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Centre for Health
Innovation and Leadership

Transforming Canada into a Global Centre for Medical Device Innovation and Adoption

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Introduction

Medical devices are a diverse group of products used to enhance the quality of patient care by restoring function, and aiding in the diagnosis, prevention, treatment and management of diseases and disabilities. Medical devices range from low-risk supplies such as bandages and thermometers to innovative imaging devices and drug eluting stents. Devices play an important role in modern health care. They improve treatment outcomes and promote less invasive procedures, reduce patient recovery time, shorten the length of hospital stays, reduce costs and enhance health system sustainability.

Canada pays a large price for publicly funded healthcare. In 2010, the combined spending on health care of the public and private sector in Canada was more than \$191.6 billion.¹ This amounted to 11.7% of Canada's total gross domestic product (GDP). Hospitals account for the largest proportion of health expenses (\$55.3 billion), followed by drugs (\$31.1 billion) and physician services (\$26.3 billion). In 2009, growth in national healthcare costs were 1.56 times greater than the growth of the nation's GDP.² Canada continues to spend an increasing percentage of its wealth on health care while the demands for services continue to grow along with the costs of healthcare service delivery. The medical device market in Canada, within this context, is approximately \$6 billion.

Canada's aging population is expected to further propel health costs upward in the foreseeable future, presenting greater demands on health systems than ever before and increasing the need for medical devices such as imaging systems, artificial hip replacements, pacemakers and blood pressure monitors.² Although cutting edge medical devices are often seen as significant and unaffordable costs for hospitals operating within limited budgets, these devices offer significant long-term cost savings, improved patient outcomes and create more efficient and effective health practices. Medical devices can be very cost effective compared to other health care treatments or technologies. In this

respect, medical devices are often proposed as an important tool in achieving health system innovation and sustainability. This paper explores how medical devices can contribute to system innovation and sustainability, and at the same time develop and encourage a domestic medical device industry that produces jobs and economic wealth for Canada. Our paper concludes that streamlined collaboration among all stakeholders can provide end-user advice to device manufacturers and allow Canadian companies to generate competitive economic advantage while better serving the needs of Canada's health systems.

Global device markets are growing, creating massive economic opportunity in both the U.S. - still the largest market for devices - and elsewhere around the world. It has been noted by PriceWaterhouseCoopers that "innovators are already going first to market in Europe and, by 2020, likely will move into emerging countries next before entering the United States."³ Within that global market, Canada has an important opportunity to become a worldwide leader in medical device innovation and production. While great potential exists for prosperity in the device sector, Canada faces a number of challenges in achieving the ability to capitalize on growing global medical device markets.

This report examines the medical device industry in Canada and identifies the value of the medical device industry as a strategy for strengthening the sustainability of Canada's public health care systems. This report explores the role of industry, government, health system stakeholders and Canadian universities in contributing to Canada's medical device sector and the economic advantage this industry offers Canada's economy. Our analysis outlines strengths that offer opportunity for Canada, and contributes specific recommendations designed to realize the potential for strengthening this sector, achieving greater capacity for patient care services, and overall health system sustainability.

Canada's Medical Device Industry

A medical device in Canada is defined by the Food and Drugs act as: any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

(a) Diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

(b) Restoring, correcting or modifying a body function or the body structure of human beings or animals,

(c) Diagnosis of pregnancy in human beings or animals, or

(d) Care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.⁴

A medical device, as defined in the Medical Devices Regulations, means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals. Software is a medical device if it is sold for the purposes given in the definition of a device or used as a component of a device.⁵

Regulatory Structure:

In Canada, medical devices are regulated by Health Canada, with the legislative mandate of protecting patients from harm by ensuring the quality of medical devices. Canada's regulatory system (the Medical Device Regulations), enacted in 1998, replaced preceding regulation from 1976.⁶ Canada's Medical Device Regulations are based on the European Medical Device Directives (MDD) of 1992.

Prior to 1992, EU member countries had separate regulatory bodies. In order to facilitate trade, regulations were harmonized under the MDD. The US started regulating medical devices under distinct Medical Device Amendments in 1976, replacing regulatory oversight by the Food, Drug and Cosmetics Act of 1938. Canada has recently been working to harmonize its regulatory framework with the US, Japan and Australia to reduce trade barriers for medical devices.⁷ As a result of global partnerships and interaction, Canada's own regulatory system remains somewhat of a hybrid of EU and US systems, with greater risk-controls than the US system and greater emphasis on efficacy reviews for high-risk devices than the EU's system.⁸

Canadian regulation demands different levels of evidence for quality assurance based on a product's risk classification. Health Canada separates medical devices into the following 4 risk categories:

- Class I: Low risk devices such as wound care and non-surgically invasive devices.
- Class II: Low-to-medium risk devices including contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).
- Class III: Medium-to-high risk devices such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically-invasive devices that are intended to be absorbed into the body or that are intended to remain in the body for at least 30 consecutive days.
- Class IV: High-risk devices such as pacemakers and surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. The device manufacturer, importer, or distributor is responsible for classifying the device.

Class I devices are exempt from licensing and do not need to obtain Health Canada approval to market. Class II devices require that applicants assert the safety and efficacy of their device without having to submit evidence to support

this conclusion. Class III and IV devices require more documentation and provision of evidence proving the safety and effectiveness of their device. When one discusses the medical device industry, they generally think about Class III and IV devices. These are more often the innovative devices that have a substantial impact on how health care services are delivered (ex. robotic surgery, pacemaker implants) which impact patient care outcomes, improve treatment options and outcomes, replace surgeries with less invasive procedures and reduce patient recovery time and duration of hospital admissions.

Class III and IV medical devices are often complex technologies that require expertise in software, signal processing, engineering, and any number of different disciplines to ensure safety, efficacy, and cost-effectiveness. Medical devices, on average, take two to five years to progress from concept to commercialization depending on their inherent complexity and regulatory classification. Medical device start-up companies in Canada often struggle with the long periods of time required for development and testing in their industry which, in turn, make it difficult to attract venture capital. Other industry factors dissuade investors by raising investment risk, not least is the fact that medical devices have a relatively short life-cycle, lasting an average 18 months on the Canadian market before being replaced by a new version.⁹ This puts immense pressure on medical device developers and companies to target larger, profitable markets with manageable regulatory hurdles to maximize periods of profitability. Traditionally, medical device companies within Canada develop products with an eye on the US market and only supply products to Canadian health systems as an afterthought to commercial success abroad. The US is the primary target market for Canadian medical device exports. In 2005, Canada exported 78% of its medical devices to the US.¹⁰

Scope of Canada's Medical Device Industry:

The medical device industry continues to grow in global economic significance. Medical device sales reached \$220 billion in 2009.¹¹ In 2008 the global medical device market grew faster than the global drug market.¹² Advances in the globalization of world markets, improvements in the standard of living in evolving economies, and an increasing elderly population in developed nations, makes the medical device industry one of the most profitable sectors in the world's economy.

Despite the global opportunity for growth in the medical device industry, Canada's track record for growth in this area remains under developed. One of the limiting features of Canada's medical device industry is its limited expenditure on research and development when compared to other countries. Over the past 20 years, R&D expenditures in the medical device industry comprised 0.014% of GDP in Canada compared to 0.167 % of GDP in the US. The US investment relative to national output is 12.08 times greater than Canada's.¹³ Globally, the local medical device industry accounts for 0.4% of Ireland's GDP, 0.6% of the UK's GDP and 0.7% of Germany's GDP.^{9, 14}

In 2004, the medical device manufacturing industry in Canada consisted of 998 firms operating 1101 facilities and employing approximately 26,000 people. Historically, Canada has suffered from a major exodus of large medical device companies such as Johnson and Johnson, Baxter, Medtronic, who have all closed plants in a number of Canadian cities. This exodus is attributed to the lack of incentives to grow and develop in this market, the regulatory burden and the size of the market. Currently, medical device manufacturing and development facilities in Canada are mostly small-and medium sized enterprises. Over half of these companies (57%) have fewer than 25 employees and 37% have 25-49 employees. Only 4% of companies are medium sized enterprises (50-150 employees) and fewer than 1% are considered large enterprises (greater than

150 employees).¹⁵ Nearly 90% of Canadian medical device facilities are Canadian owned.

A barrier to R&D investment in Canada's medical device sector is the relatively small size of most Canadian companies and their limited access to financial support. This barrier creates reluctance in both companies and potential investors to engage in R&D without certainty of their ability to afford clinical trials and lengthy regulatory processes. This creates a significant investment challenge for an industry where investors are already wary about their inability to reasonably predict risk and return on their investment.¹⁵

In 2008, Canada purchased approximately \$6.4 billion worth of medical devices,¹⁶ which accounts for less than 3% of the world market for devices. By comparison, the US medical device market was valued at more than \$100 billion in 2008; roughly 42% of the global market.¹⁷ There were nearly 5,300 medical device companies in the US in 2007, employing more than 365,000 people.¹⁷ Approximately 73 % of US medical device companies had fewer than 20 employees. 15% of US device companies had as many as 100 employees.

Canada's Strengths in the Medical Device Industry

Despite its small market and regulatory climate, Canada has substantial capacity to support growth in the medical device industry and, we contend, is an ideal home for a global medical device innovation hub. Consider that Canada boasts a highly educated population, ranking 2nd out of 17 OECD countries in high-school completion rate, 1st in college completion rate and 5th in university completion rate.¹⁸⁻²⁰ Research published by Canadian universities is world-class, ranking 8th out of 17 OECD countries in quality, higher than either the US or the UK.²¹ However, we are not “punching our weight”. Despite the well educated population and global leadership in research output, Canada ranks only 14th out

of 17 OECD countries in health innovation. The strength and growth of the medical device sector in Canada offers an opportunity for improving this rather limited track record. There is emerging evidence that the framework for building and strengthening this sector has already begun in a number of provinces.²¹

The second strength Canada brings to the Medical Device sector is an emerging capacity for collaboration among medical device companies, university researchers and health sector partners driven, in part, by government sponsored programs and policy. Industry Canada has identified 6 Medical Technology (med-tech) clusters across Canada: Vancouver, Winnipeg, Alberta, Ontario, Montreal and Halifax.²² Each cluster has access to strong, local universities and hospitals able to work with industry partners on research and development projects as well as clinical proof of concept studies.

British Columbia has more than 60 medical device companies operating in the province, with specialties in interventional and implantable cardiology, diagnostic testing and analysis, as well as orthopedic devices. Furthermore, Simon Fraser University's 4D labs support the medical devices cluster with advanced materials research. Winnipeg is home to a cluster of expertise in magnetic resonance imaging (MRI). This cluster is supported by the University of Manitoba, Winnipeg's Health Sciences Centre and the Centre for the Commercialization of Biomedical Technology. Alberta has more than 60 medical device firms located around Edmonton and Calgary. Alberta also has the National Institute for Nanotechnology and the National Research Council Institute for Biodiagnostics West.

Ontario has medical device clusters currently focused in Ottawa and Toronto, with pockets of advanced activity, especially in diagnostic imaging in London. Ontario has 24 colleges and 20 universities, as well as robust research institutes and the MaRS Centre for technology and innovation. Montreal is at the centre of Quebec's medical device industry, playing host to more than 350 companies.

Quebec has a strong optic-photonic sector, who are partnering with a number of universities with access to national research centers

Industry Canada has developed a program to support academic-industry relationships offered through Canada's Networks of Centres of Excellence (NCE). NCE's are funded by Industry Canada and are designed to support networks of researchers across Canada focused on a specific industry sector. Although many successful networks of Centres of Excellence have been established, few NCE networks have achieved substantial networks of industry partners in the medical devices sector. For example, MaRS is an NCE focused on health sector innovation, mainly supporting the commercialization of products generated by academic researchers based in university labs. The great strength of NCEs is its requirement for industry-academic researcher partnerships. This funding structure offers tremendous opportunity and incentive for collaboration among industry partners and researchers.

In addition to these emerging med tech clusters, Canada has considerable strength in the information technology sector, which could offer important collaboration with medical device companies, as information becomes a more important by-product of the technology, helping with diagnosis and treatment. Research in Motion is just one example of a successful Canadian information and information technology company which could collaborate with smaller medical device companies to achieve robust partnerships and help accelerate the medical device industry in Canada.

Canada's third strength is the nation's strong track record for conducting clinical trials. Canada currently ranks fourth in the world in clinical trial capacity, hosting 4.1% of the world's clinical trial sites.²³ Canada is the only country in the world to have academic health centres in eighty percent of the tertiary health care centres in Canada. By comparison, only 5% of US tertiary care is supported by academic health centres. Moreover, Canadian patients are demonstrably willing to participate in clinical trials. In 2007, 12% of all cancer patients

treated in Ontario's cancer centres participated in treatment-based clinical trials. Universal access to health care services and the high concentration of academic health centres in tertiary care settings provides an ideal environment for clinical trial research. Since each province has a single public health insurance provider, long-term follow-up and data gathering is much simpler in Canada than in countries with more fragmented public and private health care systems. In addition, Canada's multicultural diversity is an important environment for global companies to conduct clinical trials for new medical devices. Canada's multicultural environment offer the ability to find locally intimate knowledge of foreign cultures to support the export of new medical device products and guide successful cultural arbitrage, and the multicultural community offers medical device companies the ability to generate clinical trial data in Canada that is more generalizable to global markets than trials conducted in more homogeneous populations.

The fourth strength our research identified relates to Canada's global leadership in health technology assessment (HTA). Health technology assessment is a decision-making strategy that compares the effectiveness and cost of a new technology with competing existing technologies. The ultimate goal of HTA is to provide policy recommendations relevant to a new technology's potential for safety, efficacy, potential for health innovation and return on investment. HTAs are an important part of the procurement process in Canada, EU, and Australia. Comparative effectiveness research (CER) is very similar to HTA, but with limited focus on costs. In the Obama administration's February 2009 stimulus spending package, \$1.1 billion was allotted for CER.

HTA groups exist at l'Hôpital du Sacre-Coeur de Montréal, as well as within a consortium of health and social service centres. Ontario has two units, one in London Health Sciences Centre called the High Impact Technology Evaluation Centre (HiTEC) and one at SickKids Hospital called Technology Assessment at SickKids (TASK).²⁴ Montreal and Quebec are establishing HTA groups. Between 2002 and 2007, the McGill University Health Centre (MUHC) put forth 27 reports

with policy recommendations and 25 have been accepted and incorporated into hospital policy. Rejection or limited acceptance of 19 technologies saved the hospital approximately \$12.8 million and adoption of six new technologies successfully increased short-term investments in new technologies by \$1.0 million.²⁵

Health technology assessment groups can support medical device innovation in several key capacities. Globally renowned and trusted Canadian HTA centres can bring the best global technologies to Canada early in their development for testing, ensuring Canada gains access to state-of-the-art technologies. Strong HTA groups can also function as valuable knowledge resource centres for Canadian device manufacturers. Partnership between regulators and developers may help to expedite regulatory reform and improve innovative adoption. Partnership was an important topic of conversation at the Ontario Open for Business initiative where MEDEC advocated partnership between medical device industries and the Ontario Health Technology Assessment Committee to help guide the development of products, improve procurement processes and preserve Canadian access to global markets.

The fifth strength lies in the fact that Canadian policy has begun to support the medical device sector through tax incentives for research and development. Canada has some of the most generous scientific research and experimental development (SR&ED) tax incentives among G7 countries, however, these tax incentives do not support larger, more successful, companies.²⁶ Several Canadian provinces offer specific incentive programs. Ontario has a higher tax credit for companies contracting with business research institutes (20% versus the base credit of 10%) and Quebec has a higher tax credit for companies contracting with universities (28%). A federal tax credit offers medical device companies a 35% credit on their first \$2 million in revenue and a 20% tax credit for remaining expenditures. Provincial tax credits range from the base credit of 10% in Ontario and British Columbia to 15% in Newfoundland and Labrador, Nova Scotia, New Brunswick and Saskatchewan. Quebec offers a credit on salaries of 35%. The

impact of these tax incentives remains somewhat difficult to determine. An Alberta survey in 2001 found that of 24 survey respondents involved in SR&ED, only 5 qualified for federal SR&ED tax credits.¹⁵ In a study published by Deloitte, they found that many corporations are not claiming the SR&ED tax credits they are entitled to and that not all surveyed companies fully understood the tax credits available to them.²⁶ Tax incentives remain a vital element in the creation of a global medical device development hub in Canada.

In summary, Canada clearly brings strengths to the global medical device sector, including a highly educated population and an enviable health workforce with a strong track record in clinical trials research. Emerging evidence of strengths in med-tech hubs, academic-industry networks, policy, and tax incentives provide an important foundation for building capacity and economic competitiveness in Canada's medical device sector. Despite these inherent strengths, there remain a number of challenges and limitations for growth in this sector that must first be identified and overcome in order to advance Canada's track record and global competitiveness in the medical device industry.

The Economic Value of Medical Devices

The advancement of Canada's role in the global medical device market offers Canada the opportunity to bring the best quality of care options to Canadians more efficiently, thereby improving treatment outcomes for patients, promoting less invasive procedures, reducing patient recovery times and shortening length of stays in hospital. Improved health outcomes and reduced patient recovery time lowers the costs of treating patients and increases the capacity of the health care system to meet growing demands. The goal of all medical device innovations should be to reduce the burden on health systems while providing Canadians access to the latest innovations in medical devices for managing their health and wellness. Most evidence for the economic value of medical devices is anecdotal. For example, in a study conducted between

2007 and 2008, cardiac revascularization procedures, including angioplasty (with and without vascular stenting) were found to contribute to a reduction in cardio bypass surgeries by 7%. This decrease in open-heart surgeries is attributed to an emphasis on preventative measures as well as the adoption of minimally invasive techniques such as angioplasty. A shift away from coronary bypass surgeries towards interventional cardiology (i.e., angioplasty-based treatment) and the use of drug-eluting stents is associated with tremendous increase in the capacity for managing cardiac disease, resulting in substantial cost savings at the health system level, not to mention better outcomes for patients.²⁷

The medical device industry has gained attention recently for the relative stability of its returns despite weak economic performance of other industries in most global markets. In 2009, the medical devices industry had relatively flat growth: revenues for US publicly traded med tech companies fell by 0.1%, and European, public, med tech companies increased their revenues by only 1.1%. These numbers are not surprising considering the global economic “meltdown” which resulted in massive losses for a number of other industries.²⁸ In previous years, however, the medical device industry was much stronger. US companies increased revenue in every year since 2004, and in 2008, revenues for US companies were very strong, increasing by 11.2%.²⁸

Currently, Canada is a modest player on the global medical device stage, primarily as a purchaser and small exporter to the large US market. Despite current and projected economic gains for the medical device industry, Canada’s ability to attract and grow a strong R&D-driven medical device sector remains limited by a number of factors. Industry leaders are quick to identify the hazards of continued lackluster performance of this industry in Canada. If Canada is not able to actively support the growth of an innovative medical device industry, we risk further diminishing the quality of our national health care system. Neil Fraser, CEO of Medtronic Canada, estimates that many of Canada’s medical devices are already two generations behind in key areas

(ex. drug eluting stents) compared to those available in other countries, limiting the lifesaving and life extending benefits patients enjoy in other countries. Moreover, Canada risks losing access to some medical devices altogether. Canada is a small market compared to the US, and companies may not continue to make available or maintain cheaper, older generation devices for the Canadian health care market.

Challenges in Canadian Medical Device Innovation

Access to Capital

A supportive investment community is vital to successful medical device start-up companies and the growth of small and medium sized medical device enterprises. For start-up companies, access to external capital is especially critical. The average medical device path to market exceeds five years before a product begins recuperating initial investments.²⁹ But for many medical device start-ups and small device firms, stable and sustained financing through initial prototype and product development phases can become an impossible barrier to innovation.

Today, nearly 10% of Canadian medical device companies are spin-offs from universities, laboratories or other firms. Cash-strapped, small medical device companies often look to partnerships with venture capital firms, universities and academic hospitals to financially support the research and development of new technologies.¹⁴ The Canadian medical device industry is more or less dependent on partnerships with other institutions to research, develop, innovate and validate state-of-the-art technology. However, Canadian academic and clinical centres are often large and bureaucratic, making it difficult for inexperienced companies to access the system to achieve collaboration.¹⁴ Without access to universities and/or venture capital partnerships, small

companies can't access external government research funding, which is concentrated in large universities and other academic institutions. Thus, both private and public funding is scarce for many medical devices. Around the world, a feature of successful jurisdictions that have fostered a strong medical device industry is the close collaboration that venture capital firms, universities and other academic institutions enjoy. The strength of the US market is attributed, in part, to a strong venture capital base which typically adds additional resources during the critical development phase for medical devices. Venture capital firms may be more abundant and aligned with start-ups in the US, which adds to the overall pool of resources required to ultimately progress technologies to the point of acquiring regulatory approval.

In years past, venture capital investors were attracted to medical technologies because commercialization timelines were shorter and less expensive than pharmaceutical products and regulatory and reimbursement pathways were more straightforward.²⁷ Currently, the volume of venture capital invested in Canadian medical device companies continues to decline, making it more challenging for small companies to access the capital necessary to commercialize new products. In 2001, venture capitalists invested almost \$4 billion in Canadian medical device industries at a time when Canada held approximately 10% of the total North American venture capital for the medical device industry. By comparison, in each of the last 3 years, VCs invested roughly \$1 billion in Canadian medical device industries. In 2009, only 6.6% of total venture capital invested in North America was invested in Canada.³⁰

Canada's venture capital industry is much less mature than that of the US. Over the past decade, annual US venture capital investments in the medical device industry averaged nearly \$2.5 billion.²⁸ From 2000 to 2009, the value of venture capital investments in medical technology increased by 40% in the US and by almost 60% in Europe and Israel.²⁹

While Canadian medical device start-ups now often look to government grants to fund early efforts, both Stephen Dibert of MEDEC and Gary Hodgins of Trillium Medical Technology Association (TMTA), representing the voice of the industry, note that any government support for small and medium medical device enterprises should be made to achieve a positive return on investment. Poor investment guidance is a common complaint among Canadian medical device start-up companies who often lack investors able to provide mentorship and guidance to medical device companies.³⁰ In comparison to the US, Canada has proportionately fewer managerial employees with business degrees and a much shallower pool of technology executives.³¹ Gary Hodgins of the TMTA suggests that some of the difficulty medical device start-ups face in acquiring capital stems from their management's lack of business expertise. He suggests that innovation hubs must include collaboration with business schools to support start-up companies to develop high-quality and achievable business plans that promote stable growth.²⁹ This is something the Ivey Centre for Health Innovation and Leadership would certainly endorse and is a large part of our mandate.

With annual medical device consumption in China, India, Brazil and other developing nations in double digit rates, Canada can not afford to become less competitive as a center for global medical device venture capital investment. Within Canada, the Business Development Bank of Canada (BDC) finds itself limited in its ability to provide the VC funding medical device start-ups require, since these needs often fall outside the scope of standard "loans, investments and guarantees." Canada desperately needs to increase the flow of foreign and domestic venture capital to its medical device industries. This will be challenging for a Canadian venture capital industry that realized a 10-year IRR of -5% on cumulative investments in the medical device sector. It's going to take significant governmental, industry and academic effort to bring private LPs such as pension funds back into the Canadian medical device investment arena.

Research and Development and Product Evaluation

In order to develop, design, and commercialize innovative medical devices, a significant amount of research and development (R&D) is needed. On average, medical technology companies spend 11% of their revenue on R&D each year.⁹ This figure increases dramatically for small companies for whom up to 343% of revenue is spent on R&D.³¹ With over half of the medical device companies in Canada being small (57% have fewer than 25 employees), research and development capacity is a substantial challenge for this industry. Large medical technology companies replace a portion of their research and development with acquisitions of successful small medical device companies. Traditionally, large medical technology companies acquire smaller companies after their devices acquire regulatory approval, which minimizes the need for large investment in research, development and regulatory approval costs. Large companies prefer to acquire companies that already have a commercialized product which places a substantial burden for research and development on smaller companies with the least capacity for acquiring research resources.²⁸

For medical device start-ups and small device firms, stable and sustained financing through initial prototype and product development phases can become an impossible barrier to successfully overcome. As noted before, close to 10% of Canadian medical device companies are spin-offs from universities, laboratories or other firms. Cash-strapped small medical device companies often look to partnerships with universities and academic hospitals for research and development of new technologies.¹⁵ Thus, the Canadian medical device industry relies heavily on partnerships with other institutions to research, develop, and validate state-of-the-art technology. However, Canadian academic and clinical centres are often large and bureaucratic, making it difficult for inexperienced companies to access the system to achieve collaboration.¹⁵ Without access to universities, small companies cannot access the majority of government-provided research funding, which is concentrated primarily in universities and other academic institutions. The result in practice is that

funding for the medical device sector remains scarce. In Canada, close collaboration with universities and other academic institutions is essential to the survival and growth of any medical device company, whereas a strong venture capital base typically adds additional resources during this critical phase in the US.

The U.S. strategy to take advantage of the value of industry collaboration with academic research capacity is based on the 1980 Baye-Dole Act, which established technology transfer offices at universities to serve as liaisons between academia and industry.^{32, 33} These collaborations have been a key driver of national competitiveness³⁴ supported by a number of government initiatives³⁵. Technology Transfer Offices have led to the establishment of various forms of collaboration resulting in license agreements, spin offs and equity joint ventures.³⁶ Canada's universities have offices similar in nature to those established by the Baye-Doyle Act, however, these offices have not been as effective in creating paths to commercialization for valuable new technologies that could benefit health systems. One only needs to look at Canada's ranks as 24th among 30 OECD countries in the percentage of businesses that undertake collaborative research and development projects with other organizations, including academic institutions to know that our institutions are not achieving their full potential.^{37, 38} Canada clearly needs to strengthen technology transfer infrastructure and capacity for research and development, particularly for the medical devices sector.

Globally, there is evidence that faculty participation is a key factor in successful commercialization.^{38, 39} Entrepreneurial focus on commercialization within research intensive universities is a growing reality among universities in the United States, Europe, Australia and other developed nations facing competitive funding pressures.⁴⁰ Universities are becoming more adept at commercialization activities through experience⁴¹ and are gaining prestige as these activities generate much needed⁴² revenue. Universities that are able to create an entrepreneurial-minded environment for faculty have a higher

tendency to become involved in commercialization activities.⁴³ Recent research shows that younger, less highly-cited academics produce the highest proportion of commercial outputs and put more effort into balancing research output and commercialization than their more senior colleagues.⁴⁴

A major challenge in building partnerships between industry and academia is bridging the gaps between each party's requirements surrounding technology transfer and intellectual property disclosure. Gary Hodgins, Chairman of the TMTA, believes many Canadian universities do not fully respect and recognize the rights intellectual property of a company that initiates a contract for research and development with academic research teams. Thus, some universities make what industry partners often believe to be unreasonable demands for intellectual property distribution. In addition, the pressure to publish research outcomes for promotion and tenure advancement at Canadian Universities is a challenge for medical device companies who strive to sustain a competitive advantage by protecting key elements of intellectual property from publication³⁴. Other challenges that both academic researchers and industry partners experience include managing very different timelines and priorities for research. Industry prefers short-term, finite timelines for commercialization outputs, whereas universities typically undertake longer term programs of research which may or may not be of direct interest to industry partners.⁴⁵

Canadian medical device industries are equally in need of consultative partnerships with health professionals in clinical practice. Research and experience show that physician partnership and consultation throughout the design, testing and validation phases of new medical device technologies is a key to success for this sector. Physicians assume an important role in medical device companies by sharing expert knowledge of health care trends and health needs of specific populations which is the basis for device development. Of 26,158 medical device patents granted by the US Patent and Trademark Office between 1990 and 1996, 5,051 (19.3%) had an inventor who was a licensed physician.⁴⁶ Physician/Surgeon patents receive more citations (15.2 versus 12.7)

on average and have higher generality scores (0.41 versus 0.39) than corporate inventions due to the sense of ownership of the physician partner and the relative ease of access to clinical facilities for testing and proof of concept evaluation. As end-users and distributors of medical devices, physicians/surgeons have the opportunity to assess how devices can be successfully incorporated into patient workflow and how interfaces between clinicians, patients and new technologies can be improved, optimized and streamlined. Without physician involvement in product development, medical devices risk becoming engineering marvels with no practical capacity for system adoption. However, according to industry leaders, physician involvement with medical device developers and manufacturers in Canada is limited. Medical device companies struggle to build relationships with health professionals, particularly physicians, who are uniquely positioned as key stakeholders who are knowledgeable of real and immediate health system needs.

The US market offers an important advantage to medical device companies designing and testing their new technologies to achieve approval, known as the 510(k) which is a premarket notification (PMN) clearance from the Food and Drug Administration (FDA). 510(k) clearance allows a medical device company to bypass the expensive and time consuming randomized clinical trial process, as human data are not usually required for the application. However, 510(k) clearance requires a company to demonstrate a substantial equivalence to products already on the US market that have been cleared by the FDA or marketed before 1976. In order to do so, the medical device company submitting the 510(k) application needs to demonstrate that the difference between their “new” device and the predicate device is acceptable for FDA clearance. This permits US medical companies to attain rapid product launch and hospital integration.

In Canada, there is no equivalent 510k approval opportunity resulting in the regulatory process for approval of devices being substantially more challenging

than in the U.S. Since new devices are only on the market for approximately 18 months before new versions of the device are ready for introduction into the market, the cost to enter the Canadian market is higher and the opportunity to re-coup the cost is shorter. Moreover, in Canada, every time a new and improved version of a device enters the market, it must begin the regulatory processes all over again. The absence of a 510k type of strategy means that a company cannot continually improve a product in rapid succession (every six months) for the Canadian market. In addition, products which receive 510k approval in the US are difficult to get approved in Canada since clinical trial evidence is required by Health Canada.

Canada's evidence requirement for class III and IV devices is higher than the standards employed in the US. With Canada as a secondary market for domestic device firms, ease of access to clinical resources is particularly important for a country that needs its device developers to survive long enough to profit in the US and so that their products can in turn come back to service Canadian markets. A senior executive at GE Healthcare states that it is always necessary to perform clinical evaluation prior to launching a new device. But in Canada, regulation is so stringent that effective trials can only begin late in the process; to the point where testing occurs after the product is launched in other countries. The result: Many companies simply avoid the Canadian market for new devices.

To make matters even more expensive, each provincial jurisdiction employs their own unique regulatory hurdles. These are discussed in greater detail in the next section.

Regulatory Structure in Canada: The Challenge of Combination and Connected Devices

Canada's regulatory framework will continue to be challenged in the near future by two emerging types of devices, combination devices which facilitate drug delivery, and connected devices which record, store, transmit and display patient information. The majority of new medical devices have one or both of these functions. The challenge for obtaining approval of these new generation devices is managing three distinct, and sometimes conflicting, regulatory processes: a) device regulations, b) drug/pharmaceutical regulations, and c) privacy of information laws.

Combination devices must meet both the device regulations and the pharmaceutical regulatory processes in order to gain approval to enter the Canadian market. Medical devices can achieve Health Canada regulatory approval in as little as 4 to 6 months depending on the risk category, but pharmaceutical regulation can take many years to achieve regulatory approval. The long approval process for pharmaceuticals severely limits any opportunity for these new combination devices to be launched in Canada. The combination device is simply not profitable in the market long enough to be worth entering the market. Thus, the majority of companies avoid launching these devices in Canada or simply narrow the development of new combination devices to include only the use of previously-approved drugs for these medical devices in order to accelerate the approval process. Truly new and innovative combination devices simply do not enter the Canadian marketplace and are certainly not developed here. The loss to the industry is profound, but the loss to the health system of these innovations could be even more costly.

Similarly, electronic devices with embedded computers to enable wireless patient monitoring and transmission of patient data are governed by Canada's privacy laws. Canada's federal Privacy Act that applies to health care is known as PIPEDA (Personal Information Protection and Electronic Documents Act).

PIPEDA sets out principles that organizations, individuals, associations, partnerships and trade unions must follow when collecting, using and disclosing personal information in the course of their commercial activity. However, PIPEDA does not apply to personal information in Provinces and Territories that have legislation in place for commercial activities that are provincially/territorially regulated. PIPEDA also does not apply in Quebec. As a result, companies must navigate as many as 23 different privacy legislative processes in order to launch a new device across Canada. Considering the size of the market to begin with, it is simply not worth it for many niche use products to enter the market.

Innovative combination and connected devices that hold great promise for innovation in health care services and treatment procedures are often not available in Canada due to the challenges of achieving regulatory approval. The widely held view is that Canada's regulatory infrastructure simply isn't sophisticated enough to keep pace with medical device innovation and approval processes are so cumbersome across each provincial jurisdiction that many companies simply elect to avoid the Canadian market.

Both Europe and the U.S. may provide important "lessons learned" for achieving a stronger, more streamlined regulatory framework for the medical device industry in Canada. In Europe, the privacy laws were unified under the European Directive on Protection of Personal Data, which provides a single point of access to regulatory processes for European countries. In the US, the Health Insurance Portability and Accountability Act (HIPPA) is another example of streamlined, single regulatory standards that apply to every state in the Union. To facilitate business between the EU and the US, safe harbor principles were developed so that companies could ensure that adequate protection is given to personal information transferred between the EU and the US. Canada does not have safe haven laws that would allow Canadian data to be stored in jurisdictions where privacy laws are substantially similar to PIPEDA. The European Union and the US have both achieved a streamlined approach to

regulation that Canada could learn from in order to stimulate and strengthen the medical device industry in Canada.

Procurement and Adoption of Devices

The procurement processes of Canada's publicly funded health systems are often cited as barriers to the adoption of innovative medical devices. Restrictive procurement practice reduces the opportunity for sales of new devices; it also limits the opportunities to achieve health system outcomes such as quality patient care and health system sustainability. Hospital procurement of medical devices in Canada remains fragmented. Each of the ten provinces and three territories manages and operates its own health care system, creating 13 Canadian jurisdictions, each with different levels of centralization, different health system priorities, different statutes and different regulatory authorities. Cameron Hay, (former) CEO of Unitron Canada, suggests that the fragmentation among provincial regulators make Canada the toughest regulatory and procurement system in the world.

Why is procurement so challenging? There are two reasons: The capacity of the buyer to understand and properly evaluate the "cost" vs. "value" of a medical technology, especially in the long-term; and second, the short-term fiscal challenge and constraints faced by every institution in the health system.

Traditionally, the medical device industry marketed products directly to physicians and surgeons who would then advocate for their organizations to purchase new devices to improve the quality of patient care. Hospital supply officers would be directed by physician leadership to acquire new devices needed for patient care. Physicians and surgeons assumed an important role in clinically evaluating new medical devices, and procurement processes were managed under the direction of the chief financial officer of the hospital or clinical agency. Today, it is estimated by industry insiders that 75% of supply chain officers are "old school buyers", 20% are well-trained, and only 5% are

professionally qualified as procurement professionals who understand how to best identify total value of the products and technology they procure.⁴⁷ This traditional system of buying has changed dramatically in response to substantial fiscal restraint policies established by government policy makers to control the escalating costs of health care services.

Over the past number of years, fiscal restraint policies in health care stimulated a major shift in procurement processes in Canadian health systems. In the past, the emphasis was on patient care quality, but now the system is much more focused on cost containment and reduction. One strategy to cut costs and manage budgets employed by health agencies, particularly hospitals, was to join group purchasing organizations (GPOs). These were established to negotiate with medical device companies and other providers of goods and services to drive down costs through “bulk” purchasing. These GPO’s, in turn, become very powerful “monopolies”, who negotiate with suppliers to drive down the unit cost in return for larger contracts to supply devices to multiple agencies. In the device sector, the singular focus on the cost of devices has resulted in decisions to acquire new devices, often with little attention to quality of patient care outcomes and limited, if any, involvement of physicians or other health professionals. The net outcome of this approach achieves cost savings in the short term, but may be detrimental to innovation at the health system level. This is particularly problematic for procurement of new and innovative combination or connected devices that are more costly and serve a narrower patient population, but may offer substantive health system cost savings associated with shorter lengths of stay in hospitals or reduced need for hospital admissions.

More recently, these and other procurement challenges led Ontario to create a Broader Public Sector (BPS) Procurement Directive that prescribes procurement guidelines for the majority of public sector organizations including hospitals, school boards and community care access corporations.⁴⁸ The BPS guidelines outline the competitive processes that all public sector agencies must follow.

For example, procurement of goods, non-consulting services and construction under \$10,000 does not require a competitive process. Contracts whose value is \$10,000 or greater (up to \$100,000) require an invitational competitive procurement approach with a minimum of three suppliers invited to submit a bid for pricing, whereas projects \$100,000 or greater have a more open competitive process.

Although the development of a BPS approach achieved a more transparent competitive process, it also presented substantial challenges for the medical device industry, particularly affecting small medical device companies. Across the country, medical device procurement is managed by different GPOs applying a variety of different approaches and standards. HealthPRO is one of Canada's largest GPOs with hospital members in British Columbia, Alberta, Manitoba, Ontario, New Brunswick, Prince Edward Island, Nova Scotia, and the territory of Nunavut. MedBuy is another national GPO with members in Ontario and New Brunswick.⁴⁹ A group of MedBuy pharmacy contracts were reported to save member hospitals and healthcare organizations more than \$90 million over a 39-month contract term. This procurement encompassed thousands of items representing nearly 80 percent of product purchases in MedBuy's complete pharmacy program (or 25 percent of the total SKUs MedBuy has on contract).

While MedBuy's pharmacy procurement highlights the potential cost-saving benefits of these organizations, it also illuminates the reality that GPOs favor large companies with diverse products who can compete on cost. Smaller suppliers, regardless of the quality or superiority of their products, are often unable to bid on larger contracts due the challenge of meeting large volume requirements to satisfy group orders and the limited number of products they have to offer. The group purchasing model for procurement may offer short term cost savings to participating members, but this approach essentially ignores small companies where many innovative technologies and products are developed in niche areas of the medical device market.¹⁵ Since the majority of

Canada's medical device companies are small to medium in size, this is a major limitation for growth of the medical device sector in this country.

The outcomes of procurement agencies, relative to cost containment and purchasing power, are not surprising. In such a system, there are no incentives for these agencies to support much needed innovation in health systems. Group purchasing has influenced a dominant focus on price with very limited attention to innovation and change at the health system level. Procurement has emerged as one of the most significant challenges facing Canada's medical device industry today. MEDEC, the largest industry association for medical device companies, has long identified procurement issues as a priority concern that needs to be addressed.

The Ontario government, for one, has responded with the Ontario Ministry of Finance Open for Business initiative which is examining solutions to these challenges.⁵⁰ This initiative allows for innovative devices to gain access to hospital procurement through "Alternative Proposals" and "Value Add Incentives." These are two types of contracts where companies can propose their own alternative products in lieu of a GPO's requested product, or may add innovative new products to their proposed contracts. For example, a GPO requesting proposals for medication delivery pumps may receive an alternative drug delivery method submitted as an alternative product, or a new pump with remote monitoring and provide additional funding to support clinical research to bring the innovation to market. Alternative Proposals and Value Add Incentives are a worthy attempt to ensure innovative products gain entry into hospitals, but there is little evidence that this outcome has yet been achieved.

Many industry stakeholders fear GPO procurement practices which favour large companies not only limits opportunities for small companies to compete, but may also lead to purchasing monopolies. There is anecdotal evidence that purchasing organizations pressure medical device companies to ignore best practices that may ultimately influence quality of patient care. For example,

the re-use of single use devices is a practice that many medical device companies consider very risky. There is much debate amongst hospitals and suppliers around the reuse of single-use devices - perceived by some to have substantial potential savings.⁵¹ Single use medical devices must meet rigorous regulatory approvals that are based on the condition that the device is used only once and then discarded. However, hospitals and third party agencies can reprocess single use devices with no requirement to adhere to the regulations that had to be met by the company producing the single use device. The practice of “reprocessing” single use devices appears to be common in Canada. In 2008, CADTH surveyed Canadian acute-care facilities and found 28% of survey respondents (111 of 398 interviewed) reprocessed single-use devices. 85% of hospitals reprocessed in-house instead of using third-party re-processors. In many cases, reprocessing devices intended for single use has the potential for device malfunction or breakdown, which can place patient safety at substantially greater risk. When health organizations are challenged by device manufacturers regarding reprocessing single use devices, GPOs are powerful advocates for organizations and have the ability to retaliate and cancel contracts with any company who challenges the practice in member organizations. Thus, although GPOs were designed to augment purchasing power and achieve cost effective procurement of medical devices, the monopoly type power of these organizations has not only compromised the viability of many medical device companies, it may also be placing substantial risk on quality of patient care for hospitals and clinical settings who engage in questionable procurement approaches.

The central focus of procurement on cost in provincial health care systems in Canada is one of the most significant challenges to the medical device industry. So long as hospital procurement officers and GPOs maintain a rigid focus on a short-term cost-reductionist viewpoint, procurement will remain a barrier to the growth of the medical device industry in Canada and will severely limit the adoption of innovative medical devices to the detriment of public health system sustainability and quality of patient care. Medical devices often require

substantial up-front investments for health systems, but produce important savings that improve health system capacity and productivity far into the future. In order for Canada's health system to reap the benefits of new innovative technologies, procurement processes must consider quality of patient care and long-term system-level efficiency as key indicators for the procurement of innovative medical devices. Procurement processes should be guarded against powerful monopolies that do not serve the needs of health consumers in Canada and act as a deterrent for growth and innovation in the medical device industry.

The Global Medical Device Market

Globalization and the expansion of global trade in the medical devices sector has resulted in regulations and standards becoming increasingly harmonized across borders, making it easier for companies to access many different global markets.¹⁷ As global markets continue to grow, international competition in this sector will increase as developing countries such as China and India increase the demands for medical devices at double-digit rates. However, Canada's challenging regulatory climate poses a major limitation for medical device companies to invest and establish a presence in Canada. As a result, China, India and other emerging markets grow more attractive for medical device companies looking to bring new and innovative products to market.

China is estimated to be the sixth-largest market in the world and one of the fastest growing markets globally. The Government of China is investing in health care infrastructure and implementing a new set of health insurance programs with the objective of providing coverage to 90% of the population through its Healthy China 2020 health care reform plan.²⁸ In March 2010, China's State Food and Drug Administration (SFDA) launched a new center, the Management Center for Medical Device Standards, to rationalize and streamline the country's regulatory procedures for medical devices. The SFDA increased regulatory requirements and forced device manufacturers to register products in the

country of export before seeking registration in China. Devices demonstrating compliance with international standards (in their country of origin) no longer need to undergo testing in Chinese labs to gain approval. In 2009, the Chinese Ministry of Health restricted the purchase of medical devices that cost more than 5 million RMB (US\$710,000).

Similarly, India is an obvious growth market for medical devices. Currently, India does not comprehensively regulate the safety and efficacy of medical devices, but in 2009, India introduced new legislation known as The Central Devices Act to establish standards and regulate the safety and efficacy of devices. As this regulation takes hold, rapid growth of this market poses additional competition for small device markets such as Canada.

Traditionally, Canadian companies have always looked to the US as their main market and the FDA's 510(k) regulatory clearance as the most important regulatory approval for launching new medical devices. The 510(k) clearance has come under scrutiny recently and changes have been proposed to make it more reliable and fair. Canadian device companies are concerned that changes made to this process will increase the timelines for gaining regulatory approval, reducing product life cycles even further. As a result of the expected changes there may be opportunities for many small companies in Canada to consider shifting towards the EU and to domestic Canadian markets as their primary markets for crucial first attempts at achieving regulatory approval and gaining market entry.

In addition to potentially stricter regulations on imports in the US, the US market is also introducing a new excise tax on medical devices beginning in 2013. The excise tax will apply to all manufacturers of devices sold in the US.²⁸ New initiatives in the US may force companies to market products differently. In the Obama administration's February 2009 stimulus spending package, \$1.1 billion US was allotted for comparative effectiveness research (CER). CER is very similar to HTA in Canada. Comparative effectiveness research will shift global

evaluation standards and force companies to demonstrate effectiveness of new devices beyond quality. This will be a large shift for the US market, which has the potential to open up opportunity for the Canadian market if the major challenges in Canada can be addressed to increase the competitive strength of Canadian medical device companies.

International Best Practices in Medical Device Markets

Canada can learn from other countries that have successfully attracted medical device industry development to their home soil. Ireland, Switzerland, Singapore, The Netherlands and Puerto Rico have all achieved considerable success resulting from policies aimed at attracting and building centres of medical device industry innovation. These countries focus primarily on supporting manufacturing and exporting medical devices. Similar to Canada, all of these countries have a talented, highly educated workforce and offer funding or tax incentives to attract medical companies.

Puerto Rico is a major medical device manufacturing centre and, as protectorate of the United States, enjoys access to the U.S. market. 7.6% of medical equipment used in the United States is made in Puerto Rico, with 50% of all pacemakers and defibrillators sold in the US manufactured in Puerto Rico.⁵² The Puerto Rican government has worked hard to provide medical device companies with very attractive tax rates and easy, tariff free access to the US market.⁵³ Puerto Rico's government works hard to accommodate foreign companies and even operates a medical sector business liaison office to ensure companies are comfortable doing business in Puerto Rico.⁵²

Puerto Rico has capitalized on its ideal location to become a transportation hub for the Caribbean and has developed shipping infrastructure to support the export of devices.⁵³ The Puerto Rican education system is strong, graduating

9,000 bilingual university students a year with degrees in science, engineering, and technology.⁵² Puerto Rican wages are roughly 20% to 30% lower than those paid in the US, offering a competitive advantage in manufacturing.⁵²

Where Puerto Rico can offer tariff-free access to US markets, Canada can only offer access to its market of roughly thirty-four million people. Building medical devices in Canada is said to hold only a 4.1 % cost advantage over doing business in the US - an advantage easily wiped out by our higher regulatory cost.¹⁰ More recently, a strong Canadian dollar has further diminished the cost benefits for American businesses that may consider manufacturing in Canada.

Of the five countries we researched, Switzerland offers the best example of a country that supports its medical device industry from conception through research and development, clinical testing, and manufacturing. Medical technology is one of the fastest growing sectors in Switzerland with an average growth rate of 6-8% per year in each of the past 15 years.⁹ Sales in medical device technology reached 22.9 billion Swiss Francs (approximately \$23.5 billion Canadian dollars) in 2008.⁹

Switzerland has a global reputation for innovation. The Swiss medical technology sector consists of 700 or so companies employing 49,000 people. Many companies manufacturing in Switzerland are foreign-owned,⁹ but they are ranked fourth in the world for innovation by the Institute for Management Development and is rated as Europe's most innovative nation among a cluster of 27 European Union members (reported by the Maastricht Economic and Social Research and Training Centre on Innovation and Technology).

Switzerland effectively lured foreign medical technology companies with an attractive tax regime. The effective tax rate in Switzerland for medical device companies is 7.83%, reaching up to 25% when municipal income tax is accounted for.⁹ Switzerland has the lowest value-added-tax in Europe and is competitive with any economic region in the US.⁹

One of the key components of Switzerland's med tech industry success is the rapid adoption of medical devices into the Swiss health care system. New products can be introduced into the domestic market quickly, providing companies with rapid market access and crucial proof of concept market access.

Networking has been another key component in Switzerland's med tech industry. In 1997, the Swiss federal government set up their CTI Med Tech Initiative to promote innovation. The initiative encourages knowledge transfer between industry and academia, clinical and developmental researchers. An independent hub known as the Competence Center for Medical Technology (CCMT) offers support for device companies to partner with Swiss academic research partners that fulfill the need for research and development capacity in this sector.

Canada has much to learn from the success and achievements of other countries in strengthening the competitiveness of their medical device sector. Models demonstrated in Switzerland and Puerto Rico, in particular, offer important insights into strategic initiatives Canada can learn from to strengthen the medical device industry in this country and capitalize on the growth of this global market for substantive economic advantage.

Recommendations for a Strong Canadian Medical Device Sector

Our research shows that there are four key components that are strategically important to building and sustaining a strong medical device sector in Canada. Communication between stakeholders, research capacity, procurement, and regulatory processes are the focus of the following recommendations that would strengthen this economically important medical device sector in Canada.

1. Build a national strategy to enable links and partnerships between industry, government, and health system stakeholders to develop a strong and vibrant medical device industry.

Canada will need to:

- a. Build a national strategy for developing a strong medical device industry, focusing on regulation, legislation, and procurement. Specifically, streamline these processes within each province to limit fragmentation and to improve industry access to all health systems in Canada.
- b. Maintain an open and ongoing dialogue between the medical device industry, government and health system stakeholders. The medical device industry is constantly changing. Key stakeholders need to be able to anticipate changes in medical devices and respond appropriately in terms of regulation and procurement to support innovation adoption.

2. Create supportive environments and partnerships for the medical device industry to grow and thrive through access to research capacity and health sector innovation across Canada.

To achieve this, we recommend:

- a. Transform existing med tech hubs across the country into active networks of multi-sector partnerships that actively engage academic researchers in universities, health professionals in hospitals or clinical agencies, the community sector, and medical device companies (small and large) in collaborative partnerships to foster the development of active programs of research and development for new medical device technologies.

- b. Build capacity for research and development to act as a "pipeline" for new device innovation. Better coordination between researchers, the medical device industry, practitioners, regulators and health system leaders will augment the ability to improve health system access to more knowledge. Academics are a valuable source of much needed technical support and R&D capacity for commercializing new technologies.
- c. Create innovation laboratories in more clinical settings that support proof of concept testing of new medical devices in partnerships with medical device companies. Innovation laboratories that specialize in the medical device sector offer important advantages to clinicians who are able to lead innovation in new treatment processes and health care services by leveraging advances in the medical device industry. This has the added effect of strengthening quality of patient care and advancing the productivity and sustainability of Canada's health care system.
- d. Establish and maintain a single point of entry (using the proposed networks of innovation) for medical device industry partners to collaborate with the health sector in Canada. Market access is essential to the survival and growth of the Canadian medical device industry.
- e. Leverage Canada's strength in health technology assessment. Throughout the world, regulatory landscapes are shifting primarily from quality-based assessment to more efficacy-focused assessment. Canada has tremendous experience with HTA and can offer expert assessments to medical device companies and continue to improve local skill sets to sustain this capacity well into the future. This expertise should be marketed and promoted aggressively around the world as a competitive advantage.
- f. Develop clinical trial and health technology assessment partnerships to attract medical device companies seeking world-class clinical trials.

Canadian medical device industry partnerships shared by academia and hospitals are endangered by the preference of large and mid-sized medical device companies to pursue partnerships with universities in the US. Canadian medical device companies believe clinical trials and research collaboration with prestigious US university brands will carry more weight in promoting their products. Strong medical device clusters centred on Canadian academic health centres may create a recognizable and prestigious Canadian medical device "brand." Branding Canada's high quality medical device industry and development professionals may aid Canada in capitalizing on emerging global opportunities in the medical device sector at a time when the U.S. regulatory environment is changing and growing markets such as India and China are increasing their purchasing power.

3. Reform procurement processes to accelerate the ability of medical device companies to test and launch new technologies in the Canadian market, with the advantage of achieving more effective processes for the export of new medical device technologies globally.

We recommend:

- a. Creating mechanisms of accountability for procurement approaches that examine both the up-front investment costs of new medical devices, and the long-term health system impact of new medical devices relative to quality of patient care and the potential for innovation adoption to support health system sustainability.
- b. Replacing monopolistic procurement practices with open, collaborative practices that engage key stakeholders in evaluating and procuring innovative medical devices in Canada's health sector. The adoption of innovative technology needs to become a priority in Canadian medical device procurement approaches. GPOs cannot afford to focus solely on cost reduction; nor can the Canadian health sector be limited by

monopolistic group purchasing organizations whose influence has a negative impact on innovation in Canada's health care system and limits growth in the medical devices sector.

- c. Finding procurement approaches that leverage the expertise of small medical device companies in Canada. More than half of Canada's medical device industry is comprised of small companies employing less than 25 employees. Although it is acknowledged that several start-up companies may not intend to independently market their technologies, rather have them acquired by larger companies, procurement still assumes a critical role in stimulating growth of the medical device sector by supporting successful start-up companies and providing them revenue to grow into medium and ultimately large, globally-competitive medical device companies.
- d. Establish health industry best practices for procurement that support both innovation in Canada's health care systems and the growth of Canada's medical device industry. New government procurement policy may stimulate Canadian medical device innovation. The UK's National Health System built several collaborative commercial agencies to work with Strategic Health Authorities (SHAs) in developing expertise and establishing health industry best practices in procurement. Since April of 2009, each SHA has had the legal duty to promote innovation and continuous improvement in the commissioning and provision of health care. The UK's NHS has recognized the importance of procurement practice in achieving successful innovation adoption and is moving to facilitate best practices.

4. Reforming regulatory processes to reduce the time to market for medical devices in Canada, support research and development while adhering to high standards of safety and risk reduction.

Canada should:

- a. Continue to evolve its regulatory standards to build world leadership in speed and quality of medical device regulatory processes. Establishing streamlined regulatory paths for devices that have already obtained regulatory approval in countries with comparable standards could dramatically improve access to the medical device market for med tech companies and reduce wasteful resources that delay time to market.
- b. Learn from regulatory processes in both the EU and the US whereby a single point of access and regulatory process have been achieved to grant approval to new medical device technologies. These regimes carefully evaluate and regulate devices in a manner that is comprehensive and systematic, providing timely access to every jurisdiction within their vast markets without undo repetition. It's a model Canada could adopt across all 13 provinces and territories, though we recognize the challenge of provincial jurisdiction in achieving this goal.
- c. Work with regulatory agencies in both the US and EU to come up with a timely, transparent, and clear regulation for combination devices. Canada needs to align regulatory standards for pharmaceutical, medical device and privacy legislation for combination devices so that health systems can benefit from these new and emerging technologies. New medical devices are leveraging health information technologies and advances in pharmaceuticals to offer substantive innovations for patient care, particularly for chronic disease management. The advantages are clear. Long and arduous regulatory environments limit the

availability of these devices to health systems and compromise innovation in the health sector.

- d. Determine new ways to partner with other jurisdictions to streamline the evaluation of connected medical devices. Canada should seek to harmonize its health-information related privacy legislation across all provinces and territories. Models for unified legislation like those in the US (HIPPA) and the UK are well established and can be learned from. These regulatory regimes would be further strengthened by safe harbor agreements with countries that have comparable legislation. Canada is too small of a market to entice device manufacturers to adapt their products solely for Canada and absorb the substantive challenges and expense related to undergoing multiple regulatory processes. If Canada is unable to harmonize its privacy regulations, it risks being left behind in IT-based medical devices.

Conclusion

There is no doubt that medical devices play an important role in modern health care. They improve treatment outcomes, promote less invasive procedures, reduce patient recovery times and shorten the length of hospital stays. Medical device innovations improve health system capacity for effective preventative health care and reduce health system costs. They are a key weapon in Canada's battle to achieve health system sustainability and to gain a competitive advantage in growing global health markets. The Canadian health care system needs to utilize innovation to meet an aging population's growing demand for health care services. They are also an important potential source of jobs and economic wealth for Canada.

Canada is not a global leader in medical device development or manufacturing. We produce 3% of the world's medical device output and export 78% of that to

US markets; often bypassing domestic markets because of burdensome regulatory structures and small market size. Canada must compensate for its small market population in the attraction of global medical device leaders to ensure state-of-the-art medical devices become available in Canada.

Canada can no longer allow its medical technology start-ups to go unsupported in their quests for R&D partnerships and resources. To survive, Canada's medical device industry must be strengthened and supported by partnerships shared between industry, academia and health systems working towards innovation adoption. Successful medical device industries require access to physicians and engineers for research and development and clinical trials, access to Canadian hospitals and harmonization of privacy legislation across provinces.

Canada's current medical device procurement processes stifle medical device industry growth - in fact, industry leaders call the procurement environment in Canada "ugly." Presently, procurement managers too often limit their attention to the short-term costs of devices while ignoring the long term potential for innovation and health system productivity. To overcome this, procurement processes need to be better at engaging the expertise of health professionals, particularly physicians, to add a layer of sophistication and system-wide thinking to the procurement process. The complexity of medical device procurement has transcended the short-term cost savings of bulk purchasing. In other words, Canadian medical device procurement needs a cultural revolution and overhaul.

Despite limited performance in the global medical device sector and the inability to get state-of-the-art medical devices into our own health system, Canada has the knowledge resources and academic infrastructure to support a world-class medical device innovation hub. A well-educated, multicultural population and world-renowned health practitioners give Canada unique advantages in attracting large foreign medical device companies to work and

sell in Canada. Canada's medical technology hubs are growing and improving Canadian capacity for R&D.

This is a pivotal time in Canadian economic history where government and health leaders must take advantage of the potential for medical device innovation to improve our health system and gain global competitive economic advantage.

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