

**Senate Standing Committee on Social Affairs, Science and Technology  
Study on Robotics, Artificial Intelligence and 3d Printing**

**Health Canada's Response**

**Question #1**

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*This committee has heard from several witnesses about the fast pace of innovation in the areas of robotics, AI and 3D printing, as these areas pertain to the healthcare system, over the course of the past 12 meetings of this study. While the delivery of healthcare is under provincial jurisdiction, the safety of health products, including medical devices, is federally regulated.*

- *Does Health Canada proactively monitor technological innovation with respect to health products, for example through expert advisory panels or attendance at industry conferences? If yes, please describe the activities the department has undertaken in this regard and what effect this has monitoring had on policy development.*
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**RESPONSE:**

Yes, Health Canada proactively monitors technological innovation with respect to health products, including through expert advisory panels, attendance at conferences, and participation in international organizations. The Department also conducts forward-looking analyses to monitor scientific advances, new technologies and other trends that could have an impact on the health care system and on Health Canada's regulation of health products and food.

Health Canada employees have access to several expert advisory committees composed of subject matter experts on a wide range of subjects. These committees, such as the Science Advisory Committee on Medical Devices Used in the Cardiovascular System, are often the first line of formal advice given by external advisors in policy development processes. The Department's Director General Science Committee also invites external experts to provide advice on specific subject areas to inform the policy development process.

Health Canada's regulatory branches also hold regular meetings with companies and industry associations to understand what new products are in their development pipelines, especially those using particularly innovative technologies. We are also exploring greater alignment with the Canadian Agency for Drugs and Technologies in Health (CADTH) which could help streamline the regulatory review process for certain products.

The Health Canada Science Advisory Board (SAB) is composed of external experts that provide advice and expertise to the Health Canada community. In 2015, the SAB provided advice on opportunities for innovation in the medical devices sector and potential future challenges for regulatory oversight within Health Canada's current regulatory framework. Health Canada has also engaged the Council of Canadian Academies, an independent, not-for-profit organization to provide assessments of the scientific underpinnings of emerging technologies and issues.

Domestically, Health Canada supports organizations such as the Conference Board of Canada – an evidence-based research organization that provides forecasting and expert advice. In addition, under the Government's Innovation Agenda, Health Canada co-chairs two advisory groups with members of the Canadian Council of Innovators (CCI), a business council dedicated to helping high-growth Canadian technology firms scale up globally. The CCI Health Canada-Health Tech Medical Devices Advisory Group and the CCI Health Canada-Health Tech Digital Infrastructure Advisory Group focus on the Canadian medical manufacturing sector and on the software, data and digital health area. Along with interactions with Medical Devices Canada (MEDEC), the association for Canada's medical technology companies, engaging with these groups will provide a window into disruptive technologies. Health Canada also meets biannually with leading cardiovascular and thoracic surgeons as part of the Medical Devices Used in the Cardiovascular System Scientific Advisory Committee. In this way, Health Canada pulls in leading experts from operating rooms and academia across a plethora of technologies and procedures to obtain the best available advice for us in our role as a regulator.

Access to the international community is critical as it ensures that Canada has the opportunity to learn from world renowned experts, early adopters of technological innovations and our international counterparts. Leadership in international organizations allows Canada to influence international agendas and align Canadian progress with global trends. Health Canada collaborates with its international counterparts, for instance through the International Medical Device Regulators Forum, on joint initiatives and reducing regulatory barriers to innovation.

Health Canada employees regularly attend conferences and meetings to engage directly with experts on cutting edge science and technology. Employees attend subject-specific meetings and conferences such as those focussed on genomics and innovation in the health sector, providing insight into investment trends and the future innovations that will require regulatory oversight. Health Canada also participates in a wide variety of international fora at which innovations in the health sector are raised including the World Health Organization, Food and Agriculture Organization, and Organisation for Economic Co-operation and Development (OECD). Health Canada is an active participant in the OECD Health Committee and Working Party on Biotechnology, Nanotechnology and Converging Technologies where health economics, health systems, transnational governance, science, and risk assessments of innovative technologies are discussed. Program areas within Health Canada also participate in a wide variety of international working groups focused on the improvement of public policy, decision-making and governance.

Particularly when dealing with rapidly developing fields, it is important that policy development be undertaken with the best available information, an understanding of the direction of trending technologies, and an understanding of common policy implications with partner jurisdictions. Policy development is supported by the exchange of information and perspectives within a number of intra- and interdepartmental working groups. These working groups often seek input from external experts who are invited to present current science and associated issues to employees. The Science Policy Directorate, within the Strategic Policy Branch, is responsible for monitoring emerging science and technologies - and liaising across Health Canada, as well as across government and internationally - to ensure that Canada is informed on progress in these areas. This Directorate maintains strong departmental and interdepartmental networks at the working level that identify emerging challenges for Health Canada.

As a regulator, Health Canada keeps its focus on the ultimate beneficiaries of innovative therapies and treatments. It is imperative that the Department proactively prepares and adapts its approach so that it is ready to evaluate innovative products developed and tested using innovative methods. Health Canada uses its forward-looking analyses to inform its investment in information technologies, training, recruitment and regulatory development. Innovative health products can make a real difference in the lives of Canadians, and the Department strives to fulfil its mandate to protect the health and safety of Canadians while facilitating innovation.

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**Question #2**

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***Does this broad definition [from the Medical Devices Regulations] of a “device” capture those products developed within the robotics, AI and 3D printing sectors that have healthcare applications? If not, why not?***

***If yes, do the Medical Devices Regulations need to be updated in order to better address these new technologies?***

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**RESPONSE:**

The Medical Devices Regulations (the Regulations) are a risk-based framework to effectively and efficiently manage over 1.3 million medical devices currently commercialized in Canada. The Regulations are flexible and well adapted to accommodate innovative technologies, and so no change to the Regulations is being considered at this time.

Under the regulations, there is a set of Classification Rules based on potential hazard(s) of the device. Through these rules, devices are sorted into Classes. Class I represents the lowest risk while Class IV represents the highest. Generally, Classes increase with risk – Class I devices include toothbrushes and thermometers, while Class IV devices include pacemakers and cardiac stents. A robotic device which functions without human input would be a Class IV medical device (i.e., highest risk device). Most 3D printed devices would be considered as Class III devices. Health Canada has currently licenced four Class III devices manufactured via 3D printing methods, all for musculoskeletal applications (cranial plate, femoral and tibial cone augments and sleeves). The materials used for these components are limited to titanium alloy and hard plastics.

In instances where device manufacturers are uncertain about the classification of their robotic, AI or 3D printed medical device, they are encouraged to contact Health Canada for assistance. Health Canada classifies ‘interface products’ through the Health Products and Food Branch (HPFB) Classification Committee, which meets regularly to determine which products are most appropriately regulated by which regulatory framework.

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Question #3

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*This committee heard from Dr. Konrad Walus who is developing 3D bio-printing technology.<sup>1</sup> The "ink" used by Dr. Walus to create human tissues, and perhaps one day human organs, was described as "biomaterials and living cells."<sup>2</sup>*

*Would such a technology be captured under the Food and Drug Regulations as a biologic, along with vaccines and biotechnology products or under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations?<sup>3</sup> If neither, how should 3D bio-printing be regulated?*

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**RESPONSE:**

Health Canada considers cell-based therapies to meet the definition of "drug" under the *Food and Drugs Act*. As the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* specifically excludes cells, tissues and organs that are more than minimally manipulated, the cells applied in the proposed 3D bioprinting process would be excluded from these regulations and would generally be regulated under the *Food and Drug Regulations*.

In cases where a combination of biologic and inert materials are used, such as a scaffold printed from plastics or metal with cells or "bioink" added during the printing process, this would be considered a combination product where the entire product could be regulated either under the *Food and Drug Regulations* and/or the *Medical Devices Regulations*.

The determination of the appropriate regulatory framework for combination products is assessed on a case-by-case basis and primarily considers the principal mechanism of action by which the claimed effect or purpose of the product is achieved.

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1 Senate, Standing Committee on Social Affairs, Science and Technology, [Evidence](#), 1<sup>st</sup> Session, 42<sup>nd</sup> Parliament, 8 March 2017.

2 Ibid., 1812 (Konrad Walus, Associate Professor, Electrical and Computer Engineering, University of British Columbia).

3 [Safety of Human Cells, Tissues and Organs for Transplantation Regulations](#), SOR/2007-118.

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Question #4

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*This committee heard from Dr. Mehran Anvari who was one of the first surgeons in Canada to use robotics in surgery and who established the world's first telerobotic surgical service.<sup>1</sup> Telerobotics refers to the use of robotics for distance medicine, or telemedicine.*

*How is telerobotics currently regulated at the federal level? Is this regulatory approach sufficient or is Health Canada considering changes? Please explain.*

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**RESPONSE:**

A "device" is defined in the *Food and Drugs Act* (the Act) and a "medical device" is further defined in the Medical Devices Regulations. In broad terms, medical devices are products that are used to diagnose, treat or mitigate a disease condition in a person.

The Medical Devices Regulations are a risk-based framework to effectively and efficiently manage the over 1.3 million medical devices currently commercialized in Canada. The regulations as they are currently written are flexible and well adapted to accommodate innovative technologies, so changes are not required at this time.

Once a product has been determined to meet the definition of a "medical device", it needs to be classified. The Regulations set out a system for classifying medical devices into one of four classes; Class I representing the lowest risk and Class IV representing the highest risk. The Classification Rules for Medical Devices are found in Schedule 1 of the Regulations. These classification rules are based on criteria such as intended use, degree and duration of invasiveness, type and intensity of energy being delivered, risk of a false positive/false negative diagnosis, etc. As an example, based on the classification rules, an autonomous robotic surgical device intended to control the treatment of a patient's condition independently (i.e. sense, interpret and treat a medical condition without human intervention) would be classified in the highest risk classification – Class IV.

Health Canada has licensed robotic-assisted surgical devices which are broadly grouped into two categories: 1) systems which allow a surgeon to remotely control surgical instruments via robotic arms,

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1 CSii, [Dr. Mehran Anvari](#).

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and 2) systems which use a robotic arm to act as an instrument guide/holder, however the surgeon directly controls the surgical instrument attached to the robotic arm.

Currently licensed robotic-assisted surgery devices are not considered to be “surgical robots” since they do not perform autonomous surgical tasks - every surgical maneuver remains under direct control of the surgeon.

In terms of pre-market review prior to licensing a robotic-assisted surgical device in Canada, Health Canada requires that sufficient evidence be provided to establish that the systems have been tested appropriately. This may include simulation, animal testing, cadaver or human clinical trial data. This data is reviewed in detail and additional information is requested where applicable.

Regarding post-market surveillance of robotic-assisted surgical devices in Canada, Health Canada requires that manufacturers report adverse events (called mandatory problem reports). Healthcare professionals can also report adverse events directly to Health Canada. These reports allow Health Canada to monitor the frequency and severity of adverse events occurring with robotic-assisted surgical systems. The Medical Devices Regulations also require that the manufacturer provide a detailed explanation of the cause of the incident and any actions taken as a result of the investigation, including any corrective and preventative actions or recall of the device.

If Health Canada believes that a licensed robotic-assisted surgical device may not meet the safety and effectiveness requirements, Health Canada currently has the regulatory power to require the manufacturer to submit additional information. If the manufacturer does not comply with this request Health Canada can suspend the license so the product can no longer be sold in Canada.

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**Question #5**

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*This committee has heard from some previous witnesses during this study that Canada excels in innovation, but lags behind other countries in translating innovations into commercial products or services.*

*What role should the federal government play in this regard? Is there a role for Health Canada?*

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**RESPONSE:**

The federal government holds a number of roles related to translating innovations into commercial products or services. Direct innovation translation roles fall within the mandates of other Departments and Agencies such as Innovation, Science and Economic Development Canada and the federal funding agencies (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada).

The federal health portfolio (Canadian Food Inspection Agency, Canadian Institutes of Health Research, Health Canada and the Public Health Agency of Canada) plays the role of protecting the health and safety of Canadians by providing clear and responsive regulations for industry, supporting health research through funding agencies, and supporting innovation through grants and contributions programs.

The Canadian Institutes of Health Research (CIHR) supports the translation of new knowledge into effective health services and products. For example, the CIHR funded research at the University of Calgary into the use of cutting-edge robotic technology to deliver personalized, tailored treatments to stroke survivors. This work has caused clinicians to re-think established rehabilitation strategies. Health Canada supports innovation translation by ensuring that clear, coherent, responsive, and evidence-based regulatory systems are in place. Such regulatory systems can accommodate technological innovation and provide innovators with clear safety requirements that will be applied during evaluations. In this manner, the regulatory system can provide potential investors with



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confidence in Canadian-made innovations. Notably, Health Canada is responsible for regulatory oversight of innovations – not promotion or commercialization. Activities linked to promotion or commercialization conflict with Health Canada's role as a regulator.

Health Canada's First Nations and Inuit Health Branch (FNIHB) also provides primary health care services in remote and isolated First Nations communities including triage, emergency resuscitation and stabilization, emergency ambulatory care, and outpatient non-urgent services. These services are primarily delivered by teams of registered nurses and nurse practitioners who are supported by off-site physicians. Remote presence and telecommunications technology in remote and isolated communities will likely contribute to solutions regarding access to medical expertise and other specialists to both the clients and primary care providers in underserved remote communities. FNIHB plans to introduce remote presence technology through both robotics type technology and / or tele-streaming portable tools (e.g. doctor in a box) where the infrastructure supports such technology (e.g. broadband connectivity). A remote presence robot technology demonstration project in the remote Inuit community of Nain, Newfoundland and Labrador was awarded a 2016 Public Service Award of Excellence in the category of employee innovation.

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**Question #6**

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*In a March 2017 editorial, several experts in robotics and AI proposed a regulatory framework based on the level of autonomy of medical robots. Level 0 would correspond to robots that have no autonomy and function solely by user command, such as telerobots and prosthetic devices. Level 5 would correspond to robots that are fully autonomous and require no human intervention. The article suggested that highly or fully autonomous medical robots would no longer be classified as medical devices only, but rather could also be considered to be medical practitioners.*

*Should Health Canada consider implementing regulations specific to robots that respond to their degree of autonomy? Why or why not?*

*Do you agree with the suggestion that a fully autonomous medical robot could be considered a medical practitioner? Why or why not?*

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**RESPONSE:**

**Licensing “Level 5” Robots in the Future**

As outlined in the response to Question 4, the Medical Device Regulations uses a risk-based approach that sets out a system for classifying medical devices into one of four classes; Class I representing the lowest risk and Class IV representing the highest risk. These classification rules are based on criteria such as intended use, degree and duration of invasiveness, type and intensity of energy being delivered, risk of a false positive/false negative diagnosis, etc. As an example: based on the classification rules, an autonomous robotic surgical device intended to control the treatment of a patient's condition through a closed loop system (i.e. sense, interpret and treat a medical condition without human intervention) would be classified in the highest risk classification – Class IV.

In terms of pre-market review prior to licensing a robotic-assisted surgical device in Canada, Health Canada requires that sufficient evidence be provided to establish that the systems have been tested appropriately. Health Canada also requires that manufacturers report adverse events (called mandatory problem reports). These reports allow Health Canada to monitor the frequency and severity of adverse events occurring with robotic-assisted surgical systems. The Medical Devices Regulations also require that the manufacturer provide a detailed explanation of the cause of the incident and any actions taken as a result of the investigation, including any corrective and preventative actions or recall of the device.

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If Health Canada believes that a licensed robotic-assisted surgical device may not meet safety and effectiveness requirements, Health Canada currently has the regulatory power to require the manufacturer to submit additional information. If the manufacturer does not comply with this request, Health Canada can suspend the license so the product can no longer be sold in Canada.

Regarding the suggestion that a fully autonomous medical robot could be considered a medical practitioner, the definition of medical practitioners is a matter for the respective medical regulatory colleges. The *Medical Devices Regulations* currently defines the term "health care professional" as a person who is entitled under the laws of a province to provide health services in that province. Health Canada has not licensed any medical device which would be considered to be AI, nor has it received any investigational testing applications for clinical trials in the field of AI.

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**Question #7**

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***Does Canada's health care system have the capability and capacity to evolve to meet the challenge of adapting to the growing demands of Canadians for access to the benefits of RAID (robotics, artificial intelligence and 3D printing) enhanced health care?***

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**RESPONSE:**

Canada's health care system is continually evolving to meet the growing demand for new technologies including robotics, artificial intelligence and 3D printing (RAID). Canada's large geographic area and widely distributed population has resulted in considerable research and product development for technologies to serve remote communities, although this also creates challenges in ensuring equitable access. Health Canada is committed to working with provinces and territories toward modernizing our health system; however, management of the health care system, including decisions on new technology investments and use, is a provincial responsibility.

In terms of capability, Canada is a global leader in the development of RAID applications for the health sector. The Medical Devices Regulations provide a flexible, adaptive and innovation-friendly framework for this. Under the Regulations, Health Canada has licensed several products that show Canada's increasing capacity and capability to access RAID-enhanced health care. For example, Health Canada has licensed remote controlled robotic-assisted surgical systems for remote surgery; an x-ray guided radiotherapy robotic arm to autonomously deliver radiation therapy; 3D printed musculoskeletal devices for use in prosthetics; and software algorithms that mimic visual perception to assist with diagnosis based on medical imaging. The Regulations also provide a pathway for the authorization of custom-made devices and devices for special or emergency access.

Currently, the costs associated with widespread incorporation of RAID innovations are prohibitive. Creative funding schemes including mechanisms for risk-sharing could increase access by Canadians to these technological innovations. Stronger mechanisms for foresight within the health care sector and Health Canada, from procurement to policy development and health technology assessment, would support innovation. This is because stronger mechanisms for foresight would provide greater evidence of which would provide the most net benefit to Canadians as the demand for these technologies grow.

Health Canada recognizes the enormous potential benefits of scientific advances and the application of

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innovative technologies to health care and the 14 Canadian health care systems must adapt if they are to deliver better care and better outcomes affordably. When considering the adoption of a new technology, the whole health care system landscape is contemplated. For health care systems to adopt innovative RAID technologies, they must balance the added value of these innovations with capital costs, operational requirements and costs, fee codes, and patient needs. Providing Canadians with better care, and the social and economic benefits that will result from this, is dependent on strengthening Canada's health innovation ecosystem and adopting corresponding product and services.

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**Question #8**

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*The committee has heard concerns that assistive robots are seldom if ever never tuned off, including video recording, and that the data these robots operate under is not currently secured.*

*Is Health Canada developing privacy regulations for assistive robots?*

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**RESPONSE:**

The information gathered by medical devices would fall under Canada's current federal and provincial privacy law frameworks.

*The Privacy Act* relates to an individual's right to access and correct personal information that the Government of Canada holds on them. It also refers to the Government's collection, use and disclosure of their personal information in the course of providing services (e.g., old age pensions or employment insurance). In the example cited by the Committee, the Privacy Act would not apply since Health Canada does not collect individual patient information. In fact, Health Canada's current practice is to request that physicians maintain the anonymity of their patients in the exceptional occasions when individual patient information is relevant to a regulatory decision.

Manufacturers are responsible for remaining vigilant about identifying risks and hazards associated with their medical devices, including risks related to cybersecurity. As part of their regulatory application, they are responsible for putting appropriate mitigations in place to address patient safety risks and ensure proper device performance. Manufacturers now include information on the security profile of their device when they apply to sell their product in Canada.

Health Canada is engaged internationally on developments relating to cybersecurity and works collaboratively with other regulators, including the Food and Drugs Administration (FDA), to better understand the real cybersecurity risks as they apply to medical devices. For example, Health Canada, along with the FDA, industry and stakeholders, has representatives on DTSec, a cybersecurity standard-setting committee whose goal is to raise confidence in the security of network-connected medical devices through independent expert security evaluation.