December 16, 2022

Mr. Joël Lightbound, MP
Chair of the Standing Committee on Industry and Technology
Sixth Floor, 131 Queen Street
House of Commons
Ottawa, ON K1A 0A6
Sent via Email: INDU@parl.gc.ca

Re: Bill C-244 – An Act to amend the Copyright Act (diagnosis, maintenance and repair)

Dear Mr. Chairman,

On behalf of the Medtech Sector, we would like to thank you for allowing Medtech Canada to appear before the Standing Committee on November 14th, 2022.

In this written submission, we wish to reiterate the significant concerns regarding Bill C-244 – *An Act to amend the Copyright Act (diagnosis, maintenance, and repair)* as it impacts current safeguards that protect Canadians from unsafe practices with respect to the third-party servicing of medical devices.

We have no commentary on the direction of Bill C-244 as it relates to non-healthcare products. With respect to medical devices however, Canadians rely on regulations and laws that are currently implemented to protect consumers, healthcare providers and patients from unintended harm. Medtech Canada strongly contends that Bill C-244, as it is currently written, will expose these individuals to increased risk of harm from **unregulated** third-party medical device service providers, since it removes one of the few protections (which are currently in place today within the *Copyright Act*) that Canadians can rely upon when their equipment is serviced by **unregulated** third-party medical device service providers.

Medtech Canada fully supports **regulated** third-party medical device service providers as they are essential to our healthcare system. They have provided (and continue to provide) critical, effective, and timely services to our healthcare system as witnessed during the COVID-19 pandemic.

Medtech Canada was, therefore, surprised to hear during the Committee's review of Bill C-244, two witnesses refer to incidents in which healthcare facilities were challenged in accessing timely repairs for ventilators during the pandemic. While we understand there have been reported issues in the United States related to access to repairs for ventilators during the pandemic, there have been no such reported incidents in Canada. It should be noted that the two witnesses did

not provide detailed information regarding where these alleged incidents occurred; Medtech Canada would have great interest in following up with the facilities noted by these witnesses as part of our post-market surveillance of medical equipment.

It should also be noted that early in the pandemic, Medtech Canada and our members were extremely concerned that healthcare facilities would limit physical access and not allow Medical Technology Representatives into their facilities to continue to support servicing and/or maintenance of medical equipment. To that end, in June 2020, we issued our "*Re-entry Guidance for Health Care Facilities and Medical Technology Representatives*" to facilitate access for representatives to continue to service/maintain medical equipment.

Medtech Canada would like to re-confirm that there are no known reports of healthcare facilities not receiving appropriate and timely service by regulated third-party service providers, including during the pandemic.

Recommendation:

Medtech Canada strongly recommends that medical devices that are regulated for sale by Health Canada, be provided a specific exemption in any amendments to the *Copyright Act*.

Context:

1. Increased Protection for Patients and Healthcare Providers – Current Regulatory Framework

In recent years, there has been a heightened sensitivity and commitment by Government and Industry to the increased protection of Canadians. These protections have been implemented in various ways such as the protections put in place during the COVID-19 pandemic as well as the introduction of new policies and laws such as *Vanessa's Law.*

The introduction of *Vanessa's Law (Protecting Canadians from Unsafe Drugs Act)*[1] is a recent example of legislation intended to strengthen the protection of patients by enabling greater oversight of therapeutic products such as drugs and medical devices. This law clearly states that its scope is (among others) to:

a) *Strengthen safety oversight of therapeutic products throughout their lifecycle*

[1] https://laws-lois.justice.gc.ca/eng/annualstatutes/2014_24/page-1.html

b) *Promote greater confidence in the oversight of therapeutic products by increasing transparency*

In addition, and of most importance, Vanessa's Law states that:

"Whereas the safety of drugs and medical devices is a key concern for Canadians; And whereas new measures are required to <u>further</u> protect Canadians from the risks related to drugs and medical devices…"

As a follow-up to *Vanessa's Law*, Health Canada developed and implemented policies that the medtech industry and the healthcare system must adhere to, including the "*<u>Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Hospitals</u>*"[2] and "*<u>Guidance on summary reports and issue-related analyses for medical devices</u>*".[3]

The entities that are covered and regulated under the above laws and regulations include manufacturers and other regulated parties such as importers, distributors, and hospitals as well as third-party service providers that operate under these regulated entities – which we call regulated third-party service providers. These entities have implemented quality assurance and transparency controls such as mandatory reporting on any and all adverse outcomes. They are also subject to audits and controls to ensure ongoing compliance to the law.

Conversely, unregulated third-party service providers who operate outside of the scope of these regulated entities, are not governed by the Food and Drugs Act and are therefore not required to be certified, audited, monitored or report on adverse outcomes. Aside from the current Copyright Act, there are few, if any, regulations that apply to unregulated third-party service providers.

2. Lack of Oversight for Unregulated Third-Party Servicers

Not all third-party servicers are equal. Unlike regulated third-party servicers, unregulated third-party servicers are not required to register with Health Canada. In addition, they are not required to submit adverse events associated with devices they repair to Health Canada, original equipment manufacturers (OEMs), or their vendors (who may be regulated as a distributor or importer). They are also not required to follow Health Canada's quality system regulations. As a result, there may be no visibility to Health Canada that a device failure or patient injury was associated with unregulated third-party servicing.

This after-market surveillance by Health Canada is critical given that the expected lifetime of a medical device is estimated at a minimum of seven years. However, this number can reach up to

[2] https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/education/module-1.html

[3] https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/medical-device-reports-analyses-guidance.html

fifteen years or more depending on the device, usage, service, and maintenance. Some third-party servicers have argued that this issue could be resolved if they are provided "reasonable access" to OEM service manuals, diagnostic software and/or specialty tools. However, sharing manuals, specialized tools or software does not ensure that servicing by a third-party will be done correctly if basic Quality System Requirements (governed by Health Canada or other regulatory body) are not followed (e.g., ensuring training of personnel, evaluating parts suppliers, calibrating tools, and maintaining device service and preventive maintenance records, etc.). As an example, some OEMs train service personnel to service specific product lines and training on that product line may require three months or more with periodic recertification required (e.g., every two years).

3. Significance of Technical Protection Measures (TPMs) for Medical Devices

When it comes to medical devices, TPMs are vital to ensure the safety of patients and healthcare providers and are an integral part of what Health Canada reviews during the licensing process prior to placing a medical device onto the market. Specifically, under the Safety & Effectiveness requirements of the Canadian Medical Devices Regulations, section 20 states "If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated".

Common TPMs on medical devices ensure secure communications, require user authentication, encrypt data, strengthen password protections, allow for authenticated software updates, and provide for security and integrity of device source code. TPMs ensure that the proper users have access to the device, the device functions properly, alarms appropriately, and that malicious actors cannot access patient data.

It has been suggested that amending the *Copyright Act* will encourage more innovation by third-parties. In reality, Bill C-244 would allow unregulated third-party medical device servicers to circumvent necessary technological protections – in effect, changing a device's design – which can have serious repercussions to patient safety or device effectiveness. Innovations in Artificial Intelligence even allow devices to learn from previous experience, as in imaging software that learns to refine the identification of cancerous lesions.

If TPMs are bypassed and software modified by unregulated third-party servicers, improperly serviced medical equipment can malfunction, causing risk to patients and technicians. This risk includes serious injury or death, but also poor image quality, leading to a delayed or missed diagnosis or repeated imaging procedures. Hacking through TPMs and modifying software also presents significant security vulnerabilities and potential operational issues. Modified software is open to cybersecurity attacks from malicious actors who may access patient data, use device specifications to develop counterfeit devices or software, or intentionally modify devices to harm patients. This modified software could also introduce security vulnerabilities to any networks to

which the devices are connected including hospital networks – and place the larger health care system at risk.

4. Adverse Events with Unregulated Third-Party Service Providers

The FDA's report to Congress on the Quality, Safety, and Effectiveness of Servicing of Medical Devices per Section 710 of the Food and Drug Reauthorization Act of 2017 (FDARA) found 4,301 adverse events (also referred to as Medical Device Reports or MDRs) associated with inadequate third-party device repairs and replacement parts, including 40 deaths and 294 serious injuries. Despite the fact that third-party servicers are not required to report MDRs in the U.S., the FDA was able to obtain this information.
In addition, the FDA was notified of additional recorded incidents of at least 281 adverse events from only 6 manufacturers which covered the years from 2012 to 2017 associated with third-party servicing. For some devices (e.g., imaging devices), up to 38,500 patients and/or operators were exposed to the potential for harm.

Actual or potential events from these and other reports include:

1. *3 reported deaths related to the use of unapproved third-party parts*
2. *Delayed surgery (potential for worsening patient condition)*
3. *Prolonged surgery (may result in longer exposure to anesthesia, greater potential for infection, and more blood loss)*
4. *Infusion therapy - Air in System – potential harms include death, neurological changes, stroke, seizures, cardiac and/or respiratory arrest, pain, decreased oxygenation, arrhythmia, pulmonary hypertension*
5. *Incorrect battery used – a non rechargeable, not heat protected battery was installed in the machine which caused it to overheat and explode inside. This could have caused major injuries as the equipment operated in an environment that includes oxygen tanks*
6. *A potentially dangerous method was used to repair or service the device where third-party used TEFLON plumbing tape to insulate the live metal terminals. This could have shocked the Healthcare provider.*
7. *Used equipment purchased – system was pest infested and dirty. Equipment had 30-year-old parts in it. It was unknown as to when or if it was ever serviced or maintained and by whom*
8. *Use of unapproved non-OEM parts resulting in mass recalls to critical pumps in hospitals*
9. *Uneven adhesive applied, allowing fluid ingress and bio-accumulation (human fluid remaining in device causing risk of infections to subsequent patients)*
10. *Replacement of parts that may hold critical information such as Serial Number – making the equipment lose traceability for recall purposes*
11. *Screwdriver tip lodged in patient*
12. *Operator injury, counterpoise support system arm (80-93 pounds) struck operator*

13. *Potential for repeat CT scans and contrast administration with concomitant risk of additional radiation exposure*
14. *Potential for burns including internal or oral 3rd degree burns which may not be apparent until burning tissue is sensed*
15. *Potential for concussions and/or fractures*
16. *Delays in infusion therapy with delay of pharmacological effects and/or worsening of condition including death*
17. *Insufficient or excessive infusion therapy or interruption of therapy and/or worsening of condition including death*
18. *Temporary hearing loss; ringing in ears*
19. *Tubing was installed incorrectly and was cut / unstable. This could have caused injury to the operator and the patient*
20. *Software was modified to allow third-party access to calibration and diagnostic menus – this caused the software to remain open during the operation of the machine*
21. *Table safety switches had been turned off during a repair and were not turned back on. Additionally, service part was not one recommended by OEM. This could have caused major patient injury should there had been one on the bed.*
22. *Serviced Table footswitch was not functioning as per specification and table mattress was missing Velcro on a tilt table system – potential major injury due to patient fall risk from bed.*
23. *Non-OEM-Batteries damaged while trying to make them fit into the equipment – potential hazard to healthcare and patient due to damaged batteries and equipment.*
24. *Safety switches were disabled on equipment*
25. *Potential Data Integrity breach - accidental or purposeful removal of authentication methods could lead to physical security concerns and make it easier for malicious actors to access medical devices*
26. *Potential Unvalidated remote monitoring software installation could have serious implications for patient safety. These control mechanisms and safety protocols of the device are intricately connected to the device operation and any significant change, including an installation or override, could have a negative effect on device performance and safety.*
27. *Potential for access to encrypted data. Patient health information may be exposed and compromised.*

Recommendation:

Medical devices are significantly different from home appliances and consumer electronics. They are heavily federally regulated devices requiring licenses and OEMs must provide extensive evidence of clinical benefit and safety standards before those devices are placed on the market in Canada. Existing safeguards that confirm efficacy, safety and clinical benefit would be jeopardized if unregulated third-parties are able to hack through TPMs and modify

medical devices.

Medtech Canada requests an amendment to the *Copyright Act* to exempt medical devices as per below:

> ***Nothing in this Act shall apply to a device as defined in the Food and Drugs Act (R.S.C. 1985, c. F-27, s. 2) or a digital electronic product or embedded software manufactured for use in a medical setting including diagnostic, monitoring, or control equipment or any product or related service offered.***

Conclusion:

In summary, to preserve the confidence in the safety and efficacy conferred through the regulatory processes of Health Canada, and to continue to ensure the protection of our patients and healthcare providers, we strongly recommend that medical devices that are regulated for sale by Health Canada, be provided a specific exemption in any amendments to the *Copyright Act.*

About Medtech Canada

Medtech Canada is the national association representing the medical technology industry in Canada. Our association advocates for achieving patient access to leading edge, innovative technology solutions that provide valuable outcomes. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our health care system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities across the country.