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ARTICLES

REGULATION OF HEALTH-RELATED ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES: THE CANADIAN STORY

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INTRODUCTION

New technologies offer the hope that Artificial Intelligence (AI), which we define below, will positively transform Canada's healthcare system, and help address the system's many access, quality, and safety problems. For example, avoidable errors on the part of healthcare professionals is a leading cause of injury even in advanced healthcare systems.[1] Studies suggest that AI tools could dramatically improve healthcare quality by using big data to

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1 See Risk Analytica, *The Case for Investing in Patient Safety in Canada* (2017), online (pdf): *Canadian Patient Safety Institute* <patientsafetyinstitute.ca/en/About/Documents/The%20Case%20for%20Investing%20in%20Patient%20Safety.pdf> (setting out Canada's statistics). See also Benjamin A Rodwin et al, "Rate of Preventable Mortality in Hospitalized Patients: A Systematic Review and Meta-analysis" (2020) 35:7 J General Internal Medicine 2099 (where rates of provider-caused error were found to be lower in the USA than previously thought. The rates remain high even on their count).

improve surgical safety.[2] For instance, the OR Black Box is designed to identify surgical distractions and errors using data capture and AI analysis; it should eventually provide real-time recommendations to surgeons that will minimize the chances of preventable errors in surgery.[3] It is also hoped that efficiency gains from AI may free healthcare providers from mundane, routine tasks and provide them with the "gift of time" to work with complex patients and provide compassionate care.[4]

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2 See Eric J Topol, "High-Performance Medicine: The Convergence of Human and Artificial Intelligence" (2019) 25 Nature Medicine 44; Effy Vayena & Alessandro Blasimme, "The Ethics of AI in Biomedical Research, Medicine and Public Health" in Markus D Dubber, Frank Pasquale & Sunit Das, eds, *The Oxford Handbook of Ethics of AI* (Oxford: Oxford UP, 2020) 703; David W Bates et al, "The Potential of Artificial Intelligence to Improve Patient Safety: A Scoping Review" (2021) 4:1 npj Digital Medicine 54. Canadian clinical use is limited: see Amol A Verma et al, "Implementing Machine Learning in Medicine" (2021) 193:34 Can Med Assoc J E1351. AI is used in the Canadian healthcare sector: see Canadian Medical Protective Association (CMPA), "Can I Get an (Artificial) Second Opinion?: Benefits and Risks of AI Technologies in Medicine" (Ottawa: CMPA, 2019), online (pdf): *CMPA* <cmpa-acpm.ca/static-assets/pdf/about/annual-meeting/19_annual_Smeeting_ai_paper-e.pdf>; Canadian Institute for Advanced Research (CIFAR) AI for Health Task Force, "Building a Learning Health System for Canadians: Report of the Artificial Intelligence for Health Task Force" (2020), online (pdf): *CIFAR* <cifar.ca/wp-content/uploads/2020/11/AI4Health-report-ENG-10-F.pdf>; Royal College of Physicians and Surgeons of Canada (RCPSC), "Task Force Report on Artificial Intelligence and Emerging Digital Technologies" (2020), online: *RCPSC* <royalcollege.ca/rcsite/health-policy/initiatives/ai-task-force-e>; Canadian Medical Association (CMA), "The Future of Technology in Health and Health Care: A Primer" (Ottawa: CMA, 2020); CIFAR, "AI and Healthcare: A Fusion of Law and Science: An Introduction to the Issues" (2021), online (pdf): *CIFAR* <cifar.ca/wp-content/uploads/2021/05/AI-Healthcare-A-Fusion-of-Law-Science-II.pdf> [*Fusion*].

3 For details on the OR Black Box, see <surgicalsafety.com> [OR]. For early results, see James J Jung et al, "First-year Analysis of the Operating Room Black Box Study" (2020) 271:1 Annals Surgery 122.

4 To read about the benefits, including this "gift", see Eric Topol, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again* (New York: Basic Books, 2019). See also Swati Goyal, "An Overview of Current Trends, Techniques, Prospects, and Pitfalls of Artificial Intelligence in Breast Imaging" (2021) 14 Reports in Medical Imaging 15.

Despite its transformative potential, we must also acknowledge and address the many challenges posed by health-related AI. For example, potentially unsafe AI could be widely deployed through the healthcare system and, if left unchecked, could greatly harm patients. Other challenges include concerns about AI violating privacy rights or the possibility that AI may entrench or create new unfounded biases such that historically marginalized groups continue to receive less or inappropriate care.[5] Whether health-related AI delivers on its potential will partly be a function of whether it is possible to design and implement functional

[5] See Sara Gerke, Timo Minssen & Glenn Cohen, "Ethical and Legal Challenges of Artificially Intelligence-Driven Healthcare" in Adam Bohr & Kaveh Memarzadeh, eds, *Artificial Intelligence in Healthcare* (Cambridge: Academic Press, 2020) 295 and Vayena & Blasimme, *supra* note 2 as representative works highlighting these issues and informed consent as central ethical issues. As providers rely on AI tools for clinical decision making, new moral and legal concerns about liability will arise, though the desirability and possibility of "substitute" decision making remains contested: see Jörg Goldhahn, Vanessa Rampton & Giatgen A Spinas, "Could Artificial Intelligence Make Doctors Obsolete?" (2018) 363 Brit Med J k4563; Ian Kerr & Vanessa Gruben, "AIs as Substitute Decision-Makers" (2019) 21:3 Yale JL & Tech 78; A Michael Froomkin, Ian R Kerr & Joelle Pineau, "When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning" (2019) 61 Ariz L Rev 33; W Nicholson Price II, Sara Gerke & Glenn Cohen, "Potential Liability for Physicians Using Artificial Intelligence" (2019) 322:18 JAMA 1765; Frank Pasquale, *New Laws of Robotics: Defending Human Expertise in the Age of AI* (Boston: Belknap Press of Harvard University Press, 2020). See Benjamin Chin-Yee & Ross Upshur, "The Impact of Artificial Intelligence on Clinical Judgment: A Briefing Document" (2020), online (pdf): *AMS Healthcare* <ams-inc.on.ca/wp-content/uploads/2020/02/The-Impact-of-AI-on-clinical-judgement.pdf>; Benjamin Chin-Yee & Ross Upshur, "Clinical Judgment in the Era of Big Data and Predictive Analytics" (2018) 24:3 J Evaluation in Clinical Practice 638 (detailing clinical judgment issues). See also Effy Vayena, Alessandro Blasimme & I Glenn Cohen, "Machine Learning in Medicine: Addressing Ethical Challenges" (2018) 15:11 PLOS Med e1002689; Michael J Rigby, "Ethical Dimensions of Artificial Intelligence in Health Care" (2019) 21:2 AMA J Ethics E121 (on ethics). This summary of benefits and potential drawbacks is inspired by, consistent with, and hopes to build on the following study: see Catherine Régis & Colleen M Flood, "AI and Health Law" in Florian Martin-Bariteau & Teresa Scassa, eds, *Artificial Intelligence and the Law in Canada* (Toronto: LexisNexis, 2021) 203.

governance and regulatory frameworks. Any governance scheme must seek to realize the benefits of health-related AI whilst minimizing any harms.[6] As Kate Crawford suggests, maintaining this balance calls for "[m]uch stronger regulatory regimes and greater rigour and responsibility around how training datasets are constructed . . . . [and for] different voices in these debates—including people who are seeing and living with the downsides of [AI-enabled] systems."[7]

In terms of the existing governance of health-related AI, Canadian federalism results in a complex and yet incomplete web of regulations that may apply.[8] Federal and provincial governments each have regulatory powers over aspects of healthcare.[9] Primary jurisdiction for healthcare professionals has been interpreted to rest with the provinces and, in turn, each province delegates some powers to sub-provincial bodies (e.g., regulatory colleges who establish and enforce health professional responsibilities). Private law may also incentivize different behaviours: for instance, tort liability could incentivize innovators to take care in their design of health-related AI or the risk of liability could chill the uptake of health-related AI by healthcare

6 See Régis & Flood, *supra* note 5; *Fusion*, *supra* note 2.

7 Zoë Corbyn, "Microsoft's Kate Crawford: 'AI is Neither Artificial nor Intelligent'" (6 June 2021), online: *The Guardian* <theguardian.com/technology/2021/jun/06/microsofts-kate-crawford-ai-is-neither-artificial-nor-intelligent>. Crawford details her views in *The Atlas of AI: Power, Politics, and the Planetary Costs of Artificial Intelligence* (New Haven: Yale University Press, 2021).

8 See Régis & Flood, *supra* note 5; Ian Kerr, Jason Millar & Noel Corriveau, "Robots and Artificial Intelligence in Health Care" in Joanna Erdman, Vanessa Gruben & Erin Nelson, eds, *Canadian Health Law & Policy*, 5th ed (Toronto: LexisNexis, 2017) 257.

9 See e.g. Colleen M Flood, William Lahey & Bryan Thomas, "Federalism and Health Care in Canada: A Troubled Romance?" in Peter Oliver, Patrick Macklem & Nathalie Des Rosiers, eds., *Oxford Handbook of the Canadian Constitution* (Oxford: Oxford University Press, 2017) 449. See also Régis & Flood, *supra* note 5 (informing the overview in this paragraph).

professionals.[10] Our analysis here focuses on one part of this regulatory ecosystem: the role of Canada's medical devices regulator, Health Canada, which determines whether devices meet safety standards and can accordingly be manufactured, imported, and sold in Canada. We thus focus primarily on the safety and efficacy issues Health Canada is charged with addressing in the medical devices context. As we will discuss below, Health Canada's mandate may need to be broadened to address the relevant issues more effectively. For example, Health Canada can currently only regulate devices "sold" in Canada (with a caveat for some research studies) and this commercial understanding of Health Canada's mandate leaves devices implemented for in-house use by a hospital for non-research purposes outside of Health Canada's regulatory scrutiny.[11] In other instances, a shift in how the regulator interprets its mandate—and the criteria it applies in regulating products—appears necessary in view of the issues AI presents. Most notably, "safety" needs to be understood more broadly to address issues surrounding an AI product's potential biases.[12] Yet our work builds on an understanding that Health Canada is—at its core—mandated to ensure product safety and efficacy and therefore that new issues presented by AI, such as the risk of bias, can and should be subsumed into how the regulator reviews AI technologies in the service of its consumer protection mandate.[13]

In Part I, we highlight the need to regulate the sale of medical devices with AI to address the possibility of error in AI analyses. This is where we argue for an expansive interpretation of "safety" to include not only errors in programming or other malfunctioning of AI but also risks of algorithmic bias and related issues of privacy

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10 See e.g. Ian Stedman & Michael Brudno, "Trust, Tort Law and The Integration of Black Box Artificial Intelligence into Clinical Care" (2021) 42:2 Health L Can 57.

11 See *Food and Drugs Act*, RSC 1985, c F-27 [*F&D Act*]; *Medical Devices Regulations*, SOR/98-298 [*MDR*].

12 See Section 3 of Part V, *below*.

13 This mandate over safety and efficacy is delegated from the Minister of Health per the instruments in note 11.

and data governance. In Part II, we explain how Health Canada currently regulates medical devices, including recent changes that potentially provide for an increased role for post-market surveillance. In Part III, we discuss in more detail how the existing regulatory scheme applies to health-related AI devices. In Part IV, we discuss Health Canada's new initiative to provide bespoke licencing pathways for novel technologies, including "adaptive" machine learning AI. Such pathways are now permitted under recent amendments to the *Food and Drugs Act* and Health Canada is presently developing details on how they will be operationalized.[14] Finally, in Part V, we assess whether recent changes are sufficient to meet the concerns we identified and whether the pathways in Part IV could address any gaps.

By providing the first detailed description of Canadian regulations of medical devices and AI in healthcare, we hope to provide a baseline from which we and others can better consider reform options.[15] We conclude by arguing that Health Canada should strongly regulate health-related AI both in the pre-market and post-market phases and not see any attention to the latter as condoning a "lighter" approach to the former. Both are critical. We

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[14] See *F&D Act*, *supra* note 11, s 21.91–21.96, as amended by SC 2019, c 29, s 169 (permitting the pathways). See e-mail from Health Canada Release to stakeholders (21 June 2021), "Call for Experts—Developing regulatory requirements for Adaptative Machine Learning-enabled Medical Devices" (e-mail on file with authors) [Health Canada, "Call"] (discussing ongoing developments).

[15] Existing descriptions of Canada medical devices are either somewhat dated or smaller parts of larger studies: see e.g. Joel F Finlay, Brian Henderson & Devidas Menon, "Medical Device Regulation in Canada: Direction for Change" (1994) 28:3 Health Pol'y 185; Yi-Jung Chen et al, "A Comparative Study of Medical Device Regulations: US, Europe, Canada, and Taiwan" (2018) 52:1 Therapeutic Innovation & Regulatory Science 62. Others focus on particular programs: see Roland K Maier, Devidas Menon & Tania Stafinski, "The Medical Devices Special Access Program in Canada: A Scoping Study" (2018) 13:3 Health Pol'y 40. On other countries, see e.g. Stan Benjamens, Pranavsingh Dhunnoo & Bertalan Meskó, "The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms: An Online Database" (2020) 3 npj Digital Medicine 1; Filippo Pesapane et al, "Artificial Intelligence as a Medical Device in Radiology: Ethical and Regulatory Issues in Europe and the United States" (2018) 9:5 Insights into Imaging 745.

further argue that in pre-market assessment, Health Canada should explicitly address bias and privacy issues within its remit on safety and that it should work towards transparent evidentiary standards for "safe" AI. In the course of these analyses, we highlight the need for federal investment in Health Canada's regulatory efforts and the development of representative datasets on which AI can be trained.

I. THE NEED FOR REGULATION

A. THE PHENOMENON

Let us start with definitions.

Artificial Intelligence (AI) is the use of computer systems to perform tasks traditionally requiring human cognition without direct human intervention after initial programming.[16] Humans provide inputs into a computer system that permits a computer or computer-controlled "artificial" entity to perform the tasks without further human aid.

Machine learning AI (ML) is AI that collects new inputs through its own operation and adapts to produce new, hopefully improved, outcomes (predictions, analyses, etc.).[17]

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16 Defining AI is notoriously difficult. A collection like Dubber, Pasquale & Das, *supra* note 2 will contain several competing definitions. See also Selmer Bringsjord & Naveen Sundar Govindarajulu, "Artificial Intelligence" (2018) in Edward N Zalta, ed, *The Stanford Encyclopedia of Philosophy* (2020), online: *Stanford Encyclopedia of Philosophy* <plato.stanford.edu/entries/artificial-intelligence/>. This definition is common and tracks use in key regulatory documents, and is thus apt for our purposes. See e.g. World Health Organization (WHO), "Ethics and Governance of Artificial Intelligence for Health" (Geneva: World Health Organization, 2021), online: *WHO* <who.int/publications/i/item/9789240029200>.

17 See Stuart J Russell & Peter Norvig, eds, *Artificial Intelligence: A Modern Approach*, 4th ed (Hoboken: Pearson, 2021). This definition builds on texts above and incorporates the defining feature of ML identified by Russell & Norvig, which is its ability to "adapt to new circumstances and to detect and extrapolate patterns". A narrower definition could require that ML self-audit and -correct its operations. Health Canada is primarily interested in ML that changes over time and so cannot be expected to produce the same output

Neural networks connect many simple processing nodes into algorithmic processes that can train to respond to similar nodes in a manner aiming to mimic human cognition. Neural networks are a form of ML.[18]

Deep learning is a high-powered species of neural network with numerous "layers" of nodes, many of which may be hidden (viz., are not, strictly speaking, input or output layers).[19]

Health-related AI is heterogenous and ranges from computers that read and interpret medical scans, smartwatch-based heart monitors, and algorithms that make staffing recommendations to algorithms that make initial triage assessments about whether a patient needs to see a doctor and those that provide real-time recommendations on how to improve surgery.[20] Health-related AI may be used under the supervision of humans or autonomously, such that, e.g., AI "robots" could eventually even perform surgery without human oversight.[21] The enormous heterogeneity of AI reflects the heterogeneity of healthcare needs and responses and makes the design of appropriate governance more complex, as discussed further below.

B. The Issues

The use of AI in healthcare raises safety concerns. One issue is how to ensure that only safe AI tools are on the market—whether

each time an input is produced. We follow them in being interested primarily in this form of "adaptive" ML; see Health Canada, "Call", *supra* note 14.

18 See Yann Lecun, Yoshua Bengio & Geoffrey Hinton, "Deep Learning" (2015) 521:7553 Nature 436 (as the classic source here). See also RCPSC, *supra* note 2. See also Larry Hardesty, "Explained: Neural Networks" (14 April 2017), online: *MIT News* <news.mit.edu/2017/explained-neural-networks-deep-learning-0414> (as a useful "lay" summary).

19 See *ibid*.

20 See Topol, "High", *supra* note 2; *Fusion*, *supra* note 2; OR, *supra* note 3. Other examples include tools that identify, classify, or diagnose cancers and strokes and that predict treatment effectiveness and disease prognosis; see Fei Jiang et al, "Artificial Intelligence in Healthcare: Past, Present and Future" (2017) 2:4 Stroke & Vascular Neurology 230.

21 See Elizabeth Svoboda, "Your Robot Surgeon Will See You Now" (2019) 573 Nature S110.

adopted into public "Medicare" or available for sale and use in the private sector. Some features of AI make it especially difficult to predict risks or identify adverse events. For instance, "adaptive" ML changes over time, by definition, as it learns. Consequently, not all risks stemming from ML use are identifiable *before* ML is adopted into healthcare; an ex ante licence demonstrating ML safety at the time an application is made to the regulator may then be of limited value.[22] Health Canada has not yet approved a medical device with adaptive ML for the Canadian market, but now plan to permit adaptive ML products through a new framework detailed below.[23] The regulatory challenge is significant. The nature of some AI "decision makers", like deep learning neural networks, means that neither regulators nor healthcare professionals can understand how a decision is reached.[24] Such AI "reasoning" can even remain opaque to the AI's developers, rendering the AI into a "black box".[25] Opacity may

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22 These are viewed as longer-term governance issues surrounding health-related ML, likely because AI are not yet sufficiently autonomous to raise genuine concerns about unforeseeable risks. Yet debates on whether and when health-related AI will be "autonomous" remain contentious. See Robert Challen et al, "Artificial Intelligence, Bias and Clinical Safety" (2019) 28:3 Brit Med J Quality & Safety 231 at 235. Compare sources in notes 2, 4–5, etc. See also Tony Antoniou & Muhammad Mamdani, "Evaluation of Machine Learning Solutions in Medicine" (2021) 193:36 CMAJ E1425 (noting that post-market clinical validation may be required to ensure safety, though they do not discuss legal options for same).

23 See Health Canada, "Call", *supra* note 14.

24 See Frank Pasquale, *The Black Box Society: The Secret Algorithms That Control Money and Information* (Cambridge: Harvard University Press, 2015). See also William Nicholson Price II, "Black-Box Medicine" (2015) 28:2 Harvard JL & Tech 419; William Nicholson Price II, "Medical Malpractice and Black-Box Medicine" in I Glenn Cohen et al, eds, *Big Data, Health Law and Bioethics* (Cambridge: Cambridge University Press, 2018) 295 (discussing healthcare-specific worries).

25 See *ibid*. See also Carl Macrae, "Governing the Safety of Artificial Intelligence in Healthcare" (2019) 28:6 Brit Med J Quality & Safety 495 (also discussing this as a safety issue). Yet some note that human decision making is not always understandable and question whether understanding is required to address these risks. See Alex John London, "Artificial Intelligence and Black-Box Medical Decisions: Accuracy versus Explainability" (2019) 49:1

make it hard to identify problems (adverse events, bias, etc.) in advance or in practice.[26] Requiring "explainable" AI may not resolve all these issues: "explanations" often provide a proxy for how AI works, not direct understanding, and some AI tools could be safe and effective without being explainable.[27]

Another safety-related concern is that of algorithmic bias. AI is only as good as the data fed into it ("rubbish in, rubbish out").[28] If training datasets used by AI programmers systematically under-represent groups (e.g., women, Indigenous Peoples, Black Peoples, and Peoples of Colour, or other groups that have been marginalized), bias can result.[29] Bias is linked closely to safety

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Hastings Center Report 15; Marinus Ferreira, "Inscrutable Processes: Algorithms, Agency, and Divisions of Deliberative Labour" (2021) 38:4 J Applied Philosophy 646. WHO, *supra* note 16, accordingly takes a context-specific approach to how to resolve conflicts between explainability and performance. As discussed *below*, attempts to promote explainability may also raise their own concerns, which we cannot fully canvass here.

26 Recall the last two notes.

27 In addition to the caveats in note 25, there are additional issues. See e.g. Boris Babic et al, "Beware Explanations from AI in Health Care" (2021) 373:6552 Science 284; Marzyeh Ghassemi, Luke Oakden-Rayner & Andrew Lane Beam, "The False Hope of Current Approaches to Explainable Artificial Intelligence in Health Care" (2021) 3:11 Lancet Digital Health e745. These include explainability tools providing a false sense of security in AI, compounding possibilities of error produced by introducing one technology to explain another, and the possible need to validate that with yet another tool.

28 See Sandra G Mayson, "Bias In, Bias Out" (2019) 128:8 Yale LJ 2218.

29 See Ziad Obermeyer et al, "Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations" (2019) 366:6464 Science 447; Melissa D McCradden et al, "Ethical Limitations of Algorithmic Fairness Solutions in Health Care Machine Learning" (2020) 2:5 The Lancet Digital Health E221; George A Adam et al, "Hidden Risks of Machine Learning Applied to Healthcare: Unintended Feedback Loops Between Models and Future Data Causing Model Degradation" (2020) 126 Proceedings of Machine Learning Research 1. See also Mayson, *supra* note 28; Cathy O'Neil, *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy* (DC: Crown Books, 2016); Ruha Benjamin, "Assessing Risk, Automating Racism" (2019) 366:6464 Science 421. AI can also provide a technologically-infused false air of neutrality to pre-existing bias that they thereby help to entrench. See Ruha Benjamin, *Race After Technology: Abolitionist Tools for the New Jim Code* (Medford: Polity, 2019).

concerns, for bias can undermine the accuracy of diagnosis or treatment recommendations, as, e.g., when skin cancer diagnosis is accurate for Caucasians but not People of Colour. As Ayanna Howard notes, "[m]odels about people are rarely accurate for people that are not represented in the data" and use of inaccurate models for AI could raise safety issues.[30] Algorithmic bias may also arise where the data AI is trained upon or collects is theoretically representative but, because of racism or sexism *already within the system*, does not reflect the real needs of patients from marginalized groups. For example, data may include Black men but assumes their needs are X when in fact their needs are X + Y but Y has been unattended to because of racial bias already existing within the healthcare system.[31] This bias problem may be compounded by legal/professional incentives to use and rely upon AI in healthcare decision making. Automation bias, the tendency for humans to be overconfident in and unduly deferential to machine-based recommendations, makes this concern acute.[32] One cannot assume that these problems can be cured via post-market surveillance and ML tools evolving to real-world needs. In the real world, those who have been marginalized may not have access to AI technologies because they are not part of public plans or covered by private health insurance.[33] One thus

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30 See Robert Monarch, "Anecdotes from 11 Roles Models in Machine Learning" (21 September 2021), online: *Towards Data Science* <towardsdatascience.com/anecdotes-from-11-role-models-in-machine-learning-d01bc0d65dcd>. See also Challen et al, *supra* note 22; Antoniou & Mamdani, *supra* note 22; Joseph Paul Cohen et al, "Problems in the Deployment of Machine-Learned Models in Health Care" (2021) 193:35 Can Med Assoc J E1391.

31 Recall note 29 sources.

32 See *above* sources on how AI can impact provider reasoning, especially in note 5. On automation bias, see David Lyell & Enrico Coiera, "Automation Bias and Verification Complexity: A Systematic Review" (2017) 24:2 J American Medical Informatics Association 423. See also Ravi B Parikh, Stephanie Teeple & Amol S Navathe, "Addressing Bias in Artificial Intelligence in Health Care" (2019) 322:24 JAMA 2377 at 2377 (on its bias implications).

33 Issues in Obermeyer et al, *supra* note 29 parallel this concern.

cannot assume that algorithmic bias issues will erode over time as ML tools evolve and learn from real-world data.[34]

Privacy concerns are also related to the safety and algorithmic bias questions. AI needs to aggregate and harvest vast amounts of health information to be accurate, and yet this data could potentially be repurposed and shared with third parties.[35] Many privacy protections will apply in the medical device context,[36] but to date Canadian personal health information legislation typically exempts "deidentified" data from its protections.[37] Powerful AI

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34 For more on the causes of and potential Canadian legal solutions to bias issues, see Bradley Henderson, Colleen M Flood & Teresa Scassa, "Artificial Intelligence in Canadian Healthcare: Will the Law Protect Us from Algorithmic Bias Resulting in Discrimination?" (2022) 19:2 CJLT 475.

35 On re-identification, see e.g. W Nicholson Price II & I Glenn Cohen, "Privacy in the Age of Medical Big Data" (2019) 25 Natural Medicine 37 at 40; Blake Murdoch, "Privacy and Artificial Intelligence: Challenges for Protecting Health Information in a New Era" (2021) 22:122 BMC Medical Ethics at 3. See Zahra Azizi et al, "Can Synthetic Data be a Proxy for Real Clinical Trial Data? A Validation Study" (2021) 11:4 Brit Med J Open e043497 (suggesting that reidentification of clinical trial data has not happened yet but even they grant that it remains possible at e043497). On privacy generally, see e.g. Frank A Pasquale, "Redescribing Health Privacy: The Importance of Information Policy" (2014) 14 Houston J Health L & Policy 95; Frank A Pasquale & Tara Adams Ragone, "Protecting Health Privacy in an Era of Big Data Processing and Cloud Computing" (2014) 17 Stan Tech L Rev 595; I Glenn Cohen & Michelle M Mello, "Big Data, Big Tech, and Protecting Patient Privacy" (2019) 322:12 JAMA 1141; Ian Kerr, "Schrödinger's Robot: Privacy in Uncertain States" (2019) 20 Theoretical Inquiries L 123. On the need for large amounts of data, see e.g. Mélanie Bourassa Forcier et al, "Integrating Artificial Intelligence into Health Care through Data Access: Can the GDPR Act as a Beacon for Policymakers?" (2019) 6:1 JL & Biosciences 317 at 318.

36 In addition to the federal *Privacy Act*, RSC, 1985, c P-21 and *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5 [*PIPEDA*], each province has privacy laws like New Brunswick's *Freedom of Information and Protection of Privacy Act*, SNS 1993, c 5 or health privacy laws like Ontario's *Personal Health Information Protection Act, 2004*, SO 2004, c 3, Sched A [*PHIPA*]. PIPEDA presents an exception to general rules on the paramountcy of federal law with its explicitly statement that provincial laws can apply in areas of overlap.

37 See *ibid*. The first major exception to this rule went into force in October 2021, shortly before submission of the original draft of this text. Quebec now regulates de-identified and anonymized data under statutory amendments

tools increase risks of reidentification of individuals.[38] Various proposals have been offered for safeguarding privacy when using AI tools or even developing privacy-preserving AI—including requirements for data trusts,[39] federated learning,[40] differential privacy,[41] and synthetic data[42]—but each is subject to forceful criticisms and does not fully address all safety-related issues.[43]

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introduced in *An Act to modernize legislative provisions as regards the protection of personal information*, Recueil annuel des lois du Québec 2021, c 25. For discussion, see Elizabeth Raymer, "New Quebec privacy legislation comes into effect" (5 October 2021), online: *Canadian Lawyer* <canadianlawyermag.com/practice-areas/privacy-and-data/new-quebec-privacy-legislation-comes-into-effect/360463>.

38 See I Glenn Cohen & Michelle M Mello, "HIPAA and Protecting Health Information in the 21st Century" (2018) 320:3 JAMA 231.

39 See e.g. P Alison Paprica et al., "Essential Requirements for Establishing and Operating Data Trusts: Practical Guidance Co-developed by Representatives from Fifteen Canadian Organizations and Initiatives" (2020) 5:1 International J Population Data Science 1353 (also suggesting how they could operate in Canadian law).

40 See e.g. Georgios A Kaissis et al, "Secure, Privacy-Preserving and Federated Machine Learning in Medical Imaging" (2020) 2 Nature Machine Intelligence 305. For a useful discussion of federated learning's potential benefits and drawbacks, see Tian Li et al, "Federated Learning: Challenges, Methods, and Future Directions" (May 2020) IEEE Signal Processing Magazine 50.

41 See Cynthia Dwork, "Differential Privacy" in Michele Bugliesi et al, eds, *Automata, Languages and Programming: 33rd International Colloquium, ICALP 2006, Venice, Italy, July 10–14, 2006, Proceedings, Part II*, (Berlin/Heidelberg: Springer-Verlag, 2006) at 1–12 (discussing "differential privacy" as a measure of increased risk to privacy of different interventions and discusses various methods of achieving acceptably low thresholds at 8–11. The term is, however, used to refer to particular methods thereof).

42 See e.g. Murdoch, *supra* note 35; Azizi et al, *supra* note 35; and sources therein. The list of options here is not exhaustive. See also e.g. WHO, *supra* note 16 at 40–41 (discussing general regulatory options); Stephanie OM Dyke et al, "Evolving Data Access Policy: The Canadian Context" (2016) 1:1 FACETS 138 (for a Canadian focus).

43 Potential critiques are legion. A few representative points must suffice. See Paprica et al, *supra* note 39 (granting that "data trust" refers to many different institutional forms and most forms require many additional safeguards); see also Murdoch, *supra* note 35 (highlighting the need for good real-world data which one can "synthesize"). A reviewer suggests workable trade-offs between data privacy and data utility may not be possible using

Outstanding privacy concerns are related to algorithmic bias and safety issues in this way: some groups who have been marginalized in society may be reluctant to permit the use of their data to support AI development,[44] but AI developed without this data may be biased and make errors in diagnoses and treatment recommendations. At the same time, some tools that AI developers may adopt in attempts to safeguard privacy may come with accuracy trade-offs that could themselves raise safety concerns.[45] Regulators will likely also have to strike the requisite balance between these values.

If coherent legal frameworks do not address the foregoing concerns about algorithmic bias and privacy, this could erode trust by the public in AI use in healthcare and create a significant chasm between the development and implementation of an innovation. Some authors call this rift the most "inconvenient truth" about AI.[46] It could result in many lost opportunities for valuable AI developments likely to improve the Canadian healthcare system.[47]

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any mechanism and that one can use proxies to address some concerns—e.g., technical audits of the risk of re-identification posed by an AI tool—while questioning any approach to privacy as a panacea. For one proxy, see Krista Wilkinson et al, "Less Than Five is Less Than Ideal: Replacing the 'Less than 5 Cell Size' Rule with a Risk-Based Data Disclosure Protocol in a Public Health Setting" (2020) 111:5 Can J Public Health 761.

44 See LLana James, "Race-Based COVID-19 Data may be used to Discriminate against Racialized Communities" (2020), online: *The Conversation* <theconversation.com/race-based-covid-19-data-may-be-used-to-discriminate-against-racialized-communities-138372> (building partly on the concerns of O'Neil, *supra* note 29 and Benjamin, *ibid*).

45 Recall how some of the problems with IBM Watson for Oncology stemmed from training on synthetic cases: see Gerke, Minssen & Cohen, *supra* note 5 at 302. Some studies suggest that synthetic data can be almost as accurate as real cases: see Azizi et al, *supra* note 35. However, it is premature to suggest that this data will always perform as well, particularly since synthetic data will need to adapt to real-world changes to be useful: see Chen et al, *supra* note 15.

46 See Trishan Panch, Heather Mattie & Leo Anthony Celi, "The 'Inconvenient Truth' About AI in Healthcare" (2019) 2:77 npj Digital Medicine.

47 It may also lead to and a failure to leverage valuable financial and research efforts due to unusable or underused AI, though the financial elements of this trade-off are not within Health Canada's direct remit. See also Nathan Cortez,

This non-use of AI tools that would otherwise protect Canadians' health could also undermine public "safety".

C. The Challenge

Addressing these issues is complex in Canada because of the constitutional division of powers issues and overlapping laws/regulations. As heralded earlier, our focus in this paper is on Health Canada's regulation of medical devices as a means of ensuring the safety of health-related AI. In limiting our analysis in this way, we do not discount the importance of understanding and evaluating the efficacy of the *entire* ecosystem of governance applying to AI in healthcare: public legislation and regulation at the federal, provincial and professional (regulatory colleges) levels and private laws (e.g., product liability laws and contract law between AI manufacturers and users where contracts "absolve" manufacturers from liability).[48] Yet it seems to us that a deep dive into medical device safety and efficacy regulation is an important first step.[49]

II. THE PRESENT REGULATORY FRAMEWORK

Health Canada regulates the approval of medical devices as safe for use within Canada. The regulatory framework is sourced in the *Food and Drugs Act* (the *Act*) and accompanying *Medical Devices*

"Regulating Disruptive Innovation" (2014) 29 Berkeley Tech LJ 176; Christian Lovis, "Unlocking the Power of Artificial Intelligence and Big Data in Medicine" (2019) 21:11 J Medical Internet Research E16607.

48 See Régis & Flood, *supra* note 5.

49 Health Canada's clinical trials rules set clinical study requirements that interact with localized Research Ethics Board review requirements: see e.g. *F&D Act*, *supra* note 11. See The Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *"Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans"* (2018), online: *Government of Canada* <ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html> (impacting issues *below*). But note TCPS enforcement problems: see Jocelyn Downie, "The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal" (2006) 13:1 Accountability in Research 75.

Regulations (the *Regulations*).[50] Canada's system provides for two main tools for ensuring medical device safety: (1) explicit requirements relating to safety and misleading labelling/advertising with penalties for violating a prohibition on unsafe devices and (2) an ex ante manufacturing, importation, and distribution licencing scheme.[51] Health Canada also has mechanisms for post-market surveillance of medical devices and, as explored further below, their recently increased focus on post-market review will have to significantly develop to monitor ML over time.[52]

Under the *Act*, a medical "device" is a type of "therapeutic product," namely any "instrument, apparatus, contrivance, or other similar article, or an *in vitro* reagent" used in disease diagnosis, treatment, mitigation, or prevention; bodily restoration/modification/correction; pregnancy diagnosis or pre- or postnatal care; and conception prevention related to human beings.[53] This definition captures products ranging from bandages and manual toothbrushes to pacemakers and mechanical heart valves. Its scope includes any product that "consists of or contains software" that otherwise fits under the definition.[54] This potentially puts many forms of health-related AI within the ambit of the *Act* and *Regulations*.[55]

As noted, the *Regulations* currently only apply to the importation or sale of and clinical trials on medical devices and so do not cover all uses.[56] To "sell" under the *Act* does not require a transfer of ownership and explicitly covers the "lease" of a

50 See *F&D Act*, *supra* note 11; *MDR*, *supra* note 11.

51 See *ibid*. The following paragraphs *below* include details, including pinpoint citations.

52 See *ibid*.

53 *F&D Act*, *supra* note 11, s 2. The definition of "medical device" there excludes those who bring about their result by "solely by pharmacological, immunological or metabolic means or solely by chemical means". The definition of "therapeutic product" excludes "natural health product[s]".

54 See *MDR*, *supra* note 11, s 20.

55 See Part III, *below*.

56 See *F&D Act*, *supra* note 11, ss 2, 3.1–3.3, 19, 21; *MDR*, *supra* note 11, ss 2–5.

device.[57] However, the present regime generally only applies to commercial uses of and formal clinical research trials involving humans on medical devices,[58] which means devices developed and implemented for in-house use (e.g., within a hospital or alliance of hospitals), rather than commercial purposes or formal trials with humans, are not subject to regulatory oversight.

Canada's federal Minister of Health delegates most of its regulatory authority over medical devices under the *Act* and regulations to Health Canada's Medical Devices Directorate (MDD).[59] The MDD's Bureau of Evaluation, which is "responsible for reviewing applications for new and amended medical

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57 See *F&D Act*, *supra* note 11, s 2.

58 See *ibid*. While *MDR*, *supra* note 11, also discuss "manufacturing", the definition of "manufacturers" in s 1 is connected to the prior definition of "sell" in the *F&D Act*, *supra* note 11, s 2. As discussed *below*, the new "Advanced Therapeutic Products" pathway covers "use", rather than sale, potentially avoiding some issues here. A recent amendment to the *Act* prohibits a clinical trial unless there is prior regulatory approval: see *ibid*, s 3.1–3.3, as amended by SC 2019, c 29, s 166. This 2019 amendment only went into force via an Order-in-Council, which simultaneously provided exemptions for COVID-19-related trials; see Government of Canada, "ARCHIVED Interim Order No. 2 Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19" (2021), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-2-clinical-trials-medical-devices-drugs.html>. The amendments technically prohibit clinical trials on devices that have not been approved for an investigational study or COVID-19-specific exemptions; see *MDR*, *supra* note 11, s 80. Yet most public details on how this will be enforced focus on COVID-19-specific studies; see e.g. Government of Canada, "Medical Devices for COVID-19: Conducting a Clinical Trial" (2020), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/conducting-medical-device-trial.html>.

59 The Minister can delegate regulatory authority through regulations; see *F&D Act*, *supra* note 11. See also Government of Canada, "Medical Devices Directorate" (2021), online: *Government of Canada* <canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/medical-devices-directorate.html> [MDD].

devices"[60] recently added a specific "Digital Health Review Division".[61]

A. General Regulatory Requirements

The *Act* first explicitly prohibits the sale of devices that "may cause injury to the health of the purchaser or user" in the course of regular or prescribed use thereof.[62] It then prohibits "false, misleading or deceptive" advertising, labelling, etc.[63] Maximum penalties for violations of the *Act* and regulations regarding "therapeutic products" (viz., drugs and devices) are often higher than violations of provisions regarding other products (e.g., food).[64] Penalties for a first offence on summary conviction with respect to medical devices may be as high as $250,000 and/or 6 months imprisonment.[65] Violating a provision in a way that "knowingly or recklessly causes a serious risk of injury to human health" when contravening a rule regarding therapeutic products can trigger "a fine the amount of which is at the discretion of the court" and/or 5 years imprisonment on indictment.[66] This offence is not subject to the "due diligence" defence available for most other offences under the *Act* and *Regulations*.[67] Criminal sanctions

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60 See *ibid*.

61 See Health Canada, "Notice: Health Canada's Approach to Digital Technologies" (2018), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-digital-health-technologies.html>. An announcement states that this division will be responsible for Software as a Medical Device (SaMD) *and* AI, implicitly distinguishing the two: see also Health Canada, "Building Better Access to Digital Technologies" (2019), online: *Government of Canada* <canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/building-better-access-digital-health-technologies.html>. They are, of course, still responsible for cases of AI/SaMD overlap.

62 *F&D Act*, *supra* note 11, s 19.

63 *Ibid*, ss 19–20.

64 *Ibid*, ss 31–31.4

65 See *ibid*, ss 31.1(1)(a), 31.2(1)(b).

66 *Ibid*, s 31.4(1).

67 *Ibid*, s 31.3.

help fit the Act in within federal constitutional jurisdiction, but the broader scheme is regulatory in practice.[68]

B. Pre-Market Licencing Requirements

The licencing scheme in the *Regulations* specifies four "classes" of devices, characterized primarily by the devices' risk levels.[69] Standards for each class are set by the Standards Council of Canada and indexed to international norms.[70] Classification triggers different licencing requirements such that trade in higher-risk medical devices requires meeting more demanding requirements. However, all devices must meet basic safety and labelling standards.[71] For instance, all manufacturers must take "reasonable measures" to identify and eliminate or, if elimination is impossible, minimize risks and devices cannot "deteriorate under normal use" over time in ways that create adverse effects.[72] Importers and vendors must label a device, including its "conditions, purposes, and uses" and "performance specifications".[73]

Medical device manufacturers, including AI innovators who produce devices, initially self-identify as to the risk category

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68 As note 9 sources explain, "healthcare" is an area of shared federal and provincial jurisdiction. Yet both governments must justify their healthcare regulations under one or more of their respective heads of powers. Purely regulatory regimes are often said not to be proper uses of the "criminal" power; see *Reference Re Assisted Human Reproduction Act*, 2010 SCC 61. See Régis & Flood, *supra* note 5 (suggesting that *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17, may provide the authority for a criminal law-based regime). Absent clarity on the relationship between criminal and health regulations powers or a challenge to the *Act* or *Regulations*, this work takes the constitutionality of both for granted.

69 *MDR*, *supra* note 11, s 6.

70 Per *Standards Council of Canada Act*, RSC 1985, c S-16. International norms admit some exceptions. For instance, the USA only has three risk categories, rather than four, despite harmonization efforts discussed, *below*.

71 See *F&D Act*, *supra* note 11; *MDR*, *supra* note 11.

72 *MDR*, *supra* note 11, ss 10, 13 (with details in ss 11–16).

73 *Ibid*, s 21.

within which their product will fall.[74] Under the present regulatory regime, Health Canada believes it "is the role and onus of the manufacturer to determine the appropriate classification for their device."[75] The MDD may reclassify a medical device,[76] but we cannot find evidence of routine audits of classification selection.[77] Such audits may in fact be routine on the part of the regulator, but there is no public reporting thereof.

Anyone who imports or sells medical devices of any class must possess an establishment licence.[78] The MDD provides a licence upon receipt of basic information about the applicant, the device's intended use, and the safety procedures that are in place.[79] Trade

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74 See e.g. Health Canada, "Health Canada's Action Plan on Medical Device Devices: Continuously Improving Safety, Effectiveness, and Quality" (December 2018), online: *Government of Canada* <canada.ca/en/health-canada/services/publications/drugs-health-products/medical-devices-action-plan.html> ["Action Plan"]; Government of Canada, "Guidance Document: Software as a Medical Device (SaMD): Definition and Classification" (18 December 2019), online (pdf): <canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document/software-medical-device-guidance-document.pdf> ["SaMD"] (interpreting *MDR*, *supra* note 11).

75 Government of Canada, "Guidance Document: Software as a Medical Device (SaMD): Classification Examples" (2020), online (pdf): *Government of Canada* <canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document/examples/software-medical-device-guidance-examples.pdf> ["CE"].

76 If the device could be classified in multiple classes, "the class representing the higher risk applies": see *MDR*, *supra* note 11, s 7.

77 E.g., details are lacking in reports and plans, *above*. Annual reports focus on the number of licences and amendments and timeline for addressing them, rather than these issues: see e.g. Government of Canada, "Medical Devices Directorate Annual Performance Report for April 1, 2019 - March 31, 2020" (2020). A tool on the Health Canada website devoted primarily to drug inspections contains some data on devices but does not discuss reclassification: see Health Canada, "Medical Device Inspections", online: *Government of Canada* <drug-inspections.canada.ca/md/index-en.html>.

78 *MDR*, *supra* note 11, s 44; see also *F&D Act*, *supra* note 11, ss 2, 3.1.

79 See *MDR*, *supra* note 11, ss 44–45. This licence is subject to annual review per s 46.

in Class II–IV medical devices also requires that the manufacturer possess a medical device licence.[80] All medical device licence applications must include basic product information (its name, class, and identifier), basic manufacturer information (e.g., its name and address), and the list of standards the manufacturer met to ensure its compliance with other safety norms.[81] Other requirements differ across Classes II–IV, as summarized in the following table.[82]

Table 1: Medical device licence application requirements

Class	Information on How Features Contribute to Purpose	Evidence of Effectiveness	Information on Foreign Use/ Incidents	Risk Assessment and Quality Plan
I	N/A (Medical Device Licence Not Required)			
II	Not Required	Attestation that objective evidence of effectiveness exists	Not Required	Not Required
III	Required	Summary of studies / conclusions drawn from them, and bibliography of published reports on effectiveness	Required	Not Required
IV	Required	Requirements for Class III + detailed information on all studies, including pre-clinical and clinical studies, process validation studies, software validation studies (if applicable), and literature studies	Required	Required

Only Class III and IV devices require *positive* evidence from studies about their efficacy. Even then, only Class IV applications appear to require "clinical studies" and "detailed" information

80 *Ibid*, ss 26, 27. See ss 28–31 for special cases.

81 See *ibid*, s 32.

82 This table summarizes the requirements outlined in *MDR*, *supra* note 11.

thereon.[83] Licencing decisions are largely made based on information provided by applicants, although the MDD may request additional information about a device if the information above is insufficient to assess its safety.[84] The MDD can refuse to issue a licence if the applicant does not comply with regulatory rules and must do so if the device does not fulfill the safety conditions; the MDD can also suspend a licence if it provides written notice, time for correction, and a hearing (or absent a hearing if necessary to prevent death or injury).[85] Manufacturers must, in turn, provide annual reports confirming that the relevant safety standards are still met.[86]

The pre-market licencing process is not *solely* reliant on information provided by applicants. Health Canada can refer to "information brought to . . . [its] attention" to make some decisions.[87] Further applications for a medical device licence must include a Quality Management System Certificate ensuring conformity with ISO 13485, an international quality standard.[88] While the certificate comes to the MDD via the applicant, a third-party accreditor initially produces it.[89] Accreditation bodies set and monitor international ISO standards and are themselves subject to international medical device-specific quality assurance standards.[90]

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83 See *ibid*, ss 10, 32 (while section 32 explicitly mentions the need for "clinical studies", section 10 discusses the effectiveness of all devices but does not require that studies be done to demonstrate it).

84 See *ibid*, s 35.

85 See *ibid*, ss 38, 40–41.

86 See *ibid*, s 43(1).

87 *Ibid*, ss 25, 39, 59.

88 See *ibid*, ss 32(2), 32(3)(j), 32(4)(p).

89 See e.g. British Standards Institution (BSI), "Medical Device Single Audit Program" (2021), online: *BSI* <bsigroup.com/en-CA/Medical-Devices/Our-services/Medical-Device-Single-Audit-Program-MDSAP/> (discussing their dual ISO/MDSAP audit).

90 See e.g. International Accreditation Forum (IAF), "Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)" (2020), online (pdf): *IAF* <iaf.nu/iaf_system/uploads/documents/IAF_MD8_Issue_4_29062020.pdf>.

The MDD, again via delegated authority, can request more information for risk assessment purposes and order assessments, tests and/or studies of a device.[91] It can order labelling/packaging modifications to prevent injuries.[92] It can also make orders to prevent or remedy violations of the *Act* or its regulations.[93] Where there is a "serious or imminent risk of injury", it can order a recall or other corrective actions, including placing conditions on sale.[94]

C. Post-Market Review Procedures

Post-market surveillance and reporting requirements are less developed than pre-market requirements. However, we discuss recent amendments that now permit Health Canada to order post-market tests and studies of device efficacy and expand reporting requirements below. We also go on to analyze whether these are sufficient to meet concerns regarding health-related AI.

1. Surveillance

Maintaining a licence under the *Act* and *Regulations* requires a manufacturer to comply with post-market surveillance requirements. The "annual review" of establishment licences largely relies on information provided by the applicant, but the MDD can refer to "any other relevant information in . . . [its] possession."[95] Maintaining a medical device licence, in turn, requires maintaining a current Quality Management System Certificate and manufacturers submit to third-party audits to do so, though the frequency of these audits is unclear.[96]

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91 See *F&D Act*, *supra* note 11, ss 21.1, 21.31–21.32.

92 See *ibid*, s 21.2.

93 See *ibid*, s 27.3. Among the provisions listed here, this one may not be fully delegated to the MDD, which places a caveat only on this sentence. The Minister of Health can also issue time-limited interim orders under s 30.1.

94 *Ibid*, s 21.3.

95 *MDR*, *supra* note 11, ss 46, 46.1.

96 See *ibid*, s 32.1. On the certificate, see e.g. information in sources in notes 89–90.

Health Canada can also appoint inspectors to ensure compliance.[97] Inspectors can request information from those subject to the regulations and enter buildings in which the regulated parties work to check compliance.[98] They can also remove, forfeit, or destroy illegally imported goods.[99] Health Canada inspects some manufacturing facilities—including some outside Canada, though international rules below may limit such inspection—and conducts compliance verification reviews for manufacturers, importers, and vendors.[100] Yet there is, again, little data on the frequency with which Health Canada uses such monitoring and enforcement provisions.[101]

As of June 2021, per changes designed to implement "Vanessa's Law" , the MDD can also order new tests and studies for efficacy as part of the review process.[102] The MDD can, for instance, now

97 See *F&D Act*, *supra* note 11, s 22.

98 See *ibid*, ss 22–23. Notably, the Regulatory Operations and Enforcement Branch appoints inspectors, not the MDD.

99 See *ibid*, s 27.1.

100 See "Action Plan", *supra* note 74 at 6. Foreign inspections have increased in recent years despite these limitations; see Government of Canada, "Medical Devices Action Plan: Progress Report" (2021), online: <canada.ca/en/health-canada/services/publications/drugs-health-products/medical-devices-action-plan-progress-report.html> ["Progress"].

101 *Ibid* aside, the most recent report, "CE", *supra* note 75, is silent on this. The website in that note includes some data on medical device inspections, but it is also limited. A 2021 search found 4 443 inspections dating back to 2011, but the coding of the inspections regarding compliance rates and enforcement actions did not account for 4 443 inspections. Indeed, the data on particular enforcement actions often covered much shorter timeframes. See *ibid*.

102 See *MDR*, *supra* note 11, ss 62.1–62.2. The statute implements changes; see Government of Canada, "Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations (Post-market Surveillance of Medical Devices)", 154:26 Canada Gazette, Part II, online: *Government of Canada* <gazette.gc.ca/rp-pr/p2/2020/2020-12-23/html/sor-dors262-eng.html> ["Amendments"]. See *F&D Act*, *supra* note 11, s 21.31 (technically providing the power to order assessments). That power was conditional on regulatory specifications realized by these amendments. See *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), SC 2014, c 24 (receiving Royal Assent in 2015 and modifying the *FDA*). It aimed to increase regulatory

order safety and effectiveness reports.[103] However, the MDD's powers to request more information for risk-assessment purposes and order assessments, tests, or studies of the devices are subject to conditions requiring reasonable grounds to believe the risk-benefit ratio has significantly changed or that there is a lack of information needed to make that calculus.[104] Decisions about whether to use these powers must also consider "whether the activities that the licensee will be ordered to undertake are feasible" and "[if] less burdensome ways of obtaining additional information about the device's effects on the health or safety of patients, users or other persons" are available.[105] This suggests that these powers are meant to be a last resort.

There are no *unique* penalties for failing to comport with post-market requirements. But regular penalties apply and if, e.g., a safety-related issue arises after a medical device is on the market, the MDD can recall it, suspend a licence, or refuse to amend a licence.[106] Stakeholders must keep distribution records for devices to make recalls easier.[107] While these proceedings can take time, quick action is possible. For instance, Health Canada can suspend establishment licences and medical device licences where there are "reasonable grounds to believe that" there is a violation of the *Act* or associated regulations, there are false or misleading statements in an application, or a suspension is necessary to

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scrutiny of drugs following the death of Vanessa Young following an adverse drug reaction. It introduced hospital-specific adverse effects reporting and additional post-market scrutiny. For information, see e.g. Government of Canada, "Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): Questions/Answers" (2014), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/questions-answers-regarding-law-protecting-canadians-unsafe-drugs-act-vanessa-law.html>.

103 See *MDR*, *supra* note 11, s 62.1–62.2. The following citations implement "Amendments", *supra* note 102.

104 See *MDR*, *supra* note 11, s 62.1.

105 *Ibid*, s 62.2.

106 See *F&D Act*, *supra* note 11, s 21.3.

107 See *MDR*, *supra* note 11, s 52.

mitigate health risks.[108] Suspensions must follow the time necessary for any "corrective action" and an opportunity to be heard; yet these requirements do not apply if a suspension is necessary to "prevent injury to the health or safety" of humans.[109]

2. Reporting Requirements

The *Regulations* require manufacturers and importers of medical devices, hospitals, and the narrow class of healthcare providers with special authorization to use custom-made devices to report "incidents" to the MDD.[110] Distributors, other healthcare facilities and providers, and patients are not subject to such requirements.[111] Yet mandatory reporting for long-term care facilities and private clinics is envisioned as part of future reforms.[112] Information provided through incident-reporting processes can trigger a recall or licence suspension.[113]

(a) Manufacturers/Importers

Manufacturers and importers (but not distributors) of medical devices are bound to report any "incident" occurring in Canada and must accordingly "submit . . . information in respect of any serious risk of injury to human health that the holder receives or becomes aware of and that is relevant to the safety of the device".[114] The recent changes designed to implement Vanessa's Law in the medical device context further specified these

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[108] See *ibid*, ss 40, 49. In practice, the Director General of Health Canada formally approves suspensions via authority delegated from the Minister of Health based on recommendations from the MDD.

[109] *Ibid*, ss 40–41, 49–50. Per s 51.1, licences are cancelled after 12 months of suspension.

[110] *Ibid*, ss 59–62; *F&D Act*, *supra* note 11, s 21.8.

[111] See e.g. *ibid*; "Amendments", *supra* note 102.

[112] See "Action Plan", *supra* note 74 at 4. Health Canada is now "encouraging" such reports: see "Progress", *supra* note 100.

[113] See notes, *above*, summarizing provisions in *F&D Act*, *supra* note 11; *MDR*, *supra* note 11.

[114] *MDR*, *supra* note 11, s 61.2. The following citations again implement "Amendments", *supra* note 102.

requirements. So, as of June 2021, the reporting provisions in the *Regulations* require providing information about risks identified by regulatory agencies, changes in labelling, and recalls, etc., both within and outside of Canada.[115]

Those same new regulatory requirements also require summary reports of adverse effects, incidents, and safety risks, on a biennial basis for Class II devices and an annual basis for Class III and Class IV devices.[116] This helps ensure that incidents are reported at regular intervals and not merely as notable incidents arise. "Abnormal" (viz., off-label) use need not be reported, though Health Canada must evaluate discretionary off-label use reports that are made.[117]

(b) Healthcare Institutions and Providers

Hospitals must report some issues with regulated medical devices to the MDD. Under the *Act*, any specified "prescribed health care institution" must report any "medical device incident that involves a therapeutic product."[118] Incidents include a device failure, a deterioration in its effectiveness, or "any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user or

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115 See *ibid*. On Vanessa's Law, recall note 102.

116 See *MDR*, *supra* note 11, s 61.4.

117 See Government of Canada, "Incident Reporting for Medical Devices: Guidance Document" (2021), online: <canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/incident-reporting-medical-devices-guidance-2021.html> ["Incident"]. "Off-label use" here refers to use for purposes other than those explicitly approved by the regulator and indicated on the packaging; see e.g. Canadian Agency for Drugs and Technologies in Health (CADTH), "Off-Label Use of Drugs" (2017), online (pdf): *CADTH* <cadth.ca/sites/default/files/pdf/off_label_use_of_drugs_pro_e.pdf> (focusing on drugs but with parallel application to and clear implications for devices). For possible policy implications, see R S Stafford, "Off-Label Use of Drugs and Medical Devices: A Review of Policy Implications" (2012) 91:5 Clinical Pharmacology & Therapeutics 920.

118 *F&D Act*, *supra* note 11, s 21.8.

other person or could do so were it to recur."[119] While the *Act* could require reporting by many institutions, regulations specify that only "hospitals" qualify as "prescribed health care institutions" for these purposes.[120]

Under the Regulations, healthcare providers are only bound to report incidents related to the use of "custom-made" medical devices for which they received "special access" authorization for emergency purposes or due to the failure of conventional therapies.[121] They are not subject to other reporting requirements or even listed as possible "incident reporters" in Health Canada's relevant guidance documents.[122] Health Canada appears to have no plans to require reporting adverse events by physicians or other providers in reform proposals.[123]

(c) Patients

Patients and other consumers are not duty-bound to report incidents but may do so.[124] Manufacturers, importers, and distributors must maintain records of complaints reported to them by consumers; manufacturers and importers must report any complaints that identify an "incident".[125] Consumers can directly report issues to Health Canada through an online portal.[126] Consumers are "strongly encouraged" to report issues they

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119 *MDR*, *supra* note 11, s 62(4).

120 See *ibid*, s 62. There is also an exemption for incidents related to devices offered through the exceptional "special access" programs, the details of which we bracketed for this analysis: see *ibid*, ss 62(4), 72(1), 83(1).

121 See *ibid*, ss 71, 77.

122 See *ibid*; "Incident", *supra* note 117.

123 See "Action Plan", *supra* note 74; "Progress", *supra* note 100.

124 No requirements appear in statutes or other documents with which we are familiar: see *MDR*, *supra* note 11; *F&D Act*, *supra* note 11.

125 *MDR*, *supra* note 11, ss 57–62.

126 See Health Canada, "Report a Medical Device Problem: Consumers" (last modified 30 December 2019), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/medical-device/consumer.html>.

experience or witness.[127] A single report is usually insufficient to "signal" an issue, but Health Canada evaluates all signals.[128]

III. APPLICATION OF THE FRAMEWORK TO AI IN/AS MEDICAL DEVICES

With this regulatory backdrop established, we can now turn to describe the specific regime developed for non-adaptive AI and software that is not part of hardware, "software as a medical device" (SaMD), before turning to address "unlocked" or adaptive ML in Part IV.

Health Canada defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[129] As mentioned earlier, applicants initially decide themselves which risk classification (see Table 1, *above*) they fall within and thus what level of regulatory scrutiny will apply to them. However, Health Canada guidance provides examples to help understand what risk classification should apply to different kinds of SaMD.[130] Health Canada views SaMD classification as a function of the "State of Healthcare Situation" (Critical; Serious; Non-Serious) and "Significance of Information Provided" (Treat or Diagnose; Drive Clinical/Patient Management; Inform Clinical/Patient Management).[131] Examples provided indicate that "all active

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127 See *ibid*. Health Canada notes that healthcare providers can assist in that process.

128 See Health Canada, "Report a Side Effect" (last modified 3 February 2022), online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>. Its title notwithstanding, this link discusses "issues" as a class and links to reporting mechanisms that address more than just "adverse reactions".

129 "SaMD", *supra* note 74 at 7. Despite the distinction in note 61, the dearth of AI-specific guidance leaves SaMD as the primary subject of existing guidance. Some SaMD is AI, but they are non-identical.

130 See sources *above* and *below*, most notably including "SaMD", *supra* note 74.

131 See "SaMD", *supra* note 74; International Medical Device Regulators Forum (IMDRF), "'Software as a Medical Device': Possible Framework for Risk Categorization and Corresponding Considerations" (2014), online (pdf): *IMDRF* <imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-

diagnostic devices, including any dedicated software, that supply energy for the purpose of imaging or monitoring physiological processes" will be Class II devices.[132] This suggests most health-related software would fall within Class II. Class I SaMD examples include software "intended for use in rehabilitation and active range of motion assessment."[133] At the other end of the regulatory spectrum, any "closed-loop system", a device "that enables the device to sense, interpret and treat a medical condition without human intervention",[134] will be in Class IV.[135] The *ability* to perform these functions suffices to qualify as a Class IV device, so manufacturers theoretically should not be able to avoid higher scrutiny by simply stating there will be human oversight of a device that could otherwise operate alone.

Before assessing which risk classification category (I–IV) a SaMD product falls within, an applicant must first determine whether its SaMD product is captured by the regulations *at all*. There are two major holes in the existing regulatory oversight. The first concerns the definition of sale. The second concerns technologies designed to support physician decision making.

With respect to the definition of sale, Health Canada's guidance documents state that they will only regulate software that is sold within the meaning of the *Act*, "which generally requires the transfer of ownership of a device from one party to another."[136] However, to "sell" under the *Act* does not require a transfer of

framework-risk-categorization-141013.pdf> (using an approach adopted in SaMD). See also "CE", *supra* note 75. This tracks the suggestion of Vayena & Blasimme, *supra* note 2 at 709, where they state that "[i]t is intuitively plausible to think that ethical stakes correlate with the severity of the condition at hand or the degree of reliance on AI for serious medical tasks", though they note that AI "in health system services" also has ethical implications.

132 "SaMD", *supra* note 74 at 14. This is an interpretation of the "special rules" which could reclassify any AI used in those "special" circumstances: see *MDR*, *supra* note 11, Schedule 1.

133 "CE", *supra* note 75 at 13.

134 *MDR*, *supra* note 11, s 1.

135 See *ibid*, Schedule 1, Rule 9.

136 "SaMD", *supra* note 74 at 6. But recall the caveat about clinical trials, *above*.

ownership (it includes leasing, for example), so such a limited regulatory focus appears narrower than what is permitted under the *Act*.[137] Moreover, even the actual definition of "sale" provided for in the *Act* does not seem envisage the development and use of SaMD, for example, within hospitals (or perhaps even groups of hospitals) in the absence of commercialization, some other explicit transfer, or a formal clinical research trial.[138]

With respect to exclusion of technologies that are assistive only, Health Canada's guidance documents exclude from regulation SaMD that fulfills four conditions, namely SaMD that is (a) "not intended to acquire, process, or analyze a medical image or signal", (b) "intended to display, analyze, or print medical information", (c) "only intended to support" provider decision making, and (d) "not intended to replace . . . clinical judgment."[139] One could read this to mean that SaMD that merely assists, rather than replaces, human decision making should not be subject to regulatory oversight, but this could exclude almost all known health-related AI. For greater certainty, Health Canada specifies that the following do not qualify as SaMD:

- Software intended for administrative support of a healthcare facility,

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137 See *F&D Act*, *supra* note 11, s 2.

138 Clinical research regulations will also apply to studies evaluating such AI tools. Recall note 49 and accompanying text. We phrase this in terms of hospital use as "in-house" development is most likely in major research institutions with the resources to develop these tools. This use could occur elsewhere, including places where the TCPS 2 does not apply.

139 SaMD, *supra* note 74 at 9–10. Any software "used to treat, diagnose or drive clinical management does not generally fit under" the third criterion and so would be regulated as a device. These conditions reflect Health Canada's understanding of its mandate. The *Regulations* alone may not formally prohibit regulation of these devices. See W Nicholson Price II, Rachel Sachs & Rebecca S Eisenberg, "New Innovation Models in Medical AI" (2021) 99:4 Wash U L Rev 1121 (suggesting that the definition of "medical device" in the USA's equivalent of the *F&D Act*, *supra* note 11 may not capture AI tools meant to address the "efficiency of health system staffing operations" at 1144. They further detail exclusions from the regulation of software which appear to be analogous to those in this paragraph).

- Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, video calling,
- Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps, and
- Software intended to serve as electronic patient records or tools to allow a patient to access their personal health information.[140]

These exemptions are large enough to potentially remove many AI technologies presently moving on to the market from practical regulatory purview.

To summarize, then, there are significant regulatory gaps with respect to non-adaptive AI and SaMD:

i. device manufacturers, at least initially, choose their products' risk classification and, by extension, which level of regulatory scrutiny a product may face;

ii. regulations of devices only apply in cases of importation, sale, and clinical research trials, so a hospital may be able to develop an AI device without regulatory oversight for its own provided it is not selling the device or conducting a formal research trial;

iii. technologies that "support" clinical decision making largely escape regulatory oversight, ignoring, as a result, risks associated with automation bias, etc.;

iv. safety and efficacy reviews do not explicitly need to address risks related to algorithmic bias or privacy, though these issues may be dealt with indirectly; and

[140] SaMD, *supra* note 74 at 8–9.

v. post-market review of medical devices is underdeveloped.

IV. A NEW PATHWAY FOR BRINGING MEDICAL DEVICES ONTO THE CANADIAN MARKET

Canada's existing rules make it nearly impossible to secure a licence for devices with adaptive ML (although, as discussed above, adaptive ML may still be employed in healthcare if it falls outside of the regulations). Adaptive ML technologies likely cannot meet the regulatory requirement that software "perform as intended by the manufacturer".[141] AI-enabled Class III and IV devices also require evidence of *validation* prior to approval, which is difficult to provide where adaptive ML changes over time by definition.[142] Even if a device with adaptive ML were approved, the requirement to seek an amendment every time there is a "significant change" to the device may render the initial approval largely illusory.[143]

As we write in March 2022, the federal government is developing a new pathway for licencing medical devices (particularly those with AI) for distribution within Canadian markets. The federal government's 2020 "Health and Biosciences Sector Regulatory Review Map" states a "new approach is required to enable access to advanced treatments, and to make products safer through stronger post-market controls."[144] The most significant change is the creation of an Advanced Therapeutic Product Authorization Pathway (ATPAP),[145] developed partly in

141 *MDR*, *supra* note 11, s 20.

142 See *ibid*.

143 See *ibid*, s 34 (with a definition of "significant change" in s 2).

144 Government of Canada, "Health and Biosciences: Targeted Regulatory Review—Regulatory Roadmap" (2020), online: <canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review/roadmap.html> ["Map"].

145 For additional scholarly discussion, see Ipek Eren Vural, Matthew Herder & Janice E Graham, "From Sandbox to Pandemic: Agile Reform of Canadian Drug Regulation" (2021) 125:9 Health Policy 1115.

recognition that innovative software manufacturers should be able to use a novel regulatory approach.[146] The federal government recently amended the *Act* to create the ATPAP[147] and presently Health Canada is seeking input on how to operationalize it.[148]

Recent amendments provide the Minister of Health with the power to licence a therapeutic product, including a medical device, by adding it to a licencing schedule "if the Minister believes that the therapeutic product or products represent an emerging or innovative technological, scientific or medical development."[149] The Minister can also "make an order, with or without terms and conditions, that authorizes any person within a class of persons that is specified in the order to" trade advanced therapeutic products.[150] These terms jointly permit Health Canada, via authority delegated to it by the Minister of Health, to create bespoke regulatory pathways for novel products, like medical devices with adaptive ML.[151] Health Canada can, in short, licence "truly unique" products, like adaptive ML without going through normal regulatory review processes.[152]

The first proposed use of the ATPAP will be for "Adaptive Machine Learning-enabled Medical Devices".[153] Health Canada guidance suggests that developers granted an ATPAP authorization will still require a licence from Health Canada or a

146 See "Map", *supra* note 144.

147 Recall note 14.

148 See Health Canada, "Call", *supra* note 14. Subsequent correspondence confirms that details remain in development.

149 *F&D Act*, *supra* note 11, s 21.91(1).

150 *Ibid*, s 21.95.

151 See Health Canada, "Call", *supra* note 14. See also Vural, Herder & Graham, *supra* note 145.

152 See Health Canada, "Agile Regulations for Advanced Therapeutic Products and Clinical Trials: Discussion Paper" (2019) at 4, online (pdf): <cellcan.com/docs/Agile%20regulations%20for%20advanced%20 therapeutic%20products%20and%20clinical%20trials.pdf> ["Discussion"].

153 See Health Canada, "Call", *supra* note 14. Subsequent correspondence with Health Canada reveals that an ATPAP for fecal microbiota therapy is also in development. Which ATPAP will be the "first" to be operationalized thus also remains to be seen.

letter of permission, and would still be subject to some reporting requirements, though these remain unspecified. [154] But it is also clear that those authorized via the ATPAP will be exempt from other regulations.[155] This presents significant risks that regulatory oversight will be lighter but not necessarily better,[156] particularly if Health Canada sets its primary goal as facilitating AI innovation in healthcare and supporting innovators rather than protecting patients and the public interest. However, as we discuss below, the ATPAP also offers a potentially important opportunity to expand the concept of safety and build new evidentiary standards to govern AI that are fit for purpose given the technology's key features. Everything depends on how Health Canada operationalizes this new pathway. We accordingly turn to offer several key principles to guide its choices.

V. PRINCIPLES THAT SHOULD GUIDE THE REGULATORY RESPONSE TO AI

Recent and looming changes in the regulation of medical devices, including the ATPAP, are inspired by and try to account for differences between AI in or as medical devices and other products regulated by Health Canada. In what follows, we lay out some high-level principles that we think should guide reforms of regulatory oversight of health-related AI. Other, more specific principles will clearly be required, particularly given the heterogeneity of health-related AI, but the high-level principles should apply broadly and guide development of narrower ones.[157]

A. The Need for Strong Independent Review

One worry in regulatory theory is that an industry will capture its regulator; that is, over time, the regulator will start to act more in the interests of those that are regulated, rather than in the public

[154] See "Discussion", *supra* note 152.

[155] See *F&D Act*, *supra* note 11, s 21.96.

[156] See Vural, Herder & Graham, *supra* note 145.

[157] On the heterogeneity, recall e.g. notes 20–21 and accompanying text.

interest.[158] In the case of Health Canada's regulation of health-related AI, one has to be aware of this risk at both the pre- and post-market stages of review. Canada's anxiety about not being left behind in a portended "fourth industrial revolution" could incent it and other governments worldwide to focus on promoting and leveraging domestic innovators for economic purposes, rather than focusing on patient safety.[159] Our concern here is that Health Canada may sidestep its role to properly regulate medical devices with AI for patient safety in order to promote AI innovation, a role that we consider more properly left to the Department of Innovation, Science & Economic Development, who can support Canadian innovators through subsidies and other mechanisms.[160]

As we described above, present regulatory oversight of medical devices is arguably too lax and our concerns are compounded in the case of devices with health-related AI. For example, leaving it to industry to classify the risks of AI in medical devices themselves and relying too heavily on their self-reporting of safety-related

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158 See George J Stigler, "The Theory of Economic Regulation" (1971) 2:1 Bell J Economics & Management Science 3 (to which "regulatory capture" as a concept is commonly attributed). More recent work suggests that other factors can explain purported evidence of capture; see Daniel P Carpenter, "Protection Without Capture: Product Approval by a Politically Responsive, Learning Regulator" (2004) 98:4 American Political Science Review 613. See also Matthew Herder, "Pharmaceutical Drugs of Uncertain Value, Lifecycle Regulation at the US Food and Drug Administration, and Institutional Incumbency" (2019) 97:3 Milbank Quarterly 820 [Herder, "Pharmaceutical"] (challenging the "capture" narrative in the case of the FDA's drug regulation but highlights strategic interactions with the industry as one source of regulatory challenges. The concern that the industry may evade real oversight remains).

159 For "fourth industrial revolution" language, see Klaus Schwab, *The Fourth Industrial Revolution* (New York: Crown Publishing Group, 2017). Notably, Schwab is Chairman of the World Economic Forum. For discussion of industry's actual influence on the ATPAP, which provides an example of this concern, see Vural, Herder & Graham, *supra* note 145.

160 See "Discussion", *supra* note 152 (use of "concierge service" language in documents such as this one, a 2019 Health Canada paper, was thus concerning, though more recent Health Canada documents do not use this language).

issues can permit industry to place a key role in setting the terms of its own regulation. We thus have concerns regarding: (i) the existing lack of data on whether Health Canada audits the choice of risk category and how often devices are reclassified between the risk levels; (ii) how often inspections of device manufacturers occur; and (iii) the limited public data on prosecutions or other penalties for violating the *Act*.

Further, the prospect that the new ATPAP may be employed to permit even lighter regulatory oversight than that which presently exists for novel technologies like adaptive ML is, to us, extremely concerning. The hope is that Health Canada will use its powers post-market to closely monitor adaptive ML in real-world settings, but it is far from clear that the Digital Health Division is presently resourced sufficiently to do so.

Creating red tape helps neither developers nor patients, for the latter have an interest in having access to beneficial technologies. But any regulatory regime should be designed with the primary goal of meeting the needs of patients, not developers. Health Canada should not wait to act until problems have manifested themselves and trust has dwindled, both in government regulation and in health-related AI. They should operationalize their regulatory powers to licence beneficial AI and weed out bad products in order to serve the interests of Canadians.[161]

B. The Need for Stringent Review Throughout the Lifecycle

Without detracting from the need for pre-market review, an enormous challenge is on the horizon in terms of developing a new system of post-market review adaptive ML. Yet, harking back to our concerns regarding regulatory capture, we worry that the emphasis on post-market surveillance as part of the ATPAP reforms could be at the expense of appropriate pre-market reforms. Again, the impetus for this preference for "light" regulation is likely coming from a perception that more stringent standards will place Canadian innovators at a competitive disadvantage. The Food and Drug Administration (FDA) in the USA

[161] See also Vural, Herder & Graham, *supra* note 145.

recently ran a pilot "precertification" program in which new software technologies developed by companies with "excellent" safety records can get streamlined review processes for medical devices in exchange for increased post-market scrutiny.[162] The idea appears to be that getting products on the market quickly will foster innovation and allow users to benefit more from AI advances, while hopefully increased post-market review can catch any problems and help avoid widespread harms. A similar idea may have motivated Health Canada's ATPAP proposal for devices with adaptive ML.[163] However, there is, in our view, no principled reason to substitute post-market surveillance for pre-market clearance. Both are important components of a well-designed legal framework. Indeed, given the limited data on health-related adaptive ML in particular, we may need *more* pre-market review to ensure the safety of devices they enable.

Accordingly, we recommend that Health Canada adopt, in the form of guidance document, a requirement that all adaptive ML be required to show safety and efficacy in a well-designed clinical trial before it can be lawfully sold or incorporated into healthcare systems with a presumption that the trials be randomized control trials until the evidentiary standards for adaptive AI are clearer.[164]

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[162] See US Food and Drug Administration (USFDA), "Digital Health Innovation Action Plan" (2017), online (pdf): *USFDA* <fda.gov/media/106331/download>; USFDA, "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan" (January 2021), online: *USFDA* <fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>; USFDA, "Developing the Software Precertification Program: Summary of Learnings and Ongoing Activities" (September 2020), online (pdf): *USFDA* <fda.gov/media/142107/download>.

[163] See Vural, Herder & Graham, *supra* note 145.

[164] Randomized trials of health-related AI technologies remain rare, but are possible for at least some health-related ML; see Derek C Angus, "Randomized Clinical Trials of Artificial Intelligence" (2020) 323:11 JAMA 1043; Marije Wijnberge et al, "Effect of a Machine Learning-Derived Early Warning System for Intraoperative Hypotension vs Standard Care on Depth and Duration of Intraoperative Hypotension During Elective Noncardiac Surgery: The HYPE Randomized Clinical Trial" (2020) 323:11 JAMA 1052. Innovators should *at least* bear the onus of explaining *why* a randomized control trial is not possible in a case and how one can nonetheless avoid risks.

The way to support Canadian innovators in this regard is for the federal government to support and fund these trials, particularly for Canadian start-ups, but not to forego what is otherwise the gold standard of scientific evidence as a means to promote the industry. Other forms of AI, especially locked AI, may be evaluated in post-market settings. But, given the unknown risks posed by adaptive AI, the regulator should evaluate evidence of their safety and efficacy from controlled clinical studies prior to wider use. As we explain below, how best to design such pre-market AI trials and measure safety and efficacy is unsettled. The regulator must accordingly make efforts to standardize the design of such trials, including safety and efficacy measured, in collaboration with AI developers, fully transparent. But eschewing pre-market evidence should not be an option.

Preserving evidentiary requirements pre-approval is also important because responding to regulatory issues in the post-market sphere is often exceedingly difficult. The *promise* of lifecycle regulation is that the regulator will react to evolving evidence, but experience suggests that, for example, the FDA struggles to do much beyond attaching warnings.[165] Insofar as appeals to "trade-offs" or "balancing" are compelling, they rely on post-market review *actually* addressing safety concerns. If Health Canada provides an easier path to the market via the ATPAP, it must explain how it will operationalize stronger post-market review policies, including mechanisms for independent surveillance and incentives for accurate reporting, to offset risks.

Any "balance" between regulation and innovation should not assume that a lack of appropriate regulation is good for innovation or otherwise in the public interest.[166] For example, a program in the USA permitting drugs with limited evidence of safety onto the market more quickly in exchange for increased post-market surveillance led to several safety concerns.[167] While some causes

[165] See Herder, "Pharmaceutical", *supra* note 158.

[166] See Karen Yeung, Andrew Howes & Ganna Pogrebna, "AI Governance by Human Rights-Centered Design, Deliberation, and Oversight: An End to Ethics Washing" in Dubber, Pasquale & Das, *supra* note 2, 77.

[167] See Herder, "Pharmaceutical", *supra* note 158.

of that program's failure were the result of USA-specific political concerns,[168] this should give proponents of light regulation for devices with health-related AI pause. As AI in healthcare is in a nascent stage in terms of actual deployment in the healthcare sector, we should take a more conservative approach to regulation to help engender public trust. As we suggested at the outset of this paper, deploying unsafe AI in the Canadian healthcare system could undermine public confidence in AI, resulting in calls for a much more heavy-handed approach to regulation or stall the uptake and use of beneficial technologies.[169]

C. The Need for a Broader Understanding of Safety

A primary concern raised in the law and ethics literature on health-related AI is the risk of algorithmic bias that leads to unwarranted discrimination. As discussed earlier, if the training data on which AI is developed under-represents racialized groups, such biased or non-representative data may shape or reinforce clinical decision making (e.g., diagnosis, prescribing) that does not take the health needs of that population into account. In principle, requirements that the MDD attend to "risk" in safety reviews could encompass risks of bias, but existing regulations do not contain explicit requirements to eliminate bias or explain how these considerations are supposed to inform licencing, if at all.[170] Similarly, the ATPAP does not yet appear to address this concern. The specified "risks" in the risk-benefit calculus required do not explicitly include algorithmic bias that results in unwarranted discrimination.[171]

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168 See *ibid*.

169 See Panch, Mattie & Celi, *supra* note 46 at 2.

170 Recall "Pre-Market Review" and its application in the sections on SaMD.

171 See *F&D Act*, *supra* note 11, s 21.91(2). See also "Discussion", *supra* note 152. Health Canada, the USFDA, and the United Kingdom's Medicines and Healthcare products Regulatory Agency list the use of representative data and safeguards against algorithmic bias as best practices is a recent set of principles for AI-enabled device development; see Government of Canada, "Good Machine Learning Practice for Medical Device Development: Guiding Principles" (17 October 2021), online: <canada.ca/en/health-

Privacy concerns are more removed from Health Canada's authority to regulate product safety. Other laws, primarily at the provincial level, specify what personal health information can be shared, for what purposes, and under what circumstances. Yet aggregate data that is stripped of information that can identify individual persons is expressly exempt from most provincial laws.[172] Given this gap, Health Canada might also seek to integrate privacy considerations into its review processes to engender trust in AI. It may, in other words, seek to ensure that that the product is "safe" to use not only from the perspective of physical safety but from a social safety perspective vis-à-vis privacy. This may test jurisdictional boundaries. But without such efforts, those at risk of being excluded from the benefits of AI due to the use of skewed or under-representative datasets may be even less willing to participate in AI research and development.[173]

At minimum, Health Canada could help set industry standards via its regulatory requirements. For example, Health Canada could set expectations about using representative datasets and require developers to account for why this is not possible. If developers cannot use an appropriately representative dataset, one option is for Health Canada, as part of approval, to require warnings as to the risk of algorithmic bias and then let healthcare providers assess the risk vis-à-vis particular patients. We acknowledge that this is far from a perfect solution: a warning may not dissuade off-label use and some forms thereof could still harm users.[174] Moreover, a warning alone would not preclude AI's benefits being limited to those included in training datasets, exacerbating

canada/services/drugs-health-products/medical-devices/good-machine-learning-practice-medical-device-development.html>. This may guide their evaluations but is also non-binding.

172 Recall note 36, including *PHIPA*.

173 See James, *supra* note 44.

174 On off-label use, recall note 117. In making this claim, we take no stand on whether some off-label uses, like use of a drug at a different dosage level or a device to confront a unique problem, may be justified. See Stafford, *supra* note 117 (suggesting that regulators cannot foresee every clinical need that a tool may fulfill). The debate on off-label use generally is beyond our scope here.

distributive justice concerns around groups' access to AI.[175] Yet this approach would be a step in the right direction in terms of addressing the underlying issue.

Regardless of which regulatory option one prefers, the regulator must wrestle with, rather than ignore, these problems. Ensuring that AI is trained on representative data is important for equity purposes and could be important for ensuring that tools are safe *for all Canadians*. But regulation only permitting medical devices with AI trained on representative data is likely premature and could lead to worse health outcomes for the very people it would be designed to benefit.[176] Most AI innovators in healthcare do not collect their own training data, but instead rely on "common use of large centralized databases, upon which numerous algorithms are developed and validated."[177] While some databases include demographic data, they are limited; many are USA-based or do not include data on major clinical areas, like pediatrics.[178] Requiring more representative data without explaining where innovators will receive it is problematic. If, in turn, regulators require that innovators develop more representative data, such collection will face pushback from those worried about the collection of, for instance, race-based data.[179]

How Health Canada could regulate to address these data collection difficulties without effectively precluding AI development remains debatable, but it should aim to do so. Even the best data collection takes time. This could result in many AI tools failing to reach the market, limiting AI's potential to benefit

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175 On equity, see e.g. Maxwell J Smith et al, "Four Equity Considerations for the Use of Artificial Intelligence in Public Health" (2020) 98:4 Bull World Health Organization 290.

176 Da Silva and Flood also discuss this option in a collaborative piece. See Da Silva et al, "Regulating the Safety of Health-Related Artificial Intelligence" (2022) 17:4 Healthcare Policy 63.

177 Sujay Nagaraj et al, "From Clinic to Computer and Back Again: Practical Considerations When Designing and Implementing Machine Learning Solutions for Pediatrics" (2020) 6:4 Current Treatment Options in Pediatrics 336 at 339.

178 See *ibid*.

179 See James, *supra* note 44.

any Canadian, including marginalized or vulnerable ones. Given the importance of representative data, the federal government should adopt a broader whole-of-government policy geared to building inclusive datasets, perhaps with funding flowing to marginalized groups in partnership with AI innovators, to ensure such data exists.[180]

In terms of the ability of Health Canada to embrace algorithmic bias within its regulatory purview, there is precedent for regulators interpretation of safety in a manner that expands its scope. Prior to the 1962 enactment of major reforms to US law, which introduced a legislative requirement to provide "substantial evidence" of effectiveness before a drug could be lawfully sold, the USFDA added essentially the same requirement as a matter of regulatory practice.[181] No drug was risk-free, the agency reasoned, therefore establishing a drug's safety, which the FDA was empowered to require as of 1938, necessarily entailed providing evidence of a drug's "therapeutic utility". The FDA's new drug application form was thus amended to require manufacturers to tender evidence of a drug's safety and efficacy in 1956, six years before Congress granted it legal authority to compel substantial evidence of effectiveness.[182] Health Canada might similarly reinterpret safety, requiring different types of evidence than is typical for medical devices in an effort to respond to AI and the novel, social forms of risk it implicates.

D. The Need for Transparent Standard-Setting

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[180] The federal government recently budgeted funds for collecting such data; see Canada, Department of Finance, "Budget 2021" (2021) at 230–31, online: *Government of Canada* <budget.gc.ca/2021/home-accueil-en.html>. It is as yet unclear whether and how this data collection will occur and whether any such collection can provincial legal standards.

[181] See e.g. Roojin Habibi & Joel Lexchin, "Quality and Quantity of Information in Summary Basis of Decision Documents Issued by Health Canada" (2014) 9:3 PLOS ONE e92038.

[182] See Daniel Carpenter, *Reputation and Power Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton: Princeton University Press, 2010).

Broadening and reinterpreting safety to tackle the full range of safety issues that AI presents—including algorithmic bias- and privacy-related concerns—will add uncertainty into the system. As AI developers and regulatory scientists work to develop evidentiary standards, it is critical that those efforts be characterized by transparency for at least two reasons.

The first reason to ensure meaningful, real-time transparency is to build trust. The ATPAP represents a complete black box at present. Health Canada has signaled that it intends to develop the details of its approach in close collaboration with AI developers. To avoid the perception of regulatory capture, the process used to develop evidentiary requirements applicable to advanced therapeutic products, including the one for adaptive ML, should be completely open to public scrutiny. This transparency should not happen after the fact, for instance, by posting a summary decision for a particular advanced therapeutic product. Health Canada uses that approach for drug approvals, and it provides limited value for clinical decision making.[183] Rather, Health Canada must make its decision-making process, as well as the substantive outcome of that process, open to scrutiny in real-time.

The second reason transparency is important is scientific or innovation-related. The standards that should govern the design of clinical studies involving AI, including how to ensure that AI translates into clinically meaningful outcomes, are far from settled scientifically, especially in light of the heterogeneity of AI interventions.[184] Historically, Health Canada used transparency not only to share information but also to engage the wider scientific community in the project of developing standards for determining drug composition and other issues that vexed the regulator at the

183 See e.g. Habibi & Lexchin, *supra* note 181.

184 Compare treatment of these issues in sources in notes 2, 4–5, 19–21, etc. For some recent work on the clinical issues, see e.g. Melissa D McCradden, Elizabeth A Stephenson & James A Anderson, "Clinical Research Underlies Ethical Integration of Healthcare Artificial Intelligence" (2020) 29:6 Nature Medicine 1325; Melissa D McCradden et al, "A Research Ethics Framework for the Clinical Translation of Healthcare Machine Learning" (2022) 22:5 American J Bioethics 8.

time.[185] In this way, and over time, transparency can similarly help clarify the standards that AI developers must meet, which should itself help facilitate innovation.

E. Transnational Considerations

Finally, Canadian regulation of medical devices with AI will be affected by international law both in terms of bilateral agreements on licencing and in terms of a desire to conform to international standards. Canadian reforms must be consistent with international agreements on device regulations. Under the terms of *Regulations*, non-Canadian manufacturers from countries with recognized regulatory authorities or conformity assessment bodies only need to provide basic information about their device and a certificate of compliance from a foreign regulatory agency to receive a medical device licence, subject to a requirement to provide more information on request.[186] A foreign manufacturer does not need to provide the evidence underpinning the foreign regulator's decision about the device's safety and efficacy to Health Canada so long as the foreign regulatory body is considered competent to test conformity with Canadian standards.[187] Where implemented, this could effectively leave the review of the evidence establishing the safety and efficacy of devices from some countries to foreign regulators. One example of a program that harmonizes review but also outsources parts of regulatory review to non-Canadian agencies quality control outsourcing is the Medical Device Single Audit Program, an international program for Quality Management Systems Certificates which permits approved auditors to simultaneously assess compliance with safety and efficacy regulations in Australia, Brazil, Canada, Japan, and the USA.[188] Where a certificate is only one piece of evidence one must

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185 See Matthew Herder, "Denaturalizing Transparency in Drug Regulation" (2015) 8:2 McGill JL & Health S57.

186 See *MDR*, *supra* note 11, ss 32(1), 33, 35.

187 See *ibid*, s 33.

188 See e.g. Health Canada, "Notice: Transition to the Revised Version of ISO 13485 and its impact on the Compliance to the Quality Management System Requirements of the Canadian Medical Devices Regulations" (4 August 2016),

provide for licencing, other safety and quality safeguards remain in place. Yet the *Act* permits broader outsourcing and Canadian governments considered full recognition of foreign medical device licencing decisions. For instance, in 2016, Canada and the European Union developed plans for a mutual recognition agreement that would not have required further Canadian review of European Union-licenced devices or vice versa.[189] The agreement was never fully implemented, but something similar remains possible and negotiations could limit available domestic regulatory tools absent full recognition agreements. While harmonization is a laudable goal, Canada must take care when entering any such agreements. Canada must retain regulatory capacity with respect to potential risks of novel technologies.

In our view, Canada should set clear standards for addressing bias- and privacy-related rules that foreign accreditors must address before issuing a licence that will be valid in Canada. It should ensure strong regulatory review at the pre- and post-market stage in bilateral agreements and call on parties to explicitly address privacy and bias in their reviews. This would maintain the efficiency-based benefits of a single review procedure, address the most pressing issues, and minimize a race to the regulatory bottom by ensuring all parties must meet the same standards.

With respect to international standards, in turn, most Canadian medical device safety standards are indexed to ISO standards.[190]

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online: *Government of Canada* <canada.ca/en/health-canada/services/drugs-health-products/medical-devices/quality-systems-13485/notice-transition-revised-version-13485-impact-compliance-quality-management-system-requirements-canadian-medical-devices-regulations.html>.

189 See e.g. Government of Canada, "Agreement on Mutual Recognition Between Canada and the European Community" (2016), online: *Government of Canada* <international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/european_community-communaute_europeenne/mra/index.aspx?lang=eng#medical>. That agreement was reached by a majority Liberal government that was replaced by a minority version in 2019 and 2021 elections.

190 See e.g. *MDR*, *supra* note 11, ss 32(2), 32(3)(j), 32(4)(p) (directly incorporating the ISO's risk classification scheme); *F&D Act*, *supra* note 11, ss 1–2; SaMD, *supra* note 74; International Medical Device Regulators Forum,

Canadian regulators are free to add additional safety review requirements, but Canada should promote explicit attention to the unique risks posed by ML in the ISO classification scheme. Canada is also on the International Medical Device Regulators Forum's working group on Artificial Intelligence Medical Devices, which seeks to develop harmonized regulations for devices with AI.[191] Our hope is that they will stress the importance of attending to the considerations above when negotiating new international norms.

CONCLUSION

Aptly regulating medical devices with AI requires balance: protecting against safety-related risks, including those stemming from bias and privacy violations, and yet not putting in place any unnecessary red tape. Canada's movements towards lifecycle regulation of medical devices holds promise but there are yet to be clear signs that the federal government's governance of medical devices will be appropriately adapted to the AI context. Specifically, we worry about suggestions to promote the AI industry through lighter regulation, particularly at the pre-market stage, and that regulators can catch egregious errors post-market.

Clear rules, and their efficient application, do not necessarily mean more red tape. Health Canada should carefully evaluate the costs and benefits of any proposed regulatory innovation. Yet regulators should understand "safety" more broadly, encompassing traditional safety risks to one's physical health and risks of unfounded bias and privacy violations. To properly protect Canadians, Health Canada must be empowered to conduct pre- and post-market review that is attentive to the ways that bias/discrimination- and privacy-based concerns implicate which

"Software as a Medical Device (SaMD): Key Definitions" (9 December 2013), online (pdf): *International Medical Device Regulators Forum* <imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf> (on "medical device", "software as a medical device", "incident", and "objective evidence" definitions and SaMD classifications).

191 See International Medical Device Regulators Forum, "Artificial Intelligence Medical Devices (AIMD)" (2021), online: *International Medical Device Regulators Forum* <imdrf.org/workitems/wi-aimd.asp>.

goods should be on the market. With novel technologies and the unknown risks of adaptive ML, the regulatory emphasis should be on the gold standard of scientific evidence, randomized controlled trials, with government support to start-ups and small companies to do those trials. Just as AI innovation holds the promise to transform healthcare for the better, our regulatory competence must innovate to address the challenges that must be addressed for AI to realize its potential.[192]

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