, the US and EU make up the majority of the medical device market share with 51 and 30 per cent respectively (Altenstetter, 2012). The implications of this is that the EU and US have a great deal of influence over the global landscape of medical device development and regulation.

The power that these jurisdictions have can be observed in the literature, where a majority of papers focus on the EU and US contexts. In the reform of the Canadian regulations a key consideration is alignment between the Canadian regulations and US and EU regulatory agencies.

Furthermore, it is also important to consider the other players that comprise the medical-industrial complex (Altenstetter, 2012). While one group is the regulatory authority (e.g. Health Canada, the US Food and Drug Administration, etc.) the other group comprises the medical-technology industry and medical device companies (Altenstetter, 2012). Their influence is reinforced by trade associations (Altenstetter, 2012). The third group is made up of scientific and industry experts. Each group of the medical-industrial complex plays a role in navigating and resolving issues within regulatory frameworks at national, regional and international levels (Altenstetter, 2012).

Jurisdictional Comparison of Medical Device Regulatory Frameworks The US & EU Contexts

The US Context

In the US, medical devices are regulated by the Center for Devices and Radiological Health of the FDA through the Federal Food, Drug and Cosmetic Act which covers everything from pre-market approval to post-market surveillance (Table 1) (Maak & Wylie, 2016; Chen et al., 2018). Additionally, with a risk-based classification system, medical devices are categorized into three classes (I, II, and III) with class III being the highest risk category (Chen et al., 2018). In order to meet the requirements of the *Quality System Regulations*, manufacturers are required to follow Good Manufacturing Practices (Chen et al., 2018).

Table 1. Comparison of Medical Device Regulations for Canada, EU and the US

		European Union	**United States**	**Canada**
Competent Authority		Pre-market: Notified bodies Post-market: National competent authorities	Food and Drugs Administration (FDA)	Health Canada (HC)
Classification System		Risk-based	Risk-based	Risk-based
Classification		Class I, IIa, IIb & III	Class I, II & III	Class I, II, III & IV
Pre-market Review	Application	Self-declaration: some Class I Technical construction file & Quality Management System: Class Is, Im, IIa, IIb & III	510(k) – most Class II devices PMA: most Class III devices	Medical device license required for Classes II - IV
	(Application) User Fees	Yes	Yes	Yes
	License validity	5 years	1 year (Establishment Registration)	1 year
Post-market Surveillance (Manufacturer)	Report of a serious public health threat	Within 2 days	Within 5 days	*Not a requirement*
	Report of deaths, serious injuries	Within 10 days	Within 30 days	Within 10 days
	Other	Within 30 days	Within 30 days	Within 30 days

In the US from the pre-market side, the most common submissions fall under the Premarket Notification 501(k) (referred to simply as 501(k)) and Premarket Approval (PMA) (Chen et al., 2018). In order to qualify for the 501(k) pathway, devices have to be substantially equivalent to devices currently on the market (referred to as a predicate device in the literature) (Maak & Wylie, 2016; Chen et al., 2018). Devices that use the 501(k) pathway could have modifications or changes in the material, chemical composition, design, energy source, manufacturing process or intended use (FDA, 2018). On the other hand, a PMA review requires manufacturers to demonstrate safety and effectiveness, compared against a control, through technical documents, preclinical laboratory studies, and clinical investigations (Maak & Wylie, 2016; Chen et al., 2018). This makes the PMA route is the strictest path for devices to gain approval and is required for all class III devices. The distinction between 501(k) and PMA leads to a small but important distinction: a difference between devices that are cleared vs approved; while devices that utilize the 501(k) route are cleared, they are not approved (FDA, 2018). It is also important to note that the pre-market review requires manufacturers to pay the FDA to review their application. Referred to as "user fees", they vary depending on the type of application (e.g. 510(k) and PMA have different costs associated with them) (FDA, 2019).

From the post-market perspective there are many ways through which devices are monitored. The FDA uses tracking systems, annual Establishment Registration (of where devices are manufactured or distributed for manufacturers), mandatory reporting of device malfunctions, serious injuries and deaths for manufacturers along with voluntary reporting of adverse events from patients and healthcare facilities in order to ensure that the devices on the market are safe for the public (Chen et al., 2018; FDA, 2018). In addition, post-market surveillance studies are required for life-sustaining/supporting devices, implanted devices, devices used for pediatrics, or devices that would cause serious adverse events if they failed or malfunctioned which were

granted approval through the PMA route (Chen et al., 2018). Additionally, manufacturers have to notify the FDA of reports of serious public health threats within five days, reports of deaths or serious injuries and others (device malfunctions) within 30 days (Table 1) (Chen et al., 2018; 21CFR803, 2018).

The EU Context

Rather than a central agency being in charge of overseeing medical device regulations, the EU uses a decentralized system of notified bodies and national competent authorities (Table 1) (Maak & Wylie, 2016; Chen et al., 2018). Notified bodies are private, for-profit, companies that are certified by the EU which oversee pre-market approval while the national competent authorities (which are government agencies in each Member State) oversee post-market surveillance (Maak & Wylie, 2016; Chen et al., 2018). It should be noted that the competent authorities (of each European Member State) appoint the notified bodies to ensure that procedures are completed in accordance with the Directives (Active Implantable Medical Device Directive, Medical Device Directive, and In Vitro Diagnostic Medical Device Directive) (French-Mowat & Burnett, 2012). In regulating devices, the notified bodies use contracts with device manufacturers (Maak & Wylie, 2016). Similar to the FDA, the EU uses a rule and risk-based classification system with four graduated categories (I, IIa, IIb and III). Devices are placed into one of the categories using the classification rules, with class III devices falling into the highest classification requiring a greater level of assessment and being the highest risk devices (MEDDEV 2.4/1 Rev.9 June 2010; French-Mowat & Burnett, 2012; Maak & Wylie, 2016). In addition, similar to the FDA, class I devices are granted approval based on manufacturer's attesting compliance with Good Manufacturing Practices, proper labelling, packaging and storage requirements (Maak & Wylie, 2016). Notified bodies require data from a literature review and preclinical data showing that the device performs according to intended function (Maak & Wylie, 2016). Applications for

class III devices require preclinical and clinical evidence demonstrating the devices safety and effectiveness (Maak & Wylie, 2016). Similar to the FDA and Health Canada, user fees are utilized by the EU in order to gain approval (EMERGO, 2019). In contrast to the FDA, it is important to note that the specific notified body that is contracted by the device manufacturer determines the requirements needed for approval (Maak & Wylie, 2016). With regard to post-market surveillance, the competent authorities in each EU Member State are responsible (Maak & Wylie, 2016). The implications of this system are that pre-market approvals are not reviewed by regulatory agencies while post-market surveillance is under the purview of the regulatory agencies.

As of 2011, adverse events are recorded in Eudamed, a database for medical devices spanning the EU (Maak & Wylie, 2016). Through Eudamed, information about device manufacturers and their certificate history (including approved, revised, withdrawn, and refused), along with clinical trials can be found (Maak & Wylie, 2016). Additionally, manufacturers have to inform the relevant competent authority of serious public health threats within two days, reports of deaths or serious injuries within 10 days, and other reports (complaints, malfunctions) within 30 days.

Further updates were made to the EU regulations in 2017 to address some longstanding issues such as a lack of transparency, improved post-market surveillance, better coordination between EU Member States, improved pre-market review for high-risk devices, use of a device identification system, and the introduction of an implant card for patients (EC, 2018). In addition to these changes, improvements to the way notified bodies operate were introduced – a pilot program of joint assessments (where external Members of the EU and the European Commission were involved in the pre-market approval procedure) was reinforced (EC, 2018). Additionally, the use of independent experts was introduced in order to support Notified Bodies in making

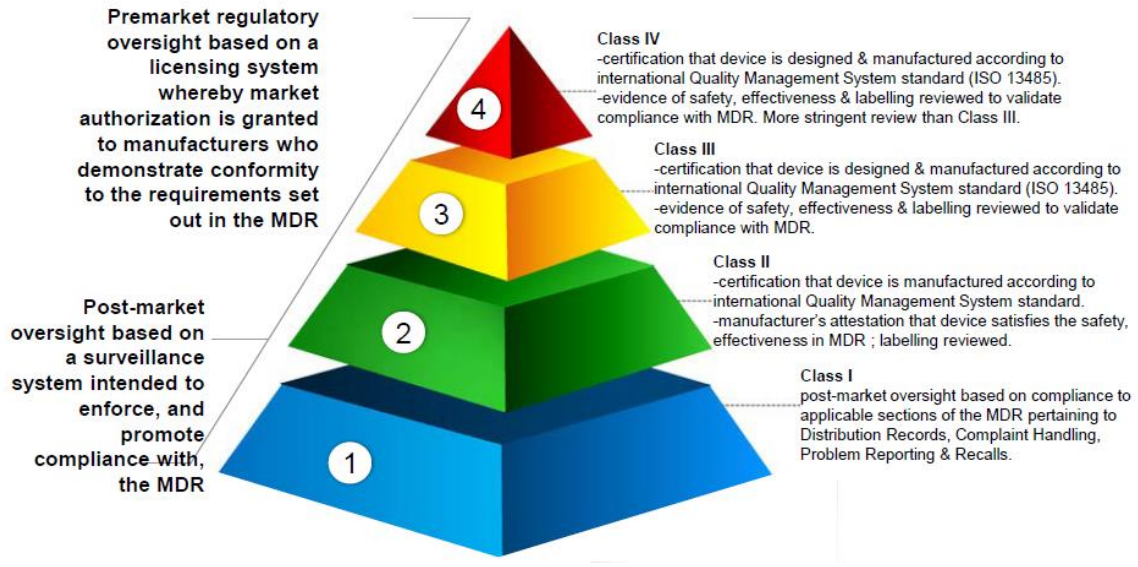
informed decisions (EC, 2018). There are two additional points to note. The first is that the Regulations apply to Iceland, Liechtenstein, Norway, Switzerland and Turkey in addition to the 28 EU Member States (Figure 2). Second, by going form three Directives to two Regulations, the EU essentially changed the approach to medical devices regulation from a suggestion to rules that need to be followed.

The Canadian Medical Device Regulatory Framework

The regulatory authority overseeing regulation of medical devices in Canada is the Therapeutic Products Directorate (TPD) of Health Canada (Table 1) (Chen et al., 2018). The *Food and Drugs Act* and *Medical Device Regulations* are the main legislative pieces overseeing medical devices in Canada (Chen et al., 2018). Aligning with the FDA and EU, Canada also uses a risk-based classification system with class IV being the highest risk and most invasive (Gagliardi et al, 2015). Through pre-market approval, post-market surveillance and quality systems, the safety, quality and effectiveness of medical devices are ascertained (Chen et al., 2018). The class, pre- and post-market requirements can be seen in Figure 4 below.

Overview of Current Regulatory Framework

Figure 4. Overview of the Regulatory System (Seely, 2018).



Pre-market Requirements

As demonstrated in Table 1 and Figure 4, the classification system that Health Canada uses to categorize medical devices is based on how much risk the device carries which is defined in Schedule 1 of the *Medical Device Regulations* as how invasive or active the device is (Gagliardi, 2015; *MDR*, 2019). While invasive devices are those that are surgically implanted or penetrate the human body, active devices are those that require a source of energy (other than energy generated by the human body or gravity) to work (Seely, 2018; *MDR*, 2019). The quality system for medical devices consists of a Medical Device License (MDL) for classes II to IV and an Establishment License for class I devices (Chen et al., 2018). Although class I devices do not require a MDL, facilities that produce medical devices require Establishment licenses and manufacturers have to adhere to proper labeling, safety and effectiveness requirements (Gagliardi et al., 2015; Chen et al., 2018). Periodic inspections of these facilities (in addition to importer and distributor facilities) are carried out by Health Canada to ensure that the requirements detailed in the *Medical Device Regulations* are met (Gagliardi et al., 2015). It is important to note that this part of the regulatory system is similar to that of the EU where the lowest-risk devices do not undergo pre-market review. It is also important to note that like the FDA and EU, Health Canada also utilizes user fees which are varied depending on the type of application submitted by the manufacturer or importer (Health Canada, 2018).

Post-market Monitoring & Surveillance

From the post-market perspective, distribution records, records of complaints and mandatory problem reporting are required of manufacturers (summarized in Figure 4) (Chen et al., 2018). However, manufacturers and importers only have to notify Health Canada of reports of deaths or serious injuries and other issues (device failure/deterioration, improper labelling or directions for use) within 10 and 30 days respectively (as mentioned in Table 1) (Chen et al.,

2018; *MDR*, 2019). This is in contrast to the EU and US where reports of serious public health threats are also provided by manufacturers (as mentioned in Table 1) (Chen et al., 2018). According to Part 803 of the FDA Code of Federal Regulations Title 21, events that constitute serious public health threats are events which require "remedial action to prevent an unreasonable risk of substantial harm to the public health" (Sec. 803.53, 21CFR803). Similarly, the European Commission defines a serious public health threat as "[a]ny event which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action" (MEDDEV 2 12-1 Rev.8 Vigilance).

Currently, the Canadian *Medical Device Regulations* require the manufacturer, importer and distributor to maintain distribution records in order for efficient recall and withdrawal of devices (*MDR*, 2019). Distribution records are also required to be updated as needed when manufacturers receive information from implant registration cards and from health care facilities or patients (*MDR*, 2019). In addition to the distribution records, manufacturers, importers and distributors have to maintain records related to problems or complaints reported by patients/consumers as well as the actions taken (investigations, responses, studies, etc.) (*MDR*, 2019).

As stated previously, mandatory reporting of problems is currently required from manufactures and importers for any issues that arise within or outside of Canada for devices sold within Canada (*MDR*, 2019). According to the *Medical Device Regulations* (2019), two reports are required for issues – a preliminary and final report which need to include details of the patient that reported the issue, all actions undertaken by the manufacturer or importer, preliminary comments and a detailed explanation of why the incident occurred, and resulting actions (increased surveillance, recall, corrective/preventative actions) from investigations undertaken.

When it comes to recall of a device, the *Medical Device Regulations* (2019) currently states that the manufacturer and importer need to notify Health Canada of recalls.

Implant registration consists of registration cards that are completed at the health care facility where the device was implanted and given to both the patient and the manufacturer (*MDR*, 2019). These cards are used to both inform the patient of the details of their implant and contact information of the manufacturer and the manufacturer of the details about the patient so that efficient tracking of the device can occur.

When it comes to reporting requirements from sources other than industry, the current mechanism is voluntary reporting from health care providers, hospitals, and patients. It is important to note that while adverse event reports can be access through the Canada Vigilance Adverse Reaction Online Database, medical devices are not included (Government of Canada, 2017). Additionally, when it comes to reporting issues with medical devices, the online form is different from the one used for other health products (Government of Canada, 2017). The lack of ease in accessing this form probably prevents people from completing it and subsequently contributes to under reporting.

Proposed Future State of Medical Device Regulations

Before considering the proposed changes that Health Canada is aiming to make to the *Medical Device Regulations*, it is important to consider other pieces of legislation that will influence Health Canada's approach. One such piece is Vanessa's Law. Named after a Oakville MP's daughter who died from a contraindication of using a prescription drug, Vanessa's Law (also known as the *Protecting Canadians from Unsafe Drug Act*) amended the *Food and Drugs Act* in order to improve the safety and regulation of therapeutic products (Government of Canada, 2016 & 2017; Young, 2016; Mazumder, 2017). In addition to medical devices, this Act applies to

prescription drugs, over-the-counter medications, vaccines, gene therapies, and cells, tissues and organs (Government of Canada, 2016 & 2017).

Table 2 lists all of the points in the *Medical Device Regulations* that Health Canada is planning on updating in their effort to modernize the regulatory oversight of medical devices. As demonstrated in Table 2, the changes that Health Canada is planning implementing focus on enhancing the pre-approval process, strengthening monitoring and follow-up on medical devices (to align with Vanessa's Law), and increasing the transparency of the pre- and post-market regulatory process (Health Canada, 2018). The main pre- and post-market changes along with the transparency measures that Health Canada is proposing to introduce will be discussed below followed by an analysis of the post-market changes through the factors listed above (burdens, innovation, health protection) in the following section.

Table 2. Summarized comparison of current and proposed changes to Canadian Medical Device Regulations. (Health Canada 2016 & 2019)

Stage in Approval Process	Current Regulations	Proposed Revision
Pre-market	Investigational testing conducted by manufacturers only	Increase clinical investigations conducted by medical professionals
	Flexibility with the type of clinical evidence provided to Health Canada to demonstrate safety and effectiveness	Review evidence requirements with an aim to strengthen requirements for higher-risk devices
	Two scientific expert advisory committees available	Increase scientific expertise
Post-market	Voluntary reporting from health care facilities (including hospitals, long-term care facilities, and private clinics)	Mandatory reporting from hospitals
	Canadian Medical Devices Sentinel Network (CMDSN) currently includes 17 healthcare organizations (hospitals)	Expanding the CMDSN to include facilities other than hospitals (e.g. long-term care facilities, private clinics)
	Manufacturers or importers notify Health Canada of incidents they become aware of	Ability to compel information from manufacturers
	Conduct inspections based on risk on a repeated process: • Domestic manufacturers – 3 years • Importers – 4 years • Domestic distributors – 5 years	Increase inspections and enforcements

Transparency Throughout the Regulatory Process	Release clinical data information through Access to Information Request	Increase public access to clinical data
	Publish summaries of decisions made for new Class IV devices	Publish summaries for new Class III and IV devices
	Incident reports for individual devices can only be accessed through Access to Information Requests	Introduce a searchable medical device incident (and approvals) database

Pre-market Changes

On the pre-market side, the two main improvements are increasing clinical research conducted by physicians (like that done for drug research) and reviewing and potentially revising the evidence requirements for higher-risk devices (Health Canada, 2019). The first of these proposed updates is important for our discussion. Currently, only manufacturers can apply for investigational testing of medical devices is lacking when compared to the investigational testing requirements for prescription drug approval by Health Canada (Health Canada, 2019). By allowing independent researchers or healthcare professionals to undertake investigation research, this would not only align the medical device regulations with those for prescription drugs but could also improve results and mitigate against bias. With independent researchers and increased sample sizes, a better understanding of how the device works can be gained and potentially prevent the entire Canadian population from being test subjects – as we currently are now. However, important questions arise from this point and are related to one point – what will the role of industry be? First, if independent researchers or healthcare professionals conduct studies on devices, how will these studies be funded? Like other industry groups (pharmaceutical drugs, natural health products, etc.) the medical device industry has a lot of money behind it (which gives them power and influence over actors in the system like Health Canada, Health Authorities, and patients). Due to this wealth and power structure, the current method of carrying out studies (within hospitals) requires financial support from the device manufacturer (e.g. referred to as

sponsor-initiated studies) at no cost to hospitals. Subsequently, an important question that will have to be addressed by Health Canada is what will studies look like if they are not financially supported by industry (e.g. manufacturers). A second important question is how will the independent researchers or healthcare professionals get access to medical devices? As these devices are considered the intellectual property of the device manufacturer, it is unlikely they would provide a device without a corresponding benefit. This power imbalance will be explored further later in this capstone.

The second change being considered on the pre-market side is also important but is limited to devices that carry higher-risk (Health Canada, 2018). It should be noted that it is not clear which classes or types of devices "higher-risk medical devices" correspond to. Perhaps the evidence requirements will be strengthened for an entire class of devices or just for devices that have similar application qualities; those modeled on previously approved versions for instance. The following passage is noted in Health Canada's Action Plan on Medical Devices:

> *"Under the current process for reviewing and approving medical devices, there is flexibility on the type of clinical evidence that can be provided to demonstrate medical device safety and effectiveness. For example, an application for a new medical device can be supported by demonstrating similarities in design and performance of an earlier version of the same device. Health Canada will review its evidence requirements related to higher-risk medical devices with a view to strengthening the evidence requirements for devices based on previously authorized versions. In conducting this review, Health Canada will also ensure alignment with international practices."*

While more clarity is needed for this point – which class or type of device will Health Canada be focusing their efforts to strengthen requirements on – it should be noted that there is a need (as noted in Canadian media reports and published articles on a number of devices including implantable cardioverter-defibrillators and hip implants) for such an improvement in evidence requirements (Maisel, 2005; Gould et al., 2006; Halperin et al., 2008; Curfman & Redberg, 2011; Kmietowicz, 2012; Hart et al., 2014; Gagliardi et al., 2015).

Post-market Changes

The first major piece proposed by Health Canada is to improve its ability to compel information from manufacturers. With the passing of Vanessa's Law, Health Canada is able to leverage more powers over device manufacturers and importers. This change will ensure that the regulation of medical devices aligns with that for other therapeutic products covered under Vanessa's Law. Health Canada currently has to wait for manufacturers to conduct testing/investigations if there are reports of a device malfunction, but will gain the ability to compel testing, assessments and investigations when it gets new information.

Another change that Health Canada has proposed is to expand mandatory problem reporting to include every Canadian hospital in addition to the current reporting requirements for manufacturers and importers. Additionally, recognizing that not every patient gets a medical device from a hospital setting, Health Canada has stated that they will be working to include health care settings other than hospitals within the post-market surveillance system (Health Canada, 2019). Some of these settings include: long-term care facilities and private clinics (Health Canada, 2019). This is intended to address the under reporting of adverse events, which may happen for a couple of reasons. With the current framework, hospitals, physicians and patients can voluntarily notify Health Canada of injuries or serious adverse events, but research has demonstrated that there are variety of factors that lead to physician under reporting of adverse medical device events (Gagliardi et al., 2017; Resnic & Majithia, 2018; Craig et al., 2019). In their study, Gagliardi et al. (2017). Of note was the perception that adverse medical device events were a regular or routine part of clinical practice and therefore unnecessary (Gagliardi et al., 2017). Additionally, Gagliardi et al. (2017) found that this perception was reinforced through a lack of (regulatory) oversight, (health care) system infrastructure, and industry response to adverse medical device events that were reported. Thus, by expanding their sources of

information, Health Canada could be in a better position to address these factors by having the ability to initiate a review, investigation or enforcement actions, in addition to improved oversight over medical device corporations.

Improving post-market surveillance is essential for a robust regulatory system since sound surveillance systems can ensure that appropriate events are captured consistently which leads to effective public health action through policy and/or program interventions. This is especially true for medical devices where the pre-market approval phase is not adequate enough to prevent 100 per cent of the risks (Resnic & Majithia, 2017). With devices being used and/or implanted in patients, strong surveillance systems are needed to ensure the regulatory system can respond quickly and efficiently to emerging threats to public health (Gagliardi et al., 2017). Appropriate surveillance can also serve as a useful tool to inform manufacturers and industry, at large, of any device issues, failures or malfunctions that need to be fixed in order to prevent future adverse medical device events (Gagliardi et al., 2017). Subsequently, the measures that Health Canada is proposing to introduce are necessary improvements for stronger post-market surveillance.

Transparency Measures Throughout the Regulatory System

Another proposed change is influenced by the transparency measures under Vanessa's Law. These transparency measures will also move the Canadian *Medical Device Regulations* closer to the regulatory framework of the EU which in 2017 enacted transparency measures to improve public confidence in their system. As noted in Table 2, the proposed increase in transparency will be impacting both the pre- and post- market phases of the Canadian regulatory framework. With better access to medical device clinical data, device approvals and incidents, this might work to improve two things: allowing patients and physicians to be better informed of the options available to them and adverse event reporting from patients and physicians. The first way in which access to previously withheld medical device information could benefit patients and

physicians is clear – with better access to medical device information, patients and physicians will be able to make informed choices about the medical device that is right for the patient. This improvement in the informed decision-making of patients and their physicians could also lead to the second benefit – increased awareness of the risks and harms that the patient could experience. With a better awareness of the risks that could be encountered with the device, patients will be in a better position to recognize potential side effects and alert their physicians quicker while physicians will be better supported (through improved reporting mechanisms) to notify Health Canada of adverse medical events.

However, the benefits of the proposed transparency measures are contingent on genuine transparency on the part of Health Canada. Recently, the Health Canada Clinical Information Portal went live (Government of Canada, 2019). Through the portal, information on drugs and devices can be reviewed; for which one device application is currently posted (Government of Canada, 2019). It should be noted that while new applications for drugs and devices will be disclosed on the portal by Health Canada, information on drugs and devices currently available on the market still needs to be requested by the public (including health care providers) which will then be placed on the portal (Health Canada, 2019). Critics have already called the new portal "an empty website[that] is a good analogy for Health Canada's approach to transparency" (Adhopia, 2019). Thus, while this transparency measure will align Canada with the EU, Health Canada has more work to do to gain the trust of the public and demonstrate that it's interests align with those of the public.

Analysis of the Proposed Post-market Changes

Recalling the purpose of this capstone, the following section will analyse the proposed changes to the Canadian *Medical Device Regulations* on their burden on industry, the health care system and patients, promotion of innovation, regulatory oversight and health risk protection. The proposed regulatory approach will also be considered using the 3-I Framework.

Impact of Proposed Changes – Burdens on Industry, the Health Care System and Patients

Table 3 restates the proposed post-market revisions along with anticipated reporting burdens on industry, the health system, and patients. It should be noted that as part of the consultation process, industry (including trade associations and lobbying groups) will have an opportunity to provide input and feedback on the proposed changes to the Regulations. While this has the potential for allowing industry greater influence on what the changes will look like, this is an opportunity for Health Canada to get industry buy-in. With this in mind, consideration for the burden on industry has been included in this capstone. Referring to the first row, it is important to note that even by changing a voluntary action into something mandatory, under reporting might still be an issue. As briefly discussed above, recognition that there is a fault with the device is one such example in addition to factors that promote and reinforce physician under reporting of adverse medical device events (Gagliardi et al., 2017). Current examples in the media where recognition of an issue with a device include vaginal mesh and metal hip implants. While patients may be sounding the alarm on a faulty or failing device, physicians might not be taking those reports seriously because they believe that the devices have been licensed based on evidence-based research.

Table 3. Reporting burden on Industry, the Health Care System and Patients for the Current and Proposed Regulations.

Current Regulations	Proposed Post-Market Revision	Burden on Industry	Burden on Health System	Burden on Patients
Voluntary reporting from health care facilities (including hospitals, long-term care facilities, and private clinics)	Mandatory reporting from hospitals	–	↑	↑
Canadian Medical Devices Sentinel Network currently includes 17 healthcare organizations (hospitals)	Expanding the Canadian Medical Devices Sentinel Network to include facilities other than hospitals	–	↑	↑
Manufacturers or importers notify Health Canada of incidents they become aware of	Ability to compel information from manufacturers for Health Canada	↑	↑/–	↑/–
Conduct inspections based on risk on a repeated process: • Domestic manufacturers – 3 years • Importers – 4 years • Domestic distributors – 5 years	Increase inspections and enforcements	↑	–	–

Key:
Or /
Same –
Increasing ↑

Summarized in Table 3, the post-market changes that Health Canada is proposing will impact Industry, the health care system and patients differently while working to increase regulatory oversight of medical device companies. Consequently, this may also work to improve the health care system infrastructure and industry responsiveness to reports of device failures or malfunctions. As can be seen from Table 3, with the new responsibilities required from hospitals and the expansion of the CMDSN, health care staff and patients will have an increased burden in reporting failures and malfunctions to Health Canada. While this is a burden for health care staff and health care facility administrators (in terms of setting aside time for reporting adverse events to Health Canada), patients and their health care providers might experience more empowerment to report issues with devices. By requiring health care facilities to report adverse events, physicians might become better aware of the limits and potential risks that patients might experience with a device and empowered to report them. Furthermore, this in turn could support patients when they are disclosing adverse reactions to their health care providers through a better surveillance system that can lead to active measures taken by Health Canada.

However, as demonstrated by the third column in Table 3, patients might see an increased burden because the beneficial outcomes mentioned above are dependent on adequate reporting systems, mechanisms and resources. A related factor of note is how will physicians (or other health care providers) be incentivised to report adverse medical device events? Not only will a strong reporting mechanism need to be in place for health care providers to submit reports, but in order for them to send reports, they will have to incentivised in some way. Perhaps updating the relevant payment structures could be a potential solution to gain health care provider buy-in. Further concerns reported by the Canadian Society of Hospital Pharmacists (2016) is ensuring hospital staff have the appropriate resources (time, training, resources) to meet the mandatory reporting requirements of Health Canada. As they explain, the operational impact of reporting all adverse events (for drugs and devices) will result in an additional burden placed on (pharmacists,) nurses, and other health care professions who work in hospitals (CSHP, 2016). This increased burden will be compounded by the reporting deadlines that Health Canada sets. The results of this will be that while there is an increased burden on the health system, the reality will be that the burden will be experienced by individual health care professionals (CSHP, 2016). This increase in workload could result in negative patient outcomes as quality of care is affected (CSHP, 2016). Another concern raised by the Canadian Society of Hospital Pharmacists is that when it comes to reporting adverse events for medical devices, more professional groups might be involved (compared to adverse event reporting for drugs) including materials management, biomedical engineering, and physicians (2016). The group also noted that while drug use is overseen in the hospital setting (the hospital pharmacy and relevant committees), there typically is no equivalent oversight for medical devices (CSHP, 2016). With these and other concerns (ability to mine data from different electronic health records used within and across provinces, limits of existing information management systems, privacy and confidentiality requirements, etc.) need to be

adequately addressed, the results could leave patients in the current situation – having to bear the costs of an inadequate regulatory system, research and advocate for their health without a lot of support from their health care providers and the larger health system (CSHP, 2016).

Impact of the Proposed Changes – Promotion of Innovation vs Regulatory Oversight and Health Risk Protection

Another dimension that needs to be considered with the current and proposed changes to the *Medical Device Regulations* is how Health Canada will be striking a balance between innovation and health risk protection or regulatory oversight (Table 4). While this balance is hard, if not impossible, for regulatory frameworks to find, Health Canada's proposed changes, generally, will work to increase health risk protection and regulatory oversight for patients. Finding a balance between innovation and health risk protection or regulatory oversight is challenging in medicine because of where the innovations are used. The human body poses a challenging and complex environment within which mitigating device malfunctions or failures is not straightforward (Consoli et al., 2016). This complexity is compounded by various levels of uncertainty that lie at the biochemical level of disease (i.e. knowing exactly what is happening at the biomechanical level in the body) all the way to the uncertainty in the devices and software that is assumed to bring about a desirable outcome (Curfman & Redberg, 2011; Consoli et al., 2016). In the face of numerous uncertainties and risks, it is important to note that no regulatory system can prevent all risk posed by medical device innovation because of the impracticality of studying every device change thoroughly (501(k) route) before it can enter the market (Resnic & Normand, 2012). However, the role of regulatory agencies (like Health Canada) is to find such a balance between promoting innovation, providing strict regulatory oversight and prioritizing health protection.

Table 4. Promotion of Innovation vs Regulatory Oversight and Health Risk Protection of Current and Proposed Post-Market Regulations.

Current Regulations	Proposed Post-Market Revision	Promotion of Innovation	Regulatory Oversight	Health Risk Protection
Voluntary reporting from health care facilities (including hospitals, long-term care facilities, and private clinics)	Mandatory reporting from hospitals	–	↑	↑
Canadian Medical Devices Sentinel Network currently includes 17 healthcare organizations (hospitals)	Expanding the Canadian Medical Devices Sentinel Network to include facilities other than hospitals	–	↑	↑
Manufacturers or importers notify Health Canada of incidents they become aware of	Ability to compel information from manufacturers for Health Canada	↑/–	↑	↑
Conduct inspections based on risk on a repeated process: • Domestic manufacturers – 3 years • Importers – 4 years • Domestic distributors – 5 years	Increase inspections and enforcements	–	↑	↑

Key:
Or **/**
Same –
Increasing ↑

In their attempt to find more balance between innovation and health risk protection, Health Canada is trying to address their (previous) lack of regulatory oversight and is consequently shifting towards increasing health protection measures. This would not only align the approach for medical device regulations with that taken for drugs and other therapeutic products (through Vanessa's Law), but also move towards the regulatory approaches of the US and EU. However, there have been published critiques arguing that each jurisdiction's approach (e.g. the regulatory agency) is not adequately responsive (Curfman & Redberg, 2011; Feder, 2012). As discussed above, two of the post-market surveillance changes that Health Canada is proposing involve the use of mandatory reporting from hospitals and the expansion of the CMDSN which may address the underreporting of adverse medical device events. In addition to these changes, Health Canada is also leveraging new abilities gained through Vanessa's Law. Particularly, it has gained new regulatory oversight capabilities over industry – such as the ability to compel information form manufacturers and recalling unsafe therapeutic products (Government of Canada, 2016 & 2017). Lastly, the final post-market surveillance measure that Health Canada is proposing is the increase of inspections and enforcement actions – again through leveraging the new capabilities

gained through Vanessa's Law as well as increasing the number of inspectors and analysts in the workforce (Health Canada, 2019). Overall, by increasing the regulatory system infrastructure and supporting it with input from government and regional sources (hospitals and the CMDSN), Health Canada is working to address the issue of underreporting from health care providers and facilities. Consequently, the public, health care providers and Health Canada will ideally gain more information and subsequently a better picture of how medical devices are working.

Understanding the Shift in Regulatory Approach - Application of the 3-I Framework

Overview of the 3-I Framework

The 3-I Framework is useful in understanding policy developments, choices and approaches. In using 3-I, ideas, interests and institutions are analysed to understand why and how policies change (Gauvin, 2014; Searer et al., 2016). In considering the roles that interests, ideas and institutions play in shaping policy approaches, power structures, values/culture, knowledge/evidence, policy networks and legacies can be identified and explored. Here I use it to consider the roles and influence different actors (industry, government, health care providers and the public) and the approach that Health Canada is taking in updating its regulatory approach when it comes to medical devices. The following sections will explore the relevant interests, ideas and institutions that should be considered for the proposed changes to the Canadian *Medical Device Regulations*.

Interests

Table 4 highlights the beneficial aspects of the proposed changes to the *Medical Device Regulations*. By increasing the protection of Canadian health, patients across the country will benefit from improved regulations. However, there are some important factors to explore in

order to gain a more complete picture of the competing interests that will impact the changes to the Regulations.

Demonstrated by Tables 3 and 4, Canadian patients and health care providers will be the group that benefits the most from the proposed changes to the *Medical Device Regulations*. With the Government's move to increase transparency throughout the regulatory process the public and health care providers will ideally be better informed and aware of the options, risks, and incidents reported to Health Canada. This will place health care providers and patients in a better position to make informed decisions on the type of device that is most suitable for a patient with a better understanding of the risks and clinical settings within which it was tested. However, as stated previously this is dependent on a genuine effort on Health Canada's part to provide the public with medical device information. Otherwise, this is simply a political gesture that won't have real meaning behind it. I believe that there is a case for this point; as described above, Health Canada has set up the *Clinical Information Portal* where the public will be able to find information on newly approved drugs and devices (Government of Canada, 2019). However, in order to get information on drugs and devices that are already on the market, the public has to fill out and submit an Access to Information request (which may not get approved). If Health Canada wanted to genuinely address transparency, why not release information related to all drugs and devices on the Canadian market? What good will information on newly approved drugs and devices do if they aren't being used yet by the public?

Recalling Tables 3 and 4, with regards to the post-market context, the interests of industry will be curtailed slightly with Health Canada's ability to compel information from device manufacturers and importers under Vanessa's Law. This measure will grant Health Canada more power and align the regulatory approach for medical devices with that of other therapeutic products. Subsequently, this aspect of the proposed policy change may not be influenced by the

interests of industry and lobbying groups as the implementation of Vanessa's Law is hopefully being enforced by the Federal Government.

Some of the proposed policy pieces that may see pushback from the medical-technology industry and medical device companies would be in the in pre-market phase as they will loose their power and control over the clinical investigations and may have to change the testing and clinical investigations done in order to meet potentially new evidence requirements for pre-market approval. However, as the proposed policy pieces (both pre-market and post-market) are in support of the public interest, the Canadian public, health care communities and societies (e.g. Physicians and Surgeons associations, Nurses associations', and patient advocacy groups) will mostly likely want to see the proposed changes get approved.

Another group, not mentioned so far are the Provincial/Territorial governments and Provincial/Territorial/Regional Health Authorities. As with the public and health care communities and societies, Provincial Governments and Regional Health Authorities would also be in favor of the proposed changes as they would work to reduce health care costs associated with adverse events, revisions and complications that occur with medical device malfunctions or failures. This is dependent on Health Canada making good use of its new abilities.

When Interests Collide – Considerations of Conflicts of Interest

However, the realities of how medical devices are used within healthcare settings will have to be considered carefully by Health Canada. This is especially true for invasive and implantable devices (pelvic floor mesh, orthopaedic implants, pacemakers, etc.). The decisions that go into approving devices (by Health Canada), funding the devices (by health care funding bodies) and incorporating the devices into practice (by health and hospital authorities as well as health care providers) are supported and/or limited by numerous factors (e.g. amount of evidence, quality of evidence, costs of device, comparability to other devices being used, health outcomes, risks, etc.).

On top of these considerations are external factors that create tensions within the regulatory system. These tensions include: user fees, sponsor-initiated studies, relationships between industry and health care providers. While this is not an exhaustive list, these points of tensions (present either independently or in combination) can create conflicts of interests for actors within the regulatory framework (e.g. Health Canada, health authorities, hospitals, and health care providers).

In order to ensure that costs of Federal Government programs and activities have financial capacity, the Treasury Board within the Government of Canada instituted a cost recovery policy in 1997 (Alpert, 2008). This means that departments across the Federal Government can attach fees to regulatory activities (Alpert, 2008). Health Canada is one such department that utilizes user fees for its cost recovery process (Table 1) (Alpert, 2008). For medical devices, user fees are attached to the pre-approval process (reviewing new applications) and amendments to licensed devices which provide a steady source of revenue of the department (Alpert, 2008). The implications of relying on this source of revenue is that a conflict of interest is evident here – Health Canada which is supposed to act as an independent regulator is taking money from industry members who they are meant to be regulating (Alpert, 2008). This issue is further complicated with the fact that user fees are tied to service standards for staff within Health Canada. If services standards are not met (e.g. the target number of days within which an application has to be reviewed and processed elapses) then the user (device manufacturer, importer) gets a corresponding discount on their future fees (Alpert, 2008). This system of penalties for the regulator and benefits for industry tries to ensure that Health Canada will be held accountable to the service standards it sets (Alpert, 2008). This raises concerns across jurisdictions that utilize user fees (including the US and EU) of are regulatory agencies actually prioritizing the interests of industry? What about the public that bears the consequences if a

device malfunctions or fails? Are the service standards realistic to allow staff enough time to review and carefully consider the evidence (research studies, quality management, manufacturing processes, etc.) before making a decision to approve devices to go on the Canadian market? Additionally, as Alpert (2008) points out, there is an inherent bias of relying on user fees which pushes regulators towards quantity over quality. The implications of promoting quantity over quality relates to medical device innovation. Regardless if the device actually provides greater benefit than harm to patients or is more effective than another device, new devices will probably introduced to the market thus supporting industry interests that innovation is always beneficial for the public. In updating the Regulations, it is unlikely that Health Canada will shift its reliance on user fees but it has to acknowledge the inherent conflict of implementing user fees creates when updating, implementing, and enforcing the Regulations.

Another source of conflict is sponsor-initiated studies of which there is a wealth of information on the impacts of pharmaceutical industry financing has on subsequent research results (Angell, 2008; Lundh et al., 2012). Generally. It has been well documented within the pharmaceutical literature that sponsor-initiated clinical investigations tend to produce results and conclusion that favors the drug. In their Cochrane review, Lundh et al. (2012) found that sponsored studies of drugs and devices had favorable results and conclusions when compared to studies sponsored by other sources. Additionally, the authors concluded that industry bias was present which could not be explained by the risk of bias assessment tools developed by the authors (Lundh et al., 2012). While this is an important consideration for regulators (who approve devices), health and hospital authorities (who purchase devices) and health care providers (who use devices) there are concerns which relate back to the proposed pre-market changes Health Canada is working to introduce. The proposed pre-market change relevant here is the way clinical research might change under the new Regulations. Recalling the discussion above, a couple of

the concerns with shifting research into the hands of independent researchers and clinicians related to the role industry would have. Specifically, how would this research be conducted without industry finance (which is a given for sponsor-initiated trials) and how would the independent investigators get access to the devices. The role that industry plays in providing financial support and resources (e.g. devices and equipment) to hospitals which undertake the research needs to be acknowledged and clearly demarcated for every player within the regulatory system. It is especially critical for Health Canada to acknowledge industry interests and its influence over medical research.

The last conflict of interest that will be described here is related to the previous point. The potential for conflicting interests when industry develops relationships with health care providers. While this has been well documented for the pharmaceutical industry, this is also a concern when it comes to the medical device industry. Brennan et al. (2006) point out that while industry supports continuing medical education, research and development of new therapeutic products, they are still beholden to their stakeholders which gives rise to the conflict between health protection and profits. How will patients be able to discern if their health care provider's recommendation is not influenced by industry support? Are there effective ways of avoiding bias within health care professions and societies? Alternatively, how can health care providers, hospital and health authorities be safe-guarded from industry influence? Thus, understanding the influence that industry has in the health care sector (e.g. providing funding, supporting educational programs and conferences, providing resources to health authorities and hospitals) is critical to regulating it. If regulatory oversight does not take into consideration the full scope of industry influence, then how can any regulatory and/or enforcement action have an impact on industry?

Ideas

In opening up the *Medical Device Regulations* to change, the value/culture and knowledge/evidence of Health Canada can be observed. In recognizing the need for change, Health Canada is taking steps to ensure that the *Medical Device Regulations* reflects the values/culture of the Federal Government at large. This refers to the values and culture that the political party in power brings to the approach the entire Federal Government takes on. One such example is transparency. With the previous Conservative party in power, public transparency was not prioritized or supported to a large extent. This changed when the Liberal party came into power. Transparency and openness is something that every Federal Government branch and agency has to incorporate into their standard operating procedures. This relates to another example that Health Canada uses in its policy development process – public consultations. Since the mandate of the agency is to protect the health and safety of Canadians, the consultation process aims to be inclusive of a diverse range of voices that will provide feedback on the direction that Health Canada wants to move toward.

There are a couple of things that should be noted. First, while health care societies, patients and patient advocacy groups, Provinces/Territories and Provincial/Territorial/Regional Health Authorities will ideally be engaged during the consultation process, industry will as well. A relevant concern here is how much influence (though corresponding levels of engagement) will industry have with the policy development process. Additionally, will the level of engagement be comparable to that of the other relevant actors (patients, health authorities, etc.)? Second, it should be noted that the approach that Health Canada is taking and the pace with which the *Medical Device Regulations* will be updated is influenced by the party in power. Thus, currently, the values and approach Health Canada is taking reflect the Liberal Party. Subsequently, the

timeline for the milestones listed in the Action Plan are influenced by the impending election and potential change in power (Health Canada, 2019).

In recognizing that the *Medical Device Regulations* need improvement to ensure the safety of Canadians, Health Canada is working to uphold its mandate as a regulator and improve its oversight of the medical device industry by leveraging related laws that can help expand its powers and abilities. Additionally, as an agency that uses evidence-based decision making, Health Canada will hopefully prioritize scientific research when it comes to the development of the regulatory pieces that will comprise the updated *Medical Device Regulations*. This comprises another idea – the value of evidence and the role of evidence-based decision making when it comes to shaping policy approaches. By leveraging scientific expertise both within and outside of Health Canada, policy advisors work to stay informed of research developments from around the world (Health Canada, 2016). Policy approaches are also reviewed by policy advisors in order to consider other approaches used by different jurisdictions. Thus, evidence (in the form of scientific research or policies from other jurisdictions) forms the foundation of policy development and supports the approaches proposed to the public during the consultation process. It is important to recognize that the approach could then be altered and/or further developed based on feedback received from stakeholders. Some stakeholders and stakeholder groups will reflect the values of not only the Federal Government, but that of the public to a large extent. Competing interests between industry, health care providers, health care societies and associations, hospitals, Provincial/Territorial/Regional health authorities and the public will ideally be given equal opportunity to find increased levels of industry regulation and health protection.

Institutions

As touched on briefly, the historic development of the *Medical Device Regulations* was (generally) always contained within that for drugs. However, the corresponding approach for

medical devices has lagged behind. Consequently, this is a valuable opportunity for Health Canada to increase the alignment between the regulatory approach used for drugs, medical devices, and other therapeutic products.

Another institution that is relevant here and the Federal-Provincial responsibilities for regulation-delivery of services. While the Federal government shares a role with Provincial/Territories in delivering health care and social services for some groups within Canada, the Provinces and Territories have the larger responsibility of health and social service delivery within their jurisdictions (Health Canada, 2018). The Federal government is also responsible for protecting the health and safety of Canadians, disease surveillance and prevention in addition to regulating various Industry groups (e.g. food, environment, agriculture, natural health products, drugs, medical devices, etc.) (Health Canada, 2018). The implications of this is that while Health Canada will set the regulations for how medical devices are governed, the two levels of government will have to work together to ensure that Provinces and Territories are able to meet the requirements of the updated regulatory approach. This is where the consultation process with policy networks will be essential in ensuring that the responsibilities of the Federal, Provincial and Territorial governments are clear and work cohesively. Policy networks comprising patient advocacy groups, health care communities and societies as well as Provincial Health Authorities would be in favor of the proposed changes as they align with increased patient safety, risk reduction and reduced costs in the long-run (for Provincial Health Authorities).

Opinion on Proposed Policy Approach

Overall, the proposed policy changes that Health Canada is intending to make to the *Medical Device Regulations* should work to improve the regulatory oversight of medical devices from the pre- to post-market stage and mitigate health risks posed by medical devices (Table 4). These changes will continue to align Canada with the US and EU. However, this consideration of aligning with other jurisdictions (especially the US and EU) may hold Health Canada back from being progressive in their approach to regulation the medical device industry and safeguard public health. Nevertheless, while regulatory oversight is important (especially considering the scope and the role of Health Canada's mandate) it is also important to realize that no regulatory system will be able to prevent 100 per cent of the risk that medical device innovation poses. Additionally, while the medical device-technology industry and medical device companies will experience increased regulatory oversight (particularity from the post-market perspective), the proposed measures have already been taken up by other jurisdictions (to a greater or lesser extent) such as the EU and US. Consequently, while the shift in Health Canada's regulatory approach might seem progressive, the reality of implementing the proposed measures might still fall short which is especially true for the proposed post-market and transparency measures. This is something critics have noted has occurred with the FDA (Feder, 2012). That being said, the proposed measures are a step in the right direction and are needed for improved health protection and informed decision making of health care providers and patients across Canada.

Reflection

Reflecting on this issue, I believe it is a threat to public health as well as a social inequity issue. While there are other issues at play (reliance on technology and innovation, different types of power in technology, access to medical device innovation) the main issues are the structural power imbalance between industry and the public. As Health Canada is supposed to act as an independent regulator, holding industry in check – we have seen how they are not independent from industry groups, and rely on financial support from Industry to carry out everyday regulatory activities. Not only is there a power imbalance within industry, the regulator, and the public, the influence industry groups have in health authority and hospital settings and with health care providers is important to recognize. Thus, the power imbalance is systemic, bleeding through many aspects of the health care system that is supposed to prioritize patients and the Canadian public first. Subsequently, a symptom of this power imbalance is that the Canadian public has become the experimental population. Instead of devices having adequate evidence of their safety and efficacy before they reach patients, they do not leading to the real possibilities of injuries, failures and malfunctions in the Canadian public. Not only does this impose extra costs on the health care system, toll on the individual and their family, the trust that the public has in what should be a system that helps (and not harms them) is damaged. This is what we are observing now – a regulator that is trying to demonstrate how it 'cares' and is in fact 'prioritizing' the Canadian public all the while continuing to rely on industry to run its activities. Thus, this capstone has allowed me not only to further the development of a critical perspective on a public health issue but explore power structures that are taken for granted and create social inequities present at the National level. This capstone has also allowed to me gain a new skill – conducting and writing a policy analysis which I hope to be utilizing after graduation, as a public health practitioner.

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