Assessing the Constitutional Validity of Substantiation Laws for Medical Device Safety and Effectiveness Under the *Medical Devices Regulations* and the *Food and Drugs Act*

by

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ABSTRACT

This thesis examines federal scientific evidence requirements for medical device safety and effectiveness under the mainstream market entry licensing pathway under Part 1 of the *Medical Devices Regulations*, and under the new 'agile' market entry pathway, the *Advanced Therapeutic Products Amendments*, which amended the *Food and Drugs Act*. Apart from a narrow category of medical devices (near patient *in vitro* diagnostic devices), scientific evidence requirements are vague and do not enumerate explicit expectations for methodologically rigorous forms of scientific evidence. Medical device safety and effectiveness could be more predictable with explicit expectations for scientific rigour. The thesis analyzes if this absence of rigour, and the breadth of discretion to define scientific evidence requirements in the executive branch of government (Health Canada) conform to standards of valid criminal law under s. 91(27) of the *Constitution Act, 1867*. The thesis also evaluates the laws' dependency on this power for their constitutional validity.

LIST OF ABBREVIATIONS USED

ACEG	Advisory Council on Economic Growth
AG	Attorney General
AI	Artificial intelligence
ATP	Advanced Therapeutic Product
ATPAs	*Advanced Therapeutic Products Amendments*
CFR	Code of Federal Regulations (United States)
CJ.	Chief Justice
F&D Act	*Food and Drugs Act* (Canada)
FCA	Federal Court of Appeal
FDA	Food and Drug Administration (United States)
*FDR*s	*Food and Drug Regulations* (Canada)
HBSR	*Health and Biosciences Sector Regulatory Review Roadmap*
ICIJ	International Consortium of Investigative Journalists
IOM	Institute of Medicine
ISO	International Organization for Standardization
IVDDs	In-vitro diagnostic devices
J./JJ.	Justice(s)
MAUDE	Manufacturer and User Facility Device Experience
MDAs	*Medical Device Amendments of 1976* (United States)
MDEL	Medical device establishment licence
*MDR*s	*Medical Devices Regulations* (Canada)
NAM	National Academy of Medicine
NP-IVDD	Near patient in vitro diagnostic devices
OAGC	Office of the Auditor General of Canada
p.o.g.g.	Peace, order and good government
PMA	Premarket Approval
QCM	Quintessential Capital Management
RCT	Randomized controlled trial
RIAS	Regulatory Impact Analysis Statement
RSC	Revised Statutes of Canada
s. / ss.	(sub)section / (sub)sections
SCC	Supreme Court of Canada
TBS	Treasury Board of Canada Secretariat
UK	United Kingdom
US	United States of America
USC	United States Code
USCA	United States Court of Appeals
USSC	Supreme Court of the United States

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CHAPTER 1 INTRODUCTION

1.1. Issue and Rationale

Medical devices,[1] which range from everyday hygiene products such as toothbrushes to complex products that help diagnose cancer, are critical to support the health and lives of Canadians. Despite the vast benefits, there are reports of unsafe and ineffective medical devices that have entered the Canadian market.[2] Concerns over medical device safety and how these products are federally regulated from a public health perspective has been reviewed several times by the Office of the Auditor General of Canada.[3] Medical device regulation as a global issue has also been the subject of a critical investigation known as the *Implant Files* organized by the International Consortium of Investigative Journalists.[4]

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[1] The definition of a medical device is made jointly in the federal *Medical Device Regulations* SOR/98-282, s 1 (current to 22 March 2022; last amended 2 March 2022) [*MDRs*] and the *Food and Drugs Act*, RSC, 1985, c F-27, s 2 (current to 22 March 2022; last amended 6 May 2021) [*F&D Act*]. Under the *F&D Act*, and *MDRs*, a "medical device" is a broad term. Most medical products that are not drugs likely fall under the definition upon a claimed therapeutic, physiologic, or structural effect on the human body regardless of the effect's therapeutic directness.

[2] See *infra*.

[3] See Canada, Office of the Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons: Chapter 2: Health Canada—Regulation of Medical Devices* (Ottawa: Minister of Public Works and Government Services Canada, 2004), online: <www.oagbvg.gc.ca/internet/docs /2004 0302ce.pdf.> [Canada, OAGC 2004]; Canada, Office of the Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons: Chapter 8: Allocating Funds to Regulatory Programs—Health Canada* (Ottawa: Minister of Public Works and Government Services Canada, 2006), online: <www.oagbvg.gc.ca/internet/English/parl_ oag_ 200611_ 08_e_14976.html> [Canada, OAGC 2006]; Canada, Office of the Auditor General of Canada, *2011 June Status Report of the Auditor General of Canada: Chapter 6—Regulating Medical Devices—Health Canada* (Ottawa: Minister of Public Works and Government Services Canada, 2011), online: <https://publications.gc.ca/site/eng/9.569400/ publication .html> [Canada, OAGC 2011].

[4] See International Consortium of Investigative Journalists (ICIJ), *The Implant Files* (2018 – 2021 last updated), online: https://www.icij.org/investigations/implant-files/ [ICIJ, *Implant Files*]; ICIJ, "Medical Devices Harm Patients Worldwide As Governments Fail On Safety", *ICIJ* (25 November 2018), online: <www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/> [ICIJ, "Medical Devices Harm Patients Worldwide"]: ("A global investigation reveals the rising human toll of lax controls and testing standards pushed by a booming industry"); see also The

Numerous reports of unsafe medical devices demonstrate reasons for concerns over medical device regulation. Textured breast implants have been associated with non-Hodgkin's lymphoma.[5] Pelvic mesh implants to treat non-life threatening conditions including pelvic organ prolapse and stress urinary incontinence have caused "life-long," "large-scale," and "exceedingly complex" pelvic-area erosion and "incapacitating" chronic groin pain[6] among other life-threatening and debilitating harms.[7] Metal-on-metal hip implants have corroded and have leaked toxic metals into patients' bloodstreams.[8] Surgical power tools (power morcellators) to grind-up intrauterine fibroids for their removal have spread hidden intrauterine cancer that in some patients greatly advanced its stage and deprived them of their chance of an extended life expectancy.[9] Weight-loss

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Editorial Board, "80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices", *New York Times* (4 May 2019), online: <www.nytimes.com/2019/05/04/opinion/sun day/medical-devices .html>.

[5] Canada, Health Canada, Information Update, "Health Canada suspends Allergan's licences for its Biocell breast implants after safety review concludes an increased risk of cancer", (28 May 2019), online: <https://recalls-rappels.canada.ca/en/alert-recall/health-canada-suspends-allergan-s-licences-its-biocell-breast-implants-after-safety>; Valérie Ouellet & Sylvène Gilchrist, "Thousands of suspected injuries tied to breast implants revealed in manufacturer data dump, CBC analysis finds", *CBC News* (13 January 2022), online: <https://www.cbc.ca/news/investigates/breast-implants-health-canada-allergan-mentor-1.6312587>.

[6] *The People of the State of California v Johnson & Johnson, Corp; Ethicon Inc; Dose 1*, 37-2016-00017229-CU-MC-CTL (Sup Ct Cal 2020) at 19-20; in Canada see settlement notice regarding this exact medical device, Rochon | Genova LLP, "Notice of Discontinuance of Johnson & Johnson Class Action – Transvaginal Mesh for Stress Urinary Incontinence and Pelvic Organ Prolapse" (3 June 2020), online: <www.rochongenova.com/wp-content/uploads/sites/1100729/2021/01/Notice-of-Discontinuance-English.pdf>.

[7] *Ibid*.

[8] Stephen Tower, "Hip Metallosis and Corrosion—A Million Harmed Due to FDA Inaction" (2019) 15:3 J Patient Safety 257; CBC News (n/a), "Metal-on-metal hip implants since 2006 may be more likely to fail: study" *CBC News* (28 April 2016), online: <https://www.cbc.ca/news/health/hip-implants-1.3558050>; see also in the context of metal-on- polyethylene hip implants, CTV News.ca Staff (unauthored), "BC man launches class-action lawsuit over hip implant" *CTV News* (31 August 2019), online: https://www.ctvnews .ca/health/b-c-man-launches-class-action-lawsuit-over-hip-implant-1.4573679>; Kim Spencer McPhee Barristers, "Settlement Approved in ASR Hip Implant Class Action" *Cision* (2 October 2021), online: <www.newswire.ca/news-releases/settlement-approved-in-asr-hip-implant-class-action-816983973.html>.

[9] See Jenya Godina, "Left to Their Own Devices: How the Dangers of Power Morcellators Went Undetected by FDA for Two Decades" (2019) 74:1 Food & Drug LJ 128 at 128; in Canada see Alison Motluk, "Caution Issued Against Use of Morcellators" (2015) 187:2 CMAJ 99; see also Denise Grady & Katie Thomas, "F.B.I. Investigates Whether Harm From Surgical Power Tool was Ignored", *New York*

balloons,[10] cardiac pacemakers,[11] and catheters to remove blood clots[12] have also been associated with causing death. These examples represent only a sample of the types of unsafe medical devices that have upon time been approved as safe and effective in Canada with tragic consequences for patients.

In addition to unsafe medical devices, concerns have been raised over ineffective medical devices that pose direct and indirect harms to the public.[13] Ineffective medical devices can delay a person's access to proven treatment and delay a person's correct diagnosis, such as cancer, which can prevent timely treatment and reduce a person's chance of survival or lifespan.[14] Ineffective medical devices can further expose the public to unnecessary surgery that may only offer a temporary placebo effect.[15]

Medtronic, Inc.'s Symplicity Renal Denervation System ("RDS") is one example

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Times (27 May 2015), online: <www.nytimes.com/2015/05/28/business/fbi-investigates-whether-harm-from-surgical-power-tool-was-ignored.html>.

[10] Susan Kelly, "FDA says 18 deaths linked to intragastric weight loss balloons", *MedTechDive* (28 April 2019), online: <www.medtechdive.com/news/fda-18-deaths-linked-to-apollo-endosurgery-intragastric-balloon-weight-loss-treatment/576874/>; see Canada, Health Canada, Dear Healthcare Professional Letter, "Intragastric Balloons and Potential Risk of Gastric and Esophageal Perforation, Pancreatitis, and Overinflation", (17 April 2019), online: <https://recalls-rappels.canada.ca/en/alert-recall/intragastric-balloons-and-potential-risk-gastric-and-esophageal-perforation> (describing associated deaths).

[11] See HeartLife Foundation, "Cardiac device implants in Canada: Are they worth the risk?", *HeartLife.ca* (14 February 2019), online: <https://heartlife.ca/2019-2-14-cardiac-device-impacts-in-canada-are-they-worth-the-risk/> (describing "poorly tested implants"); see also Patrick Malone & Associates PC, "US Watchdogs Tally $1.5 billion cost for one type of defective medical device", *JD Supra* (17 October 2017), online: <www.jdsupra.com/legalnews /u-s-watchdogs-tally-1-5-billion-cost-53798/>.

[12] Health Canada, "Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing (2020-12-15)", (date posting: 30 December 2020), online: <https://recalls-rappels.canada.ca/en/alert-recall/penumbra-jet-7-reperfusion-catheter-and-penumbra-hi-flow-aspiration-tubing-2020-12-15> [Health Canada, Penumbra Recall].

[13] United States, Food and Drug Administration (FDA), *Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products* (Silver Spring, MD, Food and Drug Administration, January 2017) at 6 [US FDA, *Memorandum*]; see also Peter Barton Hutt & Robert Temple. "Commemorating the 50th Anniversary of the Drug Amendments of 1962" (2013) 68:4 Food & Drug LJ 449 at 462: ("safety means nothing if the drug [or device] doesn't work", Dr. Robert Temple [speaking]).

[14] *Ibid*, US FDA, *Memorandum*, at 6.

[15] See Megan S Wright, "A Case for Randomized, Double-Blinded, Sham-Controlled Class III Medical Device Trials" (2015) 34:1 Yale L & Pol'y Rev 199 at 205, 207.

of this issue. This medical device was promoted as a miracle product for drug-resistant hypertension,[16] and it was endorsed at a major Canadian healthcare institution.[17] Requiring a catheter to be threaded up into an artery from the upper thigh to ablate nerves in the renal artery near the kidneys, the medical device was approved by Health Canada as safe and effective in 2012 and in the European Union and Australia.[18] The United States ("US") regulator, the Food and Drug Administration ("FDA"), failed to approve its market entry[19] and rejected the scientific evidence used to gain approval in Canada.[20] This scientific evidence consisted of a case report, two unblinded trials as well as "two dozen" confirmatory reports.[21] The US FDA required Medtronic, Inc. to meet a higher scientific evidentiary bar by requiring the company to submit a randomized,[22] blinded,[23]

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[16] *Ibid* at 205, citing Joseph Walker, "Medtronic Makes Surprise Turn on Blood-Pressure Device", *Wall Street Journal* (29 March 2014), online: <http://www.wsj.com/articles/SBloool424o527o23o46881o457 9468500895597252>.

[17] See Interventional News (unauthored), "Symplicity Renal Denervation System receives Health Canada licence", *Interventional News* (18 April 2012), online: <https://interventionalnews.com/symplicity-renal-denervation-system-receives-health-canada-licence/>.

[18] *Ibid*.

[19] Wright, *supra* note 15; see also Interventional News, *ibid*: (noting that the medical device was still under investigational testing in the United States despite approvals in Canada, the European Union, and Australia).

[20] Wright, *ibid* at 205; Scott Gottlieb, "The FDA Wants You for Sham Surgery", *Wall Street Journal* (18 February 2014), online: <www.wsj.com/articles/the-fda-wants-you-for-sham-surgery-1392769018>: ("The high-blood-pressure device, for example, is already available in Europe, where regulators approved it based on traditional studies. The FDA disregarded those results in favor of the new and larger trial using a sham.").

[21] Matthew J Shun-Shin, James P Howard & Darrel P Francis, "Removing the Hype from Hypertension: Symplicity HTN-3 illustrates the importance of randomisation and blinding for exciting new treatments" (2014) 348 BMJ 1937.

[22] See *National Cancer Institute, Dictionary of Cancer Terms*, "randomized clinical trial", online: <www.cancer.gov/publications/dictionaries/cancer-terms/expand/R>: ("A study in which the participants are divided by chance into separate groups that compare different treatments or other interventions. Using chance to divide people into groups means that the groups will be similar and that the effects of the treatments they receive can be compared more fairly. At the time of the trial, it is not known which treatment is best.").

[23] *Ibid*, "blinded study", online: <www.cancer.gov/publications/dictionaries/cancer-terms/def/blinded-study>: ("A type of study in which the patients (single-blinded) or the patients and their doctors (double-blinded) do not know which drug or treatment is being given. The opposite of a blinded study is an open label study.").

and sham (placebo)-controlled[24] surgical trial.[25] This type of study is described as "the scientifically superior means"[26] to demonstrate effectiveness if the medical device can pose a placebo effect and if it is not contrary to patient interests.[27] This study revealed that the medical device was no more effective than the placebo control.[28] The finding of this study underscores the importance of requiring a high scientific evidentiary bar for the market entry of medical devices to prevent the public from harms caused by ineffective treatments and to prevent unnecessary healthcare costs.[29]

More recently, in January 2021 Health Canada licenced LimaCorporate, s.p.a.'s SMR Stemless Reverse System, a shoulder joint implant, based on two case series studies, and several 'device-specific' reports of its safety and effectiveness.[30] The medical device was also approved in Mexico, Europe, and various countries in the Asia Pacific region.[31] For US approval, the US FDA has required the company to submit more

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[24] *Ibid*, "placebo", online: <www.cancer.gov/publications/dictionaries/cancer-terms/def/placebo>: ("An inactive substance or other intervention that looks the same as, and is given the same way as, an active drug or treatment being tested. The effects of the active drug or other intervention are compared to the effects of the placebo.").

[25] Wright, *supra* note 15, see also Gottlieb, *supra* note 20.

[26] Wright, *ibid* at 207 (Wright argues that it can be unethical to permit medical devices onto the market based on non-randomized nor blinded, non-sham-controlled surgical studies where the benefits of scientific knowledge can outweigh the risks. Wright also outlines existing support among clinician investigators and Institutional Review Boards for sham-controlled surgical trials); see also Gottlieb, *supra* note 20: ("FDA has clamped down on these ["traditional"] approaches in favor of sham surgeries, which it sees as more statistically scrupulous and free from bias.").

[27] See 21 CFR §860.7(f)(1)(iv)(b)(c) (US Code of Federal Regulations).

[28] Wright, *supra* note 15 at 205; Shun-Shin, Howard & Francis, *supra* note 21.

[29] See generally Shun-Shin, Howard & Francis, *supra* note 21; Wright, *supra* note 15 at 207; US FDA, *Memorandum supra* note 13 at 10.

[30] See Health Canada, "Regulatory Decision Summary – SMR STEMLESS – Health Canada" New device licence application" [Class III (high risk medical device), date of decision: 2019-09-19], online: <https:// hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php? lang=en&linkID =RDS11272> [Health Canada, RDS – SMR STEMLESS].

[31] Limacorporate, s.p.a., "LimaCorporate Announces The First Surgery of SMR Stemless Reverse Shoulder System In The IDE Study", *Cision, PR Newswire* (20 April 2021), online: <https://www.prnewswire.com /news-releases/limacorporate-announces-the-first-surgery-of-smr-stemless-reverse-shoulder-system-in-the-ide-study-301271806.html>.

rigourous scientific evidence,[32] specifically a randomized 'active treatment'-controlled[33] trial with 200 study participants across seven US sites using LimaCorproate, s.p.a.'s non-stemless shoulder implant as the control, which is expected to end in 2025.[34] This randomized-controlled trial ("RCT") is considered a substantially more reliable form of scientific evidence than "case series studies" or "case reports" that rank low on the hierarchy of reliable scientific evidence (Level 4, where Level 5 is least reliable).[35]

These examples suggest a need to examine Canada's medical device regulations to assess the stringency of laws that govern how medical devices legally enter the market ("premarket laws"). This thesis seeks specifically to investigate the scientific evidence requirements for proof of safety and effectiveness under: 1) the mainstream market entry route that most medical devices are subject to (*Medical Devices Regulations* ("*MDRs*"), Part 1[36] enabled by the *Food and Drugs Act*[37] ("*F&D Act*")), and; 2) the *Advanced Therapeutic Products Amendments*[38] ("*ATPAs*") that amended the *F&D Act*, which is a new "agile" market entry route for medical devices and other therapeutic products,

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[32] See *infra*.

[33] An active treatment trial compares the safety and effectiveness of an investigational treatment (i.e., a licensee medical device) to a conventional and known safe and effective treatment (the 'control' medical device); see also Robert Temple & Susan Ellenburg, "Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments" (2000) 133:6 Annals Internal Medicine 455 at 456.

[34] See United States, National Institutes of Health: US National Library of Medicine, *ClinicalTrials.gov*, "SMR Stemless Reverse vs SMR Reverse Shoulder System", (First posted: 6 January 2021), online: <https://clinicaltrials.gov/ct2/show/NCT04697004>.

[35] See Oxford Centre for Evidence-Based Medicine, "The Oxford 2011 Levels of Evidence" online: <www.cebm.net/index.aspx?o=5653> (case series studies and case reports fall into Level 4, where Level 5 (pre-clinical, i.e., non-human testing, is the least reliable form of evidence to determine effectiveness or safety of a medical product. In contrast, one RCT is Level 2; more than one RCT is Level 1.)

[36] *MDRs*, *supra* note 1.

[37] *F&D Act*, *supra* note 1.

[38] *An Act to implement certain provisions of the budget tabled in Parliament on March 19, 2019 and other measures*, SC c 29 [Bill C-97, assented to June 21, 2019] [emphasis added] [*Budget Implementation Act, 2019 No 1*], s 169 (*Advanced Therapeutic Products Amendments)* [*ATPAs*].

deemed to be an "emerging or innovative technological, scientific or medical development."[39]

Are Canada's scientific evidence requirements as stringent in comparison to other jurisdictions? Certain market entry schemes under US law, for example, enumerate explicit requirements for methodologically rigourous scientific evidence to substantiate safety and effectiveness. These US laws have been described as highly influential in popularizing RCTs,[40] and are credited as the modern origin of "evidence-based medicine" by Gordon H. Guyatt (McMaster University) who coined the term.[41] Evidence-based medicine is premised on the idea that "what is justifiable or reasonable to believe depends on the trustworthiness of the evidence, and the extent to which we believe that evidence is determined by credible processes."[42]

As Chapter 2 will document, while medical devices in Canada are required to be compatible with a high degree of safety and effectiveness upon their market entry ("safety and effectiveness requirements"),[43] the burden of proof to substantiate these requirements ("scientific evidence requirements") lack explicit expectations for methodologically rigourous forms of scientific evidence and are vague in comparison to certain US laws. The exceptions are scientific evidence requirements for a narrow category of medical devices, which are near-patient *in vitro* diagnostic devices ("NP-

[39] *F&D Act*, *supra* note 1, s 21.91(1).

[40] Frank Davidoff, "Heterogeneity: We Can't Live With It, And We Can't Live Without It" (2011) 20 BMJ: Quality & Safety i11 at i11.

[41] See Benjamin Djulbegovic & Gordon H Guyatt, "Progress in Evidence-Based Medicine: A Quarter Century On" (2017) 390:10092 Lancet 415 at 415.

[42] *Ibid* at 416.

[43] See *F&D Act*, *supra* note 1, ss 19 and 20(1); see also *MDRs*, *supra* note 1, ss 10-20.

IVDDs").[44] The absence of explicit requirements for methodologically rigourous scientific evidence for the vast majority of medical devices means that medical device safety and effectiveness is not as predictable as it could be, which increases the likelihood that the public is exposed to unnecessary risks.

These findings reflect an overall concern by some medical researchers with regards to the methodological rigour of medical research and patient safety. In a 2021 article, "Methodology over metrics: current scientific standards are a disservice to patients and society" published in the Journal of Clinical Epidemiology under the co-editorship of Canadian clinical epidemiologist Peter Tugwell, OC (Universtiy of Ottawa) it was observed that:

> [t]he overall quality of medical research remains poor, despite longstanding criticisms….We suggest that most problems stem from an underlying paradox: although methodology is undeniably the backbone of high-quality and responsible research, science consistently undervalues methodology.[45]

The authors concluded that "[r]igorous methodology is critical, and this needs to be imposed top-down without compromise."[46] Methodological rigour should therefore be explicitly reflected as a scientific evidence requirement in proof of a medical device's safety and effectiveness under Part 1 of the *MDRs*, and under the *ATPAs*.

In addition, this thesis finds that the executive branch of government (Health

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[44] See Chapter 2 for further discussion; *MDRs*, *supra* note 1, s 1: "near patient in vitro diagnostic device or near patient IVDD means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside."). This definition includes at-home pregnancy test kits and certain glucose testing devices that use human specimens.

[45] Ben Van Calster, *et al*, "Methodology over Metrics: Current Scientific Standards are a Disservice to Patients and Society" (2021) 138 J Clinical Epidemiology 219 at 219.

[46] *Ibid* at 224.

Canada)[47] has been delegated the law-making authority to define premarket entry requirements in regulations under the mainstream market entry route, and effectively under the *ATPAs*, including scientific evidence requirements for safety and effectiveness.[48] Preferably, conditions for medical device licensing that enumerate methodologically rigourous scientific evidence requirements for safety and effectiveness would be reflected in primary (Parliamentary) legislation where they are less easily amended and more stable.[49]

Against this background, the thesis investigates if the scientific evidence requirements for safety and effectiveness and the scope of enabling authority to the executive branch are constitutionally valid on federalism grounds. This issue is examined because the *F&D Act* has been in *obiter dicta* classified as valid as a whole under the criminal law power, s. 91(27) of the *Constitution Act, 1867*.[50] The constitutional validity of the *F&D Act* has also received little attention in secondary literature, and critical discussion of its constitutional validity under the criminal law power does not appear to have been raised.[51]

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[47] See Chapter 2 for further discussion.

[48] *Ibid*.

[49] *Ibid*.

[50] See *Reference re Firearms Act (Can)*, 2000 SCC 31 at para 29 [*Reference re Firearms* (SCC)]: ("[t]he *Food and Drugs Act*, the *Hazardous Products Act*, the *Lord's Day Act*, and the *Tobacco Products Control Act* have all been held to be valid exercises of the criminal law power: see *Standard Sausage Co. v. Lee*, [1933] 4 D.L.R. 501 (B.C.C.A.)"). *Standard Sausage*, however, dealt with a repealed version of the *Food and Drugs* as discussed in Chapter 3; *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, reprinted in RSC 1985, Appendix II, No 5 [*Constitution Act, 1867*].

[51] See e.g. Ron A Bouchard & Monika Sawicka, "The Mud and the Blood and the Beer: Canada's Progressive Licensing Framework for Drug Approval" (2009) 3:1 McGill JL & Health 49 at 53, n 33:

> The regulation of pharmaceuticals falls generally under the criminal head of power under s. 91(27) of the Constitution Act, 1867. Martha Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L.J. 95 at 96-99 (According to Jackman, the Supreme Court of Canada held in *R. v. Wetmore*, [1983] 2 S.C.R. 284 at 288, "that the provisions of the federal Food and Drugs Act relating to the safety of food, drugs and medical devices, were supportable under the

The absence of methodologically rigorous scientific evidence requirements to substantiate safety and effectiveness, however, under the mainstream market entry pathway and under the *ATPAs* raises questions about the dominant purpose of these laws, and their ability to be classified under the criminal law power or any other federal power under the *Constitution Act, 1867*, such as trade and commerce (s. 91(2)) or peace, order and good government ("p.o.g.g.") (s. 91). To be valid as criminal law, the law's dominant purpose would need to be characterized as a law that suppresses or safeguards threatened interests from conduct that has "evil or injurious or undesirable effects" on a public interest such as safety, health, or economics.[52] On its face, it is unclear if the dominant purpose of scientific evidence standards that lack explicit expectations or requirements for methodological rigour conveys this characterization.

Similarly, the extent of discretion that permits the executive branch of government to define scientific evidence requirements, and licensing more generally, raises further questions about its constitutional validity given that an extensive scope of discretion and delegation to the executive branch (delegation to Health Canada) may not fall within the parameters of valid criminal law. As John Mark Keyes (University of Ottawa), a legal expert in legislative drafting and former Chief Legislative Counsel in the

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> criminal law power, in as-much as they were directed at protecting the 'physical health and safety of the public'.

See also Joel Lexchin, *Private Profits Versus Public Policy: The Pharmaceutical Industry and the Canadian State* (Toronto: University of Toronto Press, 2016) at 86 (describing the *F&D Act* as criminal law); see generally Peter W Hogg & Wade K Wright, *Constitutional Law in Canada* (5th ed) (2021 online) (Toronto: Carswell), § 18:3: ("it is well-established that food and drug legislation making illegal the manufacture or sale of dangerous products, adulterated products or misbranded products is within the criminal law power.").

[52] *Reference re Validity of Section 5 (a) Dairy Industry Act*, [1949] SCR 1 at 49 (Rand J) [*Reference re Margarine*] (a valid criminal law's dominant purpose must be characterized in relation to an "evil or injurious or undesirable effect upon the public [that] the legislature has had in mind to suppress the evil or to safeguard the interest threatened.").

federal Department of Justice,[53] explains: "[a]lthough most heads of legislative authority allow broad scope for determining how the purposes they authorize may be pursued, the Supreme Court of Canada has held that the federal criminal law power is limited in terms of the types of measures or policy instruments that may be used."[54] If the enabling discretionary powers to the executive branch, which permit it to govern medical device safety and effectiveness through regulations, were held dependent on the criminal law power, this may mean that some aspects of medical device regulation need to be regulated to a greater extent by primary legislation (in Parliament) to be valid as criminal law. This thesis therefore investigates if both the scientific evidence requirements for safety and effectiveness as well as the scope of discretion and delegation to the executive branch of government is likely to be held valid under the criminal law power and it investigates if these laws are dependent on this power for their constitutional validity.

The rationale of this thesis is based on the premise that if scientific evidence requirements were held dependent on the criminal law power, the requirements may need to be more methodologically rigourous for their dominant purpose to convey they address a valid criminal law purpose and therefore fall into federal jurisdiction under the *Constitution Act, 1867*. Similarly, if the enabling discretionary powers for establishing scientific evidence requirements for safety and effectiveness were also held dependent on the criminal law power, the current scope of delegation may need to be reduced. This may require scientific evidence requirements for safety and effectiveness to be based in primary legislation, which would embed more stability for methodologically rigorous

[53] John Mark Keyes, *Executive Legislation*, 3rd ed (Toronto, ON: LexisNexis, 2021) at v.
[54] *Ibid* at 94-95.

scientific evidence into the law.

1.2. Research Questions and Thesis Organization

This thesis is divided into five main substantive chapters (Chapters 2-6) to answer three groups of research questions based on the research rationale. This section defines these questions and discusses their analysis in the thesis structure.

> RQ1: What are the substantiation standards for safety and effectiveness under the mainstream market entry pathway and under the *ATPAs*? Do these standards reflect certain model US law for methodological rigour? [Chapter 2]

These research questions inform the scope of Chapter 2. The chapter begins by describing the overall federal framework that governs medical device regulation under the *F&D Act*. It then narrows into discussing the premarket licensing requirements with a focus on defining scientific evidence requirements in proof of safety and effectiveness. The previously referenced model US law that describes methodologically rigorous standards for safety and effectiveness are then defined, which is followed by a discussion of whether these standards are reflected in Canada. Apart from NP-IVDDs, this thesis finds that methodologically rigorous scientific evidence requirements are absent, in part, because they are vague. This chapter concludes by discussing three public interest issues associated with these vague scientific evidence requirements relative to public safety.

> RQ2: If the federal government seeks to control the market entry of medical devices by issuing market authorizations (licences or orders) in relation to safety or effectiveness, which federal power(s) under s. 91 of the *Constitution Act, 1867* may be relevant to support this policy sphere? Would the federal government be dependent on the criminal law power? [Chapter 3]

Chapter 3 identifies three potentially relevant heads of federal power that *prima facie* may support this policy sphere. These powers include: the trade and commerce

power (s. 91(2)), p.o.g.g., (s. 91), and the criminal law power (s. 91(27)). Chapter 3 examines their scope to determine the extent they may support general licensing laws for medical device safety and effectiveness. Chapter 3 will serve to: 1) identify conditions that may need to exist in federal law for constitutionally valid federal regulation of medical device safety and effectiveness, and 2) serve as a reference to assess if the dominant purposes of the impugned laws, the basis of Chapters 5 and 6, are classifiable within this 'field' of federal jurisdiction.

> RQ3: Are the scientific evidence requirements under the main market entry route (ss. 9(2) and 32, Part 1 of the *MDRs*) constitutionally valid on grounds of federalism? Is the enabling authority (s. 30 of the *F&D Act*) that permits the executive branch of government to determine all aspects of medical device licensing, including scientific evidence requirements, valid? Is the agile market entry route (*ATPAs*, ss. 21.9-21.96 of the *F&D Act*) valid? [Chapters 4-6]

Chapter 4 sets up this inquiry by presenting the legal process to examine a law's constitutional validity on federalism grounds, which is applied to the impugned laws in Chapter 5 (validity of ss. 9(2) and 32 of the *MDRs*; and s. 30 of the *F&D Act*) and Chapter 6 (validity of the *ATPAs*). Chapter 5 applies this framework to first assess the validity of the scientific evidence requirements under the main market entry route for medical devices under Part 1 of the *MDRs*. It then applies this framework to assess the validity of the enabling provision under the *F&D Act* that permits this market entry scheme. Chapter 6 also applies the same framework to the *ATPAs* as a whole to determine its constitutional validity. Chapter 7 summarizes the thesis findings as well as defines the implications of this research in federal medical device regulation.

1.3. Research Method

This thesis primarily uses the doctrinal research method. Doctrinal research broadly refers to "the research process used to identify, analyse and synthesise the content of the law."[55] More specifically, "[i]n this method, the essential features of the legislation and case law are examined critically and then all the relevant elements are combined or synthesised to establish an arguably correct and complete statement of the law on the matter in hand."[56] Statements about the law incorporate "new elements of the law, whether legislation or principles, from recent case law."[57] Doctrinal methods can also integrate "creative synthesis"[58] through restatements or recasting of the law's "elements, categories and concepts" and identify and explain "preferred or better practices."[59]

This thesis undertakes an analysis of two primary sources of law, which are the *F&D Act* and the *MDRs* with a focus on assessing premarket entry requirements, specifically the scientific evidence requirements for safety and effectiveness. This analysis is based on various primary sources including comparable legislation and regulations (US legislation), non-binding guidance (policy) documents, and case law. Secondary sources are also used, including academic articles, media journalism, and grey literature from government bodies and non-governmental organizations.

The doctrinal research method is also used to explore federal powers that may be relevant to the matter of licensing of medical devices in relation to safety and

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[55] Terry Hutchinson, "Doctrinal Research: Researching the Jury" in Dawn Watkins & Mandy Burton, eds, *Research Methods in Law* (New York: Routledge, 2018) 8 at 13.

[56] *Ibid*.

[57] *Ibid* at 14.

[58] *Ibid* at 16.

[59] Martha Minow, "Archetypal Legal Scholarship – A Field Guide" (2013) 63(1) J Leg Ed 65 at 65.

effectiveness under the *Constitution Act, 1867* to understand how federal authority in this policy sphere may operate. The three powers identified (trade and commerce, p.o.g.g., and the criminal law powers) are defined according to updated SCC statements and by reference to secondary sources.

This thesis further describes the legal 'methodological' process to determine a law's constitutional validity on federalism grounds, which consists primarily of a characterization (pith and substance doctrine) and classification step. The pith and substance doctrine is defined by reference to primary sources (SCC case law), and secondary sources. Recent SCC statements that discuss and apply this doctrine are examined including *Reference re Genetic Non-Discrimination Act* (2020)[60] and *References re Greenhouse Gas Pollution Pricing Act* (2021).[61] *R. v. Morgentaler* (1993),[62] however, remains a leading pith and substance case and is used as a significant authority.[63] This legal process is followed to assess the constitutional validity of the impugned laws in Chapters 5 and 6.

This thesis ends by synthesizing the findings from a doctrinal lens. It postulates that the *Constitution Act, 1867*, and specifically the criminal law power, may be a potential tool to increase the methodological rigour of scientific evidence requirements for safety and effectiveness and may serve as a tool to embed their stability into primary legislation.

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[60] 2020 SCC 17 [*Reference re GNDA*].

[61] 2021 SCC 11 [*References re GGPPA*].

[62] [1993] 3 SCR 463 [*Morgentaler*, (1993)].

[63] Carissma Mathen & Patrick Macklem *et al*, eds, Canadian *Constitutional Law*, 6th ed (Toronto: Emond Montgomery Publications, 2022) at 191 ("[*Morgentarler*] continues to illustrate the kinds of factors a court can take into account in determining the matter or the pith and substance of a law.").

CHAPTER 2 MEDICAL DEVICE REGULATION AND PREMARKET SAFETY GAPS

2.1. Overview of Federal Framework Governing the Regulation of Medical Devices

Canada's *F&D Act* is the central statutory framework that governs the conditions of medical device market entry ("premarket laws") and the conditions permitting medical devices to remain on the market ("postmarket laws"). The *Act* is the culmination of an evolutionary series of laws that have penalized the sale of food and drugs deemed unsafe ('adulterated') or whose value was falsely or misleadingly represented ('misbranded').[64] These penal laws precede the nineteenth century and reach back to the *Statute of the Pillory and Tumbrel, and of the Assize of Bread and Ale*, 51 Hen. III, Stat. 6 enacted into English law in 1266.[65] They are also historically based in the criminal law and in common law nuisance.[66]

The overall policy matter addressed by the previous *F&D Act*[67] was described in *Standard Sausage v. Lee* (1933, BCCA) as legislation to prevent actual or threatened injury to public health and safety and to suppress fraud,[68] which was a case followed by the Supreme Court of Canada ("SCC") in *R. v. Wetmore* (1983) to characterize the

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[64] *Standard Sausage Co v Lee*, [1933] 4 DLR 501 at para 12 (1993, BCCA) [*Standard Sausage*]: ("[f]rom very early times, so far back as 51 Hen. III (1266) ch. 6, the *Statute of the Pillory and Tumbrel, and of the Assize of Bread and Ale, etc.*, there are to be found penal enactments dealing with 'corrupt victuals'.").

[65] *Ibid*.

[66] *Ibid* at paras 12-13.

[67] See *Food and Drugs Act*, RSC, 1927, ch 76. The 1927 *Act* was repealed and replaced with *An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices*, SC 1952-53, c 38, and has been subject to two revisions: 1) 1970 [*Food and Drugs Act*, 1970 RSC c F-27] and; 2) 1985 [*F&D Act*, *supra* note 1]; see also *Revised Statutes of Canada, 1985 Act*, RSC 1985 c 40 (3rd Supp), s 4 ("[t]he Revised Statutes shall not be held to operate as new law, but shall be construed and have effect as a consolidation of the law as contained in the Acts and portions of Acts repealed by section 3 and for which the Revised Statutes are substituted.").

[68] *Standard Sausage*, *supra* note 64 at paras 66 and 69.

modern *F&D Act* as criminal law.[69] The modern *F&D Act* reflects this characterization in two core sections that serve to deter the sale of unsafe medical devices and deceptive marketing. First, s.19 prohibits a person from selling a medical device that may cause injury when used as directed, such as on labelling, or when used according to custom.[70] Second, s. 20(1) prohibits a person who markets a medical device (i.e. "label, package, process, sell or advertise") in any way that is "false, misleading or deceptive or is likely to create an erroneous impression" about its "design, construction, performance, intended use, quantity, character, value, composition, merit or safety."[71] Every other product regulated under the *F&D Act*, which includes food, drugs and cosmetics contain equivalents to these central prohibitions with the exception that deceptive marketing of cosmetics is not prohibited under this statute.

A violation of these laws, or any other law under or enabled by the *F&D Act*, including any regulations and specified types of orders, is a prohibited offence that is backed with serious penal sanctions with the potential for high maximum fines (for e.g., up to $250,000 on summary conviction for a first offence/up to $5,000,000 on indictment) and/or imprisonment (for e.g., up to 6 months on summary conviction for first offence/up to two years on indictment) even if harm did not arise as a result of the

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[69] See [1983] 2 SCR 284 [*Wetmore*] at 288-89 ("it has been well understood over many years that protection of food and other products against adulteration and to enforce standards of purity are properly assigned to the criminal law. *Standard Sausage Co. v. Lee*, [1933] 4 D.L.R. 501, supplemented by addendum at [1934] 1 D.L.R. 706 is a long standing application of these principles."); see also Dickson J (prior to CJ) dissenting but not on this point at 293.

[70] *F&D Act*, *supra* note 1, s 19: ("[n]o person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.").

[71] *Ibid*, s 20 (1): ("[n]o person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.").

violation.[72] The government is not required to prove a *mens rea* 'intent' element because the default corresponding offences are ones of strict liability.[73] Strict liability offences, which are also known as public welfare offences, hold a person liable to a higher standard of knowledge and care regardless of their actual knowledge of a product's safety or value up to the point of due diligence, which is a permissible defence.[74] Public welfare offences seek to promote "high standards of public health and safety"[75] and encourage those to take "precautionary measures beyond what would otherwise be taken."[76]

If it can be proven, however, that a person knowingly or recklessly caused serious risk to human health in violation of any provision under the *Act*, any enabled regulation, or specified types of orders, the person is subject to higher maximum punishments including fines (e.g., $500,000 on summary conviction for a first offence/court's discretion on indictment) and/or imprisonment (e.g., up to 18 months on summary conviction for first offence/up to five years on indictment).[77] Each day a person violates the law (including regulations and orders) in relation to medical devices is a new offence.[78] A director, officer, agent, or other mandatary who "directs, authorizes, assents

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[72] *Ibid*, s 31.2.

[73] See *ibid*, s 31.3 (due diligence defence is permitted).

[74] *Ibid*; see also *R v Trophic Canada Ltd*, [1981] 3 WWR 158 (BCCA) (before the *Canadian Charter of Rights and Freedoms,* Part I of the *Constitution Act, 1982,* being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, *s 7* [*Charter*], breaches of certain *Food and Drug Regulations*, CRC 1978, c 870 were once held to be absolute liability offences, i.e. no defence of due diligence was permitted; see also, *R v Rube*, [1991] 54 BCLR (2d) 419 (BCCA), aff'd [1992] 3 SCR 159 (an absolute liability offence attached to the prohibition under s 5(1) was found unconstitutional on *Charter* grounds).

[75] See *R v Sault Ste Marie*, [1978] 2 SCR 1299 at 1310.

[76] *Ibid* at 1310-11.

[77] See *F&D Act*, *supra* note 1, s 31.4.

[78] *Ibid*, s 31.7.

to or acquiesces or participates" in the offence, is also liable even if they are not prosecuted.[79]

Beyond these core deterrent laws in ss. 19 and 20(1), the *F&D Act* regulates the safety and effectiveness of medical devices according to a product "lifecycle" approach. This means that medical device safety and effectiveness must be identified prior to market entry (premarket) and, in a more passive way after market entry (postmarket). Identifying a medical device's safety and effectiveness is therefore never 'final.' The lifecycle approach to medical device regulation under the *F&D Act* recognizes the need to continually assess medical device safety and effectiveness across the lifecycle of these products.

The core of premarket regulation, which is the focus of this thesis and discussed in detail in this chapter, generally revolves around the requirement to obtain a licence or other market authorization (i.e., an order) that permits a medical device's lawful import or sale, and potentially its lawful advertising.[80] Key conditions for licensing include the requirement for manufacturers to keep and/or submit scientific evidence of a medical device's safety and effectiveness,[81] and generally labelling requirements. Information required to be disclosed on the label under the mainstream market entry pathway (Part 1 of the *MDRs*) includes, but is not limited to, the manufacturer's name and address, expiry date, the medical conditions that the medical device is "manufactured, sold or represented" for use in, as well as the directions for use.[82] Currently, there are no default

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[79] *Ibid*, s 31.6.

[80] *F&D Act*, *supra* note 1, s 2: ("advertisement includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.").

[81] See *infra* for detailed discussion of licensing.

[82] See *MDRs, supra* note 1, s 21.

requirements to label a medical device under the *F&D Act* under the new 'non-mainstream' market entry pathway (*ATPAs*), although other federal or provincial statutes may govern product labelling.

Postmarket regulation, in contrast to premarket regulation, is meant to ensure the on-going safety and effectiveness of a medical device once on the market. These laws impose duties on prescribed health care institutions and manufacturers and importers to report incidents associated with the medical device to the Minister of Health (the violation of which is an offence backed with the above penal sanctions), and powers of the government to recall a medical device. In 2014, Parliament amended the *F&D Act* through amending legislation, the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law*),[83] to expand the scope of postmarketing controls. Core updates to existing postmarket laws include:

- the power of the government to require information in a person's control in relation to alleged risks of a medical device and the power to disclose this information;[84]
- the power of the government to modify a medical device's labelling to prevent injury;[85]
- the power of the government to recall a medical device where there is evidence of serious or imminent harm;[86]
- the power of the government to compel assessments, tests or studies in respect to health or safety;[87]

[83] SC 2014, c 24.

[84] *F&D Act*, *supra* note 1, ss 21.1(1)-(4).

[85] *Ibid*, s 21.2.

[86] *Ibid*, s 21.3(1)(a).

[87] *Ibid*, ss 21.31-32.

- the duty of health care institutions, as prescribed by regulation, to report a medical device incident.[88]

Both premarket and postmarket laws are supplemented by various administrative and enforcement powers enumerated under the *F&D Act*, such as the power of the government to inspect manufacturing premises or products, authorize their seizure, and destroy unlawful imports.[89]

Ensuring that medical devices are compatible with a high degree of safety and effectiveness prior to market entry, however, provides the most potential to reduce public risks because harms caused by improperly tested medical devices once on the market "often cannot be fully remedied."[90] Incidents associated with medical devices are also underreported, including in Canada.[91] One US Government Accountability Office study has estimated that only 1 in 200 (0.5%) medical device failures are reported,[92] while another study estimates a reporting range of 10%-80% depending on the medical device.[93] This thesis therefore focuses on examining the stringency of premarket

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[88] *Ibid*, s 21.8.

[89] See *ibid*, s 22 ("Inspection, Seizure and Forfeiture"), s 27.1 ("Removal, Forfeiture or Destruction of Unlawful Imports"), 27.3 ("Prevention and Remedial Measures"), s 28 ("Analysis"), s 29.1 ("Power of the Minister").

[90] US FDA, *Memorandum supra* note 13 at 6, citing Declaration of Robert Temple, MD. *Allergan, Inc v United States*, 1:09-cv-01879 (DDC, 2009).

[91] See Julie Polisena, *Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and an Investigation of the Continuous Quality Improvement Data Automatically Reported by Wireless Smart Infusion Pumps*, (PhD Thesis, University of Ottawa: Faculty of Medicine; School of Epidemiology, Public Health, and Preventative Medicine, 2015), online: <https://ruor.uottawa.ca/bitstream/10393/33414/1/Polisena_Julie_2015_thesis.pdf> (discussing numerous factors for underreporting, for e.g., concerns that documentation will be used punitively/concerns of liability; lack of awareness of the incident; shortness of time; absence of perceived harm to patient).

[92] See US Senate, *A Delicate Balance: FDA and the Reform of the Medical Device Approval Process*: Hearing Before the Special Committee on Aging, 112th Congress (2011) [Frederic S Resnic statement, citing a Government Accountability Office study], online: <https://www.govinfo.gov/content/pkg/CHRG-112shrg67694/html/CHRG-112shrg67694.htm>.

[93] James R Ward & P John Clarkson, "An Analysis of Medical Device-Related Errors: Prevalence and Possible Solutions" (2009) 28 J Medical Engineering & Technology 1 at 5.

"gatekeeper" laws. Postmarket laws, while vital to public health, can be characterized as more likely to reduce public risks once known or suspected than to prevent risks.

For example, Health Canada published a recall of Penumbra's, Inc. Jet7 Xtra Flex, a flexible catheter (small tube) used to remove blood clots through aspiration ('suction'), on 30 December 2020[94] after approximately 14 deaths and various other serious reports of patient injuries on an internationally well-known US medical device incident reporting database known as MAUDE (Manufacturer and User Facility Device Experience).[95] One of the key safety issues associated with this catheter was that its flexibility permitted it to balloon in arteries upon customary injection of contrast dye to the extent that it caused arteries to rupture, which led to patient deaths.[96] Health Canada's recall notice appeared 15 days after Penumbra, Inc. voluntarily recalled the medical device.[97] The voluntarily recall itself was only prompted after significant press attention of patient deaths and other serious injuries that began on 10 November 2020 in response to a short activist shareholder report from Quintessential Capital Management ("QCM").[98] In Canada, this medical device was not required to be clinically tested prior

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[94] Health Canada, Penumbra Recall, *supra* note 12.

[95] See US FDA, "Penumbra's Recall of the JET 7 Reperfusion Catheter Due to Distal Tip Damage" ("content current as of 01/29/2021") online: <www.fda.gov/medical-devices/medical-device-recalls/penumbras-recall-jet-7-reperfusion-catheter-due-distal-tip-damage> (describing 14 unique patient deaths among other serious patient injuries).

[96] See Quintessential Capital Management, "Penumbra and its 'killer catheter': A tale of corporate greed and seemingly blatant disregard for patients' lives" (10 November 2020), online: www.qcmfunds.com/wp-content/uploads/2020/11/QCM-on-Penumbra-presentation-Final-.pdf [QCM].

[97] Penumbra, Inc. "Urgent Voluntary Medical Device Recall Notification Immediate Action Required" (15 December 2020), online: <www.penumbrainc.com/wp-content/uploads/2020/12/JET-7XF-15Dec20.pdf>.

[98] See Bailey Lipschultz & Josh Fineman, "Short Seller QCM Questions Safety of Penumbra Stroke Device", *Bloomberg* (10 November 2020), online: <www.bloomberg.com/news/articles/2020-11-10/short-seller-qcm-questions-safety-of-penumbra-stroke-device#xj4y7vzkg>; Nathaniel Baker, "Short-Sellers Grego, Cohodes Takes Aim At Penumbra", *Forbes* (18 November 2020), online: <www.forbes.com/sites/nathanielbaker/2020/11/18/short-sellers-grego-cohodes-take-aim-at-penumbra/?sh=1d24f21b80a2/; Kevin Stankiewicz, "Shares of medical device maker Penumbra tank after short seller releases critical report",

to its market entry,[99] which will be discussed in greater detail after a discussion of the premarket laws, and specifically scientific evidentiary requirements.

With this context of medical device regulation under the *F&D Act* in mind, this chapter turns to define premarket laws in greater detail with a focus on the safety and effectiveness requirements, and relatedly the scientific evidence requirements in proof of safety and effectiveness. This review will serve as a foundation to examine the scientific evidence requirements later in this chapter.

2.2. A Focus on Premarket ("Gatekeeper") Law

2.2.1. Introduction to Licensing

To legally market a medical device, a person is required to obtain a licence according to the requirements under Part 1 of the *MDRs* if the medical device is not for: custom use (e.g., a custom foot orthotic or a 3D-printed device customized to a patient);[100] special access (e.g., humanitarian 'last-resort' access for when other legally licenced medical devices are deemed unsuitable);[101] or emergency use (e.g., to control a pandemic).[102] Medical devices intended for these purposes are subject to 'non-mainstream' premarket control laws that are not within the scope of this thesis.

CNBC (8 December 2020), online: <www.cnbc.com/2020/12/08/shares-of-penumbra-tank-after-short-seller-releases-critical-report.html>.

[99] See Health Canada, "Regulatory Decision Summary – PENUMBRA SYSTEM" [Class IV, date of decision: 2020-03-12], <online: https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10743> [Health Canada, RDS – PENUMBRA SYSTEM]; see *infra* for further discussion.

[100] See *MDRs*, *supra* note 1, Part 2 "Custom-Made Devices and Medical Devices to Be Imported or Sold for Special Access."

[101] *Ibid*.

[102] See *F&D Act*, *supra* note 1, s 30.1 "Interim Orders".

Additionally, a person who successfully applies to have their medical device deemed an "advanced therapeutic product" is not subject by default to the mainstream licensing scheme, and is instead subject to the *ATPAs*, which is a new market licensing-based scheme under the *F&D Act*.[103] Only the mainstream market entry route as well as the *ATPAs* are the focus of this thesis.

2.2.2. Rulemaking Process

Premarket regulation of medical devices is a matter that has been delegated to the executive branch of government under the mainstream market entry route (Part 1 of the *MDRs*), and in effect under the *ATPAs*. While the *ATPAs* are 'primary legislation,' in contrast to the mainstream pathway under Part 1 of the *MDRs*, they remain a skeletal licensing scheme.[104] For example, the *ATPAs* require a product to be licenced, but there are few requirements for licensing under the *ATPAs* and additional requirements that may be imposed are delegated to the executive branch of government's discretion.[105]

Specifically, the authority to enact legislation governing, in a broad sense, testing or "sale" of a medical device is delegated to the Governor in Council in this executive branch under the law-making authority (equivalent to "regulation-enabling power") of s. 30 under the *F&D Act*. The Governor in Council is the Governor General of Canada who acts "by and with the Advice" of the Queen's Privy Council for Canada.[106] In essence, it is the regulatory organization namely a federal department, which is Health Canada in

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[103] *Ibid*, ss 21.94, 21.96.

[104] See *infra* for further discussion of the *ATPAs*.

[105] *Ibid*.

[106] *Constitution Act, 1867*, *supra* note 50, s 13.

this case, that drafts and proposes substantive regulations that are promulgated as a formality by the Governor in Council.[107]

Before promulgation, proposed regulations proceed through a drafting and review process overseen by the Department of Justice ("DOJ"), the Minister that oversees the regulatory organization (in this case, the Minister of Health), the Treasury Board Secretariat, and the Privy Council Office – Orders in Council Division.[108] Proposed regulations, as well as proposed bills, are only required to be reviewed by the DOJ to determine their compliancy with the *Charter of Rights and Freedoms*.[109] They are not necessarily reviewed in terms of compliancy with federalism under the *Constitution Act, 1867*.[110]

Despite this process, promulgating regulations is considered more flexible than if licensing requirements were to proceed through a primary legislative (Parliamentary) process: "[l]egislative enactment processes are complex and can be quite time-consuming."[111] For this reason, once primary legislation is enacted it is considered "relatively stable."[112] Therefore, what underlies the current rulemaking procedure governing the market entry of medical devices is an inherently flexible rulemaking

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[107] See John Mark Keyes, *Executive Legislation*, 2nd ed (Markham: LexisNexis Canada, 2010) at 187-188: ("at the federal level in Canada proposed executive legislation has traditionally been drafted by officials in the departments or agencies responsible for its administration."); see also Canada, "Guide to the Federal Regulatory Development Process: Steps in the Regulatory Development Process" (date modified: 17 April 2014), online: https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/guide-federal-regulatory-development-process.html#t7> [Canada, "Regulatory Development"].

[108] See Canada, "Regulatory Development", *ibid*.

[109] See *Department of Justice Act*, RSC 1985, c J-2, ss 4.1-4.2; *Charter*, *supra* note 25; Wade Wright, "Against Privileging the Charter: The Case of Federal Pre-Enactment Constitutional Review" (2020) 25:1 Rev Const Stud 49.

[110] Wright, *ibid*.

[111] Keyes, 3rd ed, *supra* note 53 at 220.

[112] *Ibid*.

process where conditions for market entry are determined to a large extent by the executive branch of government.

2.2.3. Mainstream Licensing Pathway: Part 1 of the Medical Devices Regulations

2.2.3.1. Overview

Under Part 1 of the *MDRs*, licensing requirements vary according to the risk class of a medical device. According to this risk-based classification system, medical devices will be deemed to fall into one of four risk classes that ranges from Class I (lowest risk, e.g., manual toothbrush) to Class IV (highest risk, e.g., implantable cardiac pacemaker).[113] The exact rules governing risk classification are explained in Schedule 1 of the *MDRs*.[114]

A person who wishes to sell or import a Class I (lowest risk) medical device is generally required to obtain a Medical Device Establishment Licence ("MDEL").[115] The MDEL, which is required to be annually renewed,[116] is used to register the business and provide the government with various information that includes, among other requirements: notice of whether a company is an importer or distributor; name and addresses of the manufacturer; and an attestation by a senior official that the establishment maintains distribution records and has a documentation process for incident reports associated with the medical device.[117]

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[113] *MDRs*, *supra* note 1, s 6.

[114] *Ibid*, Schedule 1 "Classification Rules for Medical Devices".

[115] See *ibid*, s 44.

[116] *Ibid*, s 46.1(1).

[117] *Ibid*, s 45.

A person who wishes to sell or import a Class II-IV medical device must generally obtain a Medical Device Licence ("MDL"), which requires a person to submit various degrees of proof to the government that a medical device is safe and effective.

2.2.3.2. Safety and Effectiveness Requirements

To obtain an MDEL (generally required for Class I) or an MDL (required for Classes II-IV), a person must meet the same safety and effectiveness requirements under ss. 10-20 of the *MDRs*, which is distinct from 'burden of proof', or scientific evidence "substantiation" requirements discussed below. The safety and effectiveness requirements state generally that medical devices are to be compatible with a high degree of safety and effectiveness. For example, the *MDRs* require risks to be "compatible with a high level of protection of health and safety" if used according to the "medical conditions, purposes of uses" it is "manufactured, sold or represented"[118] as stated on the product's label.[119] Similar to this high threshold for safety, "[a] medical device…shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented."[120]

Whether the requirements for safety and effectiveness apply to uses that are not stated on the label (i.e., "off-label" uses) is unclear given that "the medical conditions, purposes and uses for which it is manufactured, sold or represented" could be an

[118] *Ibid*, s 11(1).

[119] *Ibid*, s 21(1)(h) (requiring a label to state "the medical conditions, purposes and uses for which the device is manufactured, sold or represented").

[120] *Ibid*, s 12(1).

objective determination that does not depend on a manufacturer's belief as stated on the label.[121]

In sum, technically it is the "manufactured, sold or represented" use associated with the medical device that is federally regulated in terms of safety and effectiveness rather than the 'medical device' itself. Every use a manufacturer proposes to market a medical device for must generally conform to the same standards of safety and effectiveness. For example, manufacturers are generally required to submit new scientific evidence of a proposed new use's safety and effectiveness through an Application for a Medical Device Licence Amendment, and generally must file the same scientific evidence requirements (see below) to market it for that use.[122]

2.2.3.3. Scientific Evidence ("Substantiation") Requirements

The type of scientific evidence required to substantiate the safety and effectiveness requirements varies according to: the risk class of a medical device, and; whether it is a "near patient *in vitro* diagnostic device"[123] ("NP-IVDD").[124] While the scientific evidence requirements generally become more specific for each class, and again

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[121] This matter has not been judicially reviewed in Canada. In the US, the "intended use" (the equivalent in Canada to "manufactured, sold or represented" use) of a medical device is an objective determination that is not dependent on the manufacturer's belief; see 21 CFR s 801.4 defining "Meaning of intended uses" (factors reviewed to determine a medical device's intended use include: expressions; the design of a product; "circumstances surrounding [its] distribution"; oral or written statements of representatives; and potentially a manufacturer's knowledge of a use that is not put on the label or advertised, although this factor alone cannot be evidence in itself of intended use); s. 801.4 clarifies that "[t]he intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.").

[122] See *MDRs*, *supra* note 1, s 34 (defining exact rules).

[123] See *MDRs*, *supra* note 1, s 1: ("near patient in vitro diagnostic device or near patient IVDD means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside."). As noted in Chapter 1, NP-IVDDs include, but are not limited to, at-home pregnancy test kits and glucose testing devices that use human specimens.

[124] See *ibid*, s 6 (establishing the risk classification scheme); see also *ibid,* Schedule 1 "Classification Rules for Medical Devices".

differ if the medical device is an NP-IVDD, they are broad although less so for NP-IVDDs.[125] The following describes each of the scientific evidence requirements across each risk category, including specific requirements for NP-IVDDs, beginning with an 'umbrella' requirement. The requirements are summarized at the end of this section in Table 1.

As an overarching 'umbrella' requirement applicable to all risk classes (Class I-IV) as well as NP-IVDDs, a manufacturer must hold "objective evidence"[126] to prove that a medical device ('use') is compatible with a high degree of safety and effectiveness.[127] The term "objective evidence" is defined as:

> *objective evidence* means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition *objective evidence* in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance – Vocabulary*, as amended from time to time.[128]

The above definition is incorporated by reference[129] to the most current (i.e., "as amended from time to time") definition of "objective evidence" as defined by the International Organization for Standardization ("ISO"). The current definition of "objective evidence," which is dynamic rather than static (i.e., "as amended from time to time") is currently based within ISO 9000:2015, which is the replacement and therefore the current legal definition. However, the current legal definition remains substantially equivalent to the version enacted under the *MDRs*:

> **objective evidence**

[125] See *infra*.

[126] *MDRs*, *supra* note 1, s 9(2).

[127] See *ibid*, ss 10-20.

[128] *Ibid*, s 1 "objective evidence".

[129] As enabled by *F&D Act*, *supra* note 1, s 30.5.

> data (3.8.1) supporting the existence or verity of something [data: "facts about an object (3.6.1)"]
>
> Note 1 to entry: Objective evidence can be obtained through observation, measurement (3.11.4) [measurement: "process (3.4.1) to determine a value"; process: "set of interrelated or interacting activities that use inputs to deliver an intended result], test (3.11.8),[test: "determination (3.11.1) according to requirements (3.6.4) for a specific intended use or application"] or by other means.
>
> Note 2 to entry: Objective evidence for the purpose of audit (3.13.1) generally consists of records (3.8.10), statements of fact or other information (3.8.2) which are relevant to the audit criteria (3.13.7) and verifiable.[130]

A person who wishes to sell a Class I medical device is not subject to additional scientific evidence ('substantiation') requirements beyond the requirement to hold "objective evidence." Additional scientific evidence requirements are imposed to import or sell a Class II-IV as part of the application for an MDL as enumerated under s. 32 of the *MDRs*. The following describes these additional requirements beginning with Class II, and Class II NP-IVDDs.

A person who wishes to sell a Class II (medium risk) medical device is required to submit an attestation from a senior official to confirm that it holds "objective evidence" to demonstrate it meets the safety and effectiveness requirements.[131] If, however, the Class II medical device is an NP-IVDD, a person is required to submit "an attestation … [of] testing conducted on the device…representative of the intended users and under conditions similar to the conditions of use" (see Table 1, Class II).[132]

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[130] See International Organization for Standardization (ISO), see ISO 8402:1994 (withdrawn)>revised by ISO 9000:2000 (withdrawn)>revised by ISO 9000:2005 (withdrawn)>revised by ISO 9000:2015. The ISO 9000:2015 is the most recent document to define "objective evidence" under 3.8.3, online: <www.iso.org/obp/ui/ - iso:std:iso:9000:ed-4:v1:en:term:3.8.3> (emphasis added) [ISO, "evidence"].

[131] *MDRs*, *supra* note 1, s 32(2)(c).

[132] *Ibid*, s 32(2)(e).

Medical devices in Class III (high risk) require a person to submit scientific evidence to the government to prove that the safety and effectiveness requirements have been met, as opposed to the 'attestation' requirement under Class II. This submission requires: "a summary of all studies on which the manufacturer relies …and the conclusions drawn"[133] and "a bibliography of all published reports."[134] However, only if a Class III medical device is an NP-IVDD is there a requirement to submit "a summary of …testing conducted on the device…representative of the intended users and under conditions similar to the conditions of use."[135]

Medical devices in Class IV (highest risk) require a person to submit:

- a risk assessment;[136]
- "detailed information on all studies on which the manufacturer relies…['preclinical and clinical studies; process validation studies; software validation studies, if appropriate; literature studies']"[137]
- "a summary of the studies referred to in paragraph (i) ["detailed information on all studies…"] and the conclusions drawn"[138]
- "a bibliography of all published reports"[139]
- "a medical device … manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety"[140]

Like Class III, if the Class IV medical device is a NP-IVDD, there is an additional requirement to provide "detailed information [as opposed to a "summary" for Class III]

[133] *Ibid*, s 32(3)(f).
[134] *Ibid*, s 32(3)(i).
[135] *Ibid*, s 32(3)(h).
[136] *Ibid*, s 32(4)(d).
[137] *Ibid*, s 32(4)(i).
[138] *Ibid*, s 32(4)(l).
[139] *Ibid*, s 32(4)(n).
[140] *Ibid*, s 32(4)(j).

on…testing conducted on the device…representative of the intended users and under conditions similar to the conditions of use."[141]

In summary, for Class III (high risk) and IV (highest risk) that are not in the narrow category of NP-IVDDs, which is the vast majority of medical devices, absent is the requirement to submit scientific evidence derived from testing that is: a) conducted on the device; b) representative of the intended users; and c) under conditions similar to how it will be used. This requirement only exists for NP-IVDDs. As explained in Health Canada's policy guidance document, clinical evidence of safety and effectiveness can instead derive from clinical evidence of a medical device that is similar to it in respect to its "design, features and performance."[142]

In addition to the requirement to directly substantiate the safety and effectiveness of medical devices, a person must obtain and submit a copy of a Quality Management System certificate that conforms to CAN/CSA-ISO 13485:2016 as part of the application requirements for an MDL (Class II-IV).[143] For clarification, this is a broad organizational-level certification scheme that does not bear on the scientific evidence requirements. It instead establishes various 'duties' that are divided into five themes that discuss competency requirements in medical device-related business administration:[144] 1) Quality Management System (e.g., requirement to document a quality management

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[141] *Ibid*, s 32(4)(k).

[142] Canada, Health Canada, Guidance on Supporting Evidence to be provided for New and Amended Licence Applications for Class III and Class IV Medical Devices, not including In-Vitro Diagnostic Devices (IVDDs) (date adopted: 2012/06/08, effective date: 2012/07/04), at 14 (Class III); at 31 (Class IV) (verbatim standards for Class III and IV medical devices) [Health Canada, "Guidance on Supporting Evidence"].

[143] *MDRs*, *supra* note 1, ss 32(2)(f), 32(3)(j), 32(4)(p).

[144] See ISO, "ISO 13485:2016(en) Medical devices — Quality management systems — Requirements for regulatory purposes", "Scope", online: <www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en>.

system); 2) Management Responsibilities (e.g. requirement to have a customer focus, requirement to define quality objectives, etc.); 3) Resource Management (e.g., requirement to document infrastructure needed; requirement to train staff, and other human resource requirements, etc.); 4) Product Realization (e.g., requirements to have a plan for product realization, control the design of the product, and customer communication, etc.); 5) Measurement, Analysis and Improvement (e.g., requirement to control non-conforming products, monitor customer requirements, etc.).[145]

Table 1 summarizes the above scientific evidence requirements across each risk class and specific requirements for NP-IVDDs:

Table 1 Medical Device Scientific Evidence Requirements for Safety and Effectiveness (Mainstream Market Entry)

Umbrella Requirement for All Risk Classes: A manufactures is required to keep "Objective Evidence" in proof of safety and effectiveness: "information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out … objective evidence … ISO 8402:1994, as amended from time to time"[146] ***And…***			
Class I	**Class II: s. 32(2)**	**Class III: s. 32(3)**	**Class IV: s. 32(4)**
Exempt from additional scientific requirements.	• "an attestation [of] objective evidence"	• "a summary of all studies on which the manufacturer relies …and the conclusions drawn" • "a bibliography of all published reports" Note: there is an absence for clinical studies, in contrast to column Class IV: s. 32(4).	• "a risk assessment" • "detailed information on all studies on which the manufacturer relies ['preclinical and clinical studies; process validation studies; software validation studies, if appropriate; literature studies']" • "a medical device … manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety"

[145] *Ibid*.

[146] *MDRs*, *supra* note 1, ss 9(2), 1 "objective evidence"; see ISO, "evidence", *supra* note 130.

			• "a summary of the studies referred to in paragraph (i) ["detailed information on all studies…"] and the conclusions drawn" • "a bibliography of all published reports"
	Additional Requirement for Near Patient *In Vitro* Diagnostic Devices (NP-IVDD)		
	• "an attestation … [of] testing conducted on the device… representative of the intended users and under conditions similar to the conditions of use"	• "a summary of … testing conducted on the device …representative of the intended users and under conditions similar to the conditions of use"	• "detailed information on … testing conducted on the device…representative of the intended users and under conditions similar to the conditions of use"

2.2.4. New "Licensing" Pathway: Advanced Therapeutic Products Amendments (*ATPAs*)

In addition to the mainstream market entry laws under Part 1 of the *MDRs*, Parliament recently enacted an additional market entry pathway based on the issuance of licences or orders if a medical device can be deemed an 'advanced therapeutic product' ("ATP"). The *ATPAs* are a distinct market entry route because the issuance of a licence or order exempts a person from being subject, by default, from all regulations made under the *F&D Act*, unless otherwise promulgated by the Governor in Council (effectively, Health Canada as noted above), and therefore the *MDRs*.[147]

[147] See *F&D Act*, *supra* note 1: s 21.94 (exemption from regulations if a person is issued an ATP licence, unless regulations are otherwise promulgated at the discretion of the Governor in Council as authorized under s 30(1.2)(b.2)); s 21.96 (exemption from regulations if a person is issued an ATP order, unless regulations are otherwise promulgated at the discretion of the Governor in Council as authorized under s. 30(1.2)(b.2)). Licences are provided to a person who wishes to sell an ATP medical device, see s 21.92(1); whereas orders are given to a person within a "class of persons" authorized to sell an ATP medical device, see s 21.95(1).

The Minister of Health's belief "that the therapeutic product or products represent an emerging or innovative technological, scientific or medical development"[148] determines if a medical device meets the definition of an ATP. The Minister is required to consider four broadly defined factors to aid this determination:

- "the degree of uncertainty respecting the risks and benefits associated with the therapeutic product or products and the measures that are available to adequately manage and control those risks;
- the extent to which the therapeutic product or products are different from therapeutic products for which therapeutic product authorizations have been issued under the regulations;
- the extent to which existing legal frameworks are adequate to prevent injury to health or to prevent persons from being deceived or misled; and
- the prescribed factors, if any."[149]

Consequently, a person that wishes to obtain an ATP licence or order must submit some form of scientific evidence to demonstrate that this broad standard has been met if seeking to enter the market under the *ATPAs*. These factors provide the Minister with broad discretion to exempt a person from the mainstream market entry pathway under Part 1 of the *MDRs*.

As discussed, a person can sell an ATP either through a licence or order issued by the Minister, with or without terms or conditions, as determined by the executive branch of government (Health Canada).[150] An application for an ATP licence additionally requires a person as a default standard to submit "sufficient evidence" to enable the Minister to find that the benefits of the product will outweigh its risks, and that risks would be adequately managed.[151] Therefore, a medical device granted 'advanced

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[148] *F&D Act*, *supra* note 1, s 21.91(1).

[149] *Ibid*, s 21.91(2).

[150] *Ibid*, s 21.92(3) (licence); s 21.95(1) (order).

[151] *Ibid*, s 21.92(1).

therapeutic' status, must still be safe and effective because the benefits must outweigh its risks.

An application for an order does not detail additional minimum requirements beyond evidence that would enable the Minister to find that the medical device was an ATP (an emerging or innovative "technological, scientific or medical development"[152]) considered in light of the four broad factors to guide this decision (see (a)-(d) above).

In summary, the executive branch (the Minister of Health and Health Canada) is provided with a broad grant of discretion to define an ATP and to define licensing and order conditions for the market entry of these products. Table 2 summarizes the scientific evidence requirements under the *ATPAs*:

Table 2 Medical Device Scientific Evidence Requirements for Safety and Effectiveness (ATPAs)

Evidence allowing the Minister of Health to believe that the product "represent[s] an emerging or innovative technological, scientific or medical development" Consideration is based on four broad factors: a) risks and benefits "associated" with the product; b) differences between the therapeutic product and other authorized therapeutic products; c) adequacy of legal frameworks to prevent personal injury or deception; d) any factor promulgated by regulation	
Licences (Additional Minimum Requirements)	Orders (Additional Minimum Requirements)
Applicant submits "sufficient evidence" that: • benefits outweigh risks • description of adequate risk management procedures	Unspecified

[152] *Ibid*, s 21.91(1).

2.3. Identifying Gaps for Public Risks in Premarket Law

2.3.1. What are Reliable Scientific Evidence Requirements for Safety and Effectiveness?

A critical means to ensure medical devices are compatible with a high degree of safety and effectiveness is to substantiate these claims with reliable forms of scientific evidence.[153] As stated in Chapter 1, methodologically rigorous scientific evidence to prove safety and effectiveness is pivotal to patient safety, and more broadly to accurately assess safety and effectiveness. The scientific evidence requirements in the US that apply directly to new drugs for their market entry, and that have applied to medical devices on an ad hoc basis,[154] serve as a universal "gold" standard to assess safety and effectiveness and as a benchmark to analyze Canada's scientific evidence requirements.

As introduced in Chapter 1, this US law has been described as the modern origin of evidence-based medicine,[155] and it is based under the *Kefauver-Harris Amendments* (1962).[156] Briefly summarized, this law requires a person to prove that a drug, or medical device (ad hoc), is safe and effective with, at minimum, two blinded, randomized, and well-controlled clinical trials.

Well-controlled information is defined as information that can demonstrate that the effect of a drug or medical device is not from other influences, such as from a placebo

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[153] US FDA, *Memorandum supra* note 13 at 6.

[154] See Patricia J Zettler, Eli Y Adashi & I Glenn Cohen, "A Divisive Ruling on Devices — Genus *Medical Technologies v FDA*" (23 December 2021) 385:26 New England J Medicine 2409 at 2409:

> For more than 20 years, the Food and Drug Administration (FDA) has taken the legal position that FDA-regulated devices could also be categorized as drugs under the Federal Food, Drug, and Cosmetic Act (FDCA). This interpretation afforded the FDA the flexibility to determine whether such products are best regulated according to the rigorous requirements for drugs or according to the more varied — and often less stringent — ones for devices.

[155] Djulbegovic & Guyatt, *supra* note 41; see also Davidoff, *supra* note 40.

[156] *Drug Amendments of 1962* (*Harris-Kefauver Act*), 76 Stat 780, amending 21 USC §301 [*Kefauver-Harris Amendments* (1962)].

effect, biased observation, or possible spontaneous change(s) in a disease's course.[157] This law specifies that placebo controls are necessary when a drug (or medical device) could have a placebo effect and if it would not be contrary to patient interests.[158] Elements of reliability additionally include requirements to explain: analytical methods; an appropriate selection of patients; and how biases are minimized, as elaborated in Table 3(2). Critically, the law expressly states that uncontrolled or partially controlled studies are unacceptable as the basis for proof of effectiveness.[159]

If a person seeks to depart from these rules "in whole or in part" they must obtain a waiver that clearly and concisely explains why the rules are "not reasonably applicable"[160] and justify alternative procedures to gather scientific evidence. For example, the use of one RCT as a sufficient basis for drug approval is reserved to accommodate testing of medical products intended for less common disease where there may be fewer study participants, such as certain types of cancers.[161]

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[157] 21 CFR §314.126(a).

[158] See 21 CFR §314.126(b)(2)(i), 314.126(b)(2)(iv).

[159] 21 CFR §314.126(e).

[160] 21 CFR §314.126(c).

[161] Seth Ray, "A Guide to FDA's Evolving Interpretation of How Sponsors Can Demonstrate Substantial Evidence of Effectiveness for Human Drug and Biological Products" *JDSupra* (25 March 2020), online: <www.jdsupra.com/legalnews/a-guide-to-fda-s-evolving-74753/>: ("FDA has interpreted the law as generally requiring at least two adequate and well-controlled clinical investigations, each convincing on its own, to establish effectiveness."); see 21 CFR §314.126(c) (waiver's must be sought and precisely justified).

Table 3 US Model Law: Drug and Medical Device (ad hoc) Scientific Evidence Requirements for Safety and Effectiveness

1. Legal Standard to Substantiate Safety and Effectiveness (21 USC §355)
"substantial evidence" = "adequate and well-controlled investigations, including clinical investigations"
2. Elements of an "Adequate and Well-Controlled Study" (21 CFR §314.126(b)) "The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation." (21 CFR §314.126(a))
• objectives of study clearly stated • analytical methods summarized • study's design includes a control (a comparator), to permit quantitative assessment of effects (principally, a placebo-control is required; the use of an active treatment, historical or no treatment controls are considered less reliable) • patients are randomized, and patients and investigators are blinded from knowing whether they are in the investigational or control (comparator) group • method of selecting patients ensures all patients have the disease/condition • minimization of all potential biases (when assigning patients to treatment or control groups; from observers and subjects; in the data analysis) • protocol explains blinding methods • assessment of subjects' responses are clear, well-defined and reliable • variables measured must be explained in the study protocol and report, and include explanations of observation methods, and assessment criteria • analysis of study results are "adequate" and all analytical and statistical methods are explained
3. Waiver from Rules, in Whole or in Part, is Required (21 CFR §314.126(c))
Waivers from the rules above can be granted in "whole or in part". However, the reasons for a waiver must clearly and concisely explain why the rules are not "reasonably applicable." Petitioners seeking a waiver must also justify the use of alternative procedures to gather evidence of safety and effectiveness.
4. Unreliable/Unacceptable Scientific Evidence (21 CFR §314.126(e))
Uncontrolled or partially controlled studies; isolated case reports; random experience; and "reports lacking the details which permit scientific evaluation."

The elements of a well-controlled investigation were affirmed by the Supreme Court of the United States ("USSC") in *Weinberger v. Hynson, Westcott & Dunning, Inc.* (1973).[162] The USSC stated that the elements "express well-established principles of scientific investigation. Moreover, their strict and demanding standards, barring anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by

[162] 412 US 609 (USSC 1973).

the legislative history…."[163] Dr. Robert Temple, an expert US FDA official, emphasized the universality and importance of an adequate and well-controlled investigation as the minimum requirement for all types of medical claims in a speech to commemorate the *Kefauver-Harris Amendments*' (1962) 50th anniversary:

> [i]t's important to recognize that what happened to drugs, that is, moving to an evidence-based standard for approval applies mainly to drugs. It doesn't apply to dietary supplements, and it only fairly recently came to apply to medical devices. It doesn't apply to food claims. Nonetheless, the new drug standard has changed the face of the globe. ….The well-controlled study has become the assumed standard for any medical claim.[164]

Scientific evidence requirements in the US that apply directly to higher risk medical devices, known as the "PMA scheme," or "premarket approval," reflect the above law, but are more lenient because only one well-controlled clinical investigation is the minimum requirement, as opposed to two well-controlled clinical investigations for drugs (and medical devices, ad hoc).[165] The rationale of requiring two clinical investigations is to ensure study findings of safety and effectiveness are replicable. However, non-replicability issues can be overcome if the clinical trial is well-designed and protocols are followed (blinding, etc.)[166]

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[163] *Ibid* at 2478.

[164] Hutt & Temple, *supra* note 13 at 458 [speaking]; but see *POM Wonderful, LLC v FTC*, 777 F 3d 478 (DC Cir 2015) (US Federal Trade Commission's ("FTC") attempt to require two randomized controlled trials to support therapeutic claims associated with a branded pomegranate juice); see also Ryan McCarthy, "Did the FTC Actually Lose POM Wonderful? Health Claims, Prior Substantiation, and the First Amendment" (2016) 35:2 Rev Litig 353 at 364-65: (FTC can compel more than one RCT "based on particularized concerns," which the court did not clearly define.).

[165] 21 USC 360(a)(1)(C)(3)(A): ("well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified…").

[166] See National Academies of Sciences, Engineering and Medicine, *Reproducibility and Replicability in Science* (Washington: DC: National Academies Press, 2019) at 12: ("[t]he committee reviewed current and proposed efforts to improve re-producibility and replicability across science. Efforts to strengthen research practices will improve both.").

Elements of a well-controlled study under this PMA scheme are similarly defined in terms of controlling for biases that may affect the reliability of conclusions about a medical device's safety and effectiveness. For example, these requirements include the need to have a representative sample of study participants, clear study objectives, blinding of participants and observers to reduce bias if feasible and appropriate, and a control medical device to account for potential biases.[167] The requirement for a "control" emphasizes that a placebo control, if feasible, will likely be required if the medical device could pose a placebo effect and if it is not contrary to patient interests.[168] Statistical methods must also be explained (see Table 4 (2)).[169] This PMA scheme, and specifically the requirement to test a medical device against a placebo control, prevented Medtronic Inc.'s RDS, discussed in Chapter 1, from legally entering the US market. In Canada, this medical device was allowed onto the market, but it performed below the company's claims of effectiveness when tested according to the US-required RCT methodology.

The PMA scheme also requires a person to 'clearly' justify why well-controlled investigations would "not [be] reasonably applicable" if an exemption is sought.[170] If adequate justification is provided, "valid scientific evidence [other than "well-controlled investigations, including 1 or more clinical investigations"]"[171] must be submitted. Valid scientific evidence is defined and contingent on the medical device's characteristics and

[167] 21 CFR §860.7(f).

[168] *Ibid*.

[169] *Ibid*.

[170] 21 CFR §860.7(e)(2); see also 21 USC §360c(a)(3)(B).

[171] See 21 USC §360c(a)(3)(B).

other factors, such as the adequacy of warnings placed on a medical device, and the evidence must demonstrate "clinically significant results" (see Table 4(4)).[172]

Overall, this law establishes relatively explicit and reliable scientific evidence expectations and requirements because of its primary emphasis on at least one adequate and well-controlled clinical study conducted on the medical device as a default. By requiring a person to justify why well-controlled investigations are not "reasonably applicable," the law has the necessary degree of flexibility to accommodate testing of medical devices that "face unique study design considerations,"[173] and cannot necessarily be tested according to the most rigorous type of scientific evidence for ethical reasons, which is a blinded, randomized, and placebo-controlled trial.[174]

Table 4 US Model Law: Medical Device Safety and Effectiveness Requirements for Safety and Effectiveness (Premarket Approval)

1. Legal Standard for Safety and Effectiveness (21 USC §360c(a)(3)(A))
"Reasonable assurance" = "well-controlled investigations, including 1 or more clinical investigations"
2. Principles of an Adequate and Well-Controlled Study (21 CFR §860.7(f)) "The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation."
• objectives of study are clearly stated • subjects are selected in a way that minimizes bias • observation methods, including variables measured, are explained and results are recorded • requirement for a control group:

[172] See 21 CFR §860.7(e)(1).

[173] Kushal T Kadakia, *et al*, "Renewing the Call for Reforms to Medical Device Safety – The Case of Penumbra" (2022) 182:1 JAMA Internal Medicine 59 at 60.

[174] See e.g. Daniel B Kramer *et al*, "Premarket Clinical Evaluation of Novel Cardiovascular Devices: Quality Analysis of Premarket Clinical Studies Submitted to the Food and Drug Administration 2000-2007" (2010) 17 American J Therapeutics 2 at 3: ("Blinding and randomization were not included in the study quality assessment because in many cases, it is not possible and/or ethical to implement these study design characteristics in medical device trials."); but see Wright, *supra* note 15 at 207 (as a corollary to Kramer, *et al*, as noted *supra* it has also been considered unethical to permit market entry of medical devices based on unblinded, non-randomized, or non-placebo-controlled studies.).

the nature of the control is precisely defined; placebo-control required unless contrary to patient interests or if a placebo effect would be negligible; no treatment controls, active treatment controls, and historical controls reserved for specific fact-scenarios as specified in the law. • clear explanation of steps taken to minimize bias, including in the data analysis • blinding methods and "levels" of blinding recorded • summary of analytical and statistical methods • device must be standardized in form and performance
3. Authorization Required When "Well-Controlled Investigations" Are "Not Reasonably Applicable" (21 CFR §860.7(e)(2))
Evidence shall consist "principally of well-controlled investigations", unless the Commissioner determines this requirement is "not reasonably applicable to the device," and "valid scientific evidence" otherwise exists.
4. Valid Scientific Evidence (Other than Well-Controlled Investigations) (21 CFR §860.7 (c)-(e))
Context-specific: the device's nature will depend on what type of valid scientific evidence is needed (the type and quantity of evidence could vary according to device's characteristics, its use, inclusion of warnings or restrictions, and; extent of human experience with the device). The evidence, however, must demonstrate "clinically significant results." Valid scientific evidence may include: "partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device,"
5. Unaccepted Types of Scientific Evidence (21 CFR §860.7 (c)(2))
"Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness."

2.3.2. Do Canada's Premarket Laws Reflect Reliable Scientific Evidence Requirements?

The scientific evidence requirements in Canada under Part 1 of the *MDRs* and the *ATPAs* do not reflect the model US law with some exception for all risk categories of NP-IVDDs. As defined above, NP-IVDDs explicitly require testing to be "conducted on the device…representative of the intended users and under conditions similar to the conditions of use."[175] For all other types of medical devices across each risk class, which

[175] See *MDRs*, *supra* note 1, ss 32(2)(e), 32(3)(h), and 32(4)(f).

is the vast majority of medical devices, there is an absence of explicit expectations or requirements for reliable forms of scientific evidence.

Scientific evidence requirements are vague under each reviewed market entry route. Under the mainstream market entry route (Part 1 of the *MDRs*), vagueness is reflected in terms such as "objective evidence" defined as "data (3.8.1) supporting the existence or verity of something," where "data" is defined as "facts about an object (3.6.1)" and as "obtained through observation, measurement (3.11.4), test (3.11.8), or by other means."[176] Vagueness is also demonstrated in phrases such as "studies on which a manufacturer relies," and "clinical studies," which do not mean clinical studies that were device-specific as explained in Health Canada's policy guidance document.[177] Under the *ATPAs*, vagueness is conveyed by terms including requirements to provide the government with "sufficient evidence" that benefits outweigh risks.[178]

If these terms are compared to the objective indicia for "well-controlled" studies under the model US model law summarized under Tables 3 and 4 (requirements for randomization, a control group, blinding, etc.), Canada's requirements do not establish expectations or requirements for methodologically rigourous scientific evidence for safety and effectiveness. The absence of explicit expectations and requirements for reliable forms of scientific evidence and the overall vagueness of these requirements is a shortcoming in terms of the law's ability to reduce public risks, as will be explained below.

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[176] See ISO, "evidence", *supra* note 130.

[177] See Table 1.

[178] See Table 2.

2.3.3. Issues with Vague Scientific Evidence Requirements

2.3.3.1. Methodologically Rigorous Scientific Evidence is not a Predictable Requirement

Vague scientific evidence requirements do not provide significant guarantees that a regulator will predictably compel reliable forms of scientific evidence to substantiate manufacturer hypotheses of safety and effectiveness. From a regulatory law perspective, Paul Salembier, former General Counsel at the Department of Justice (Canada) (Queen's University) and legal expert in regulatory and legislative drafting,[179] has stated that vague laws are not "legal rules" because they permit an individual person or regulatory officer to determine the rule.[180] From this perspective, the vagueness in the existing scientific evidence requirements for proof of safety and effectiveness are not legal rules because of their insufficient clarity ("objective evidence" defined as "facts about an object," etc.).

The scientific evidence requirements, to the extent they can be defined as requirements, empower a regulatory officer to determine the burden of proof for safety and effectiveness, which is not a predictable means to ensure reliable forms of scientific evidence is expected or in fact required. In turn, the lack of predictability increases the risk that the public will be exposed to potentially harmful medical devices that have not been substantiated according to a methodologically rigorous safety and effectiveness assessment process.

Even for the market entry of new drugs in Canada, the federal government does not explicitly require that a clinical trial be conducted prior to a drug being sold. In Canada, while C.08.002(2)(h) of the *Food and Drug Regulations* requires "substantial

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[179] Paul Salembier, *Regulatory Law and Practice*, 3rd ed (Toronto: LexisNexis Canada, 2021) at v.
[180] See *ibid*, at 31.

evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended,"[181] the legal standard of "substantial evidence of clinical effectiveness" is left undefined. As one court has observed: [t]here is no express provision in the Act or Regulations requiring that clinical trials be conducted and resulting data be provided to Health Canada. Counsel for Health Canada informed the Court that Health Canada relies on its interpretation of sections C.08.002 (2)(g) and (h) of the *Regulations*."[182] As this quote implies, Health Canada is effectively legislating in respect to scientific evidence requirements with relatively few legal constraints, which is consistent with scientific evidence requirements for medical device substantiation.

2.3.3.2. Risk of Public Corruption and Information Capture

Salembier further states that vague laws that permit subjective rulemaking create a risk for public corruption.[183] Salembier defines corruption broadly as "the use of discretionary powers by any official in a manner designed to benefit the official himself or herself or those close to him or her, or to benefit the political party to whom the official belongs."[184] Corruption may be blatant or more subtle.[185] For example, in the context of regulated industries, a regulatory official may interpret vague scientific

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[181] *Food and Drug Regulations*, CRC 2020, c 870, C.08.002(2)(h) (emphasis added) [*FDRs*].

[182] *Wellesley Therapeutics Inc v Canada (Minister of Health),* 2010 FC 573 at para 61; see also *Hospira Healthcare Corp v Canada (AG)*, 2010 FCA 345 (emphasizing that the Minister has discretion in terms of what the standard will be to meet "substantial evidence" at para 6 ("[i]n our view, the Minister has a discretion as to the nature and form of the information that will be accepted as meeting the requirements of paragraphs C.08.002(2)(*g*) and (*h*)."); *Hospira Healthcare Corp v Canada (AG)*, 2010 FC 213 at para 29 "([t]he Minister is permitted to make determinations that fall within a range of acceptable outcomes [regarding the type of scientific evidence]. Requiring clinical tests is particularly reasonable since legislators specified that the information must be sufficient to enable the Minister to assess the drug's safety and effectiveness.").

[183] Salembier, *supra* note 179 at 23.

[184] *Ibid*.

[185] *Ibid* at 23-24.

evidence requirements in ways that reduce the rigour of scientific evidence requirements to reduce costs for the industry for purposes of economic rent seeking (public choice theory).[186] More subtlety, regulators may also refrain from imposing rigourous and more costly scientific evidence requirements for reasons of job security and general avoidance of conflict.[187]

Beyond the risk of corruption, vague scientific evidence requirements may also create a situation where a regulator is subject to biased information streams about appropriate thresholds for scientific evidence that flow from well-funded interest groups who may provide biased explanations to regulators.[188] In 2005, for example, some Members of Parliament called for several members of Health Canada's breast implant review panel to be removed over conflicts of interest because these members were said to be representative of breast implant manufacturers.[189]

While it can be said that "a discretionary decision-making power…does not automatically open the door to injustice, discrimination and corruption, particularly when the discretion is exercised by more than one decision-maker," Salembier still states that the "conferral of a discretionary power does, however, add an element of unpredictability to the law, which undermines the Rule of Law and invites corruption."[190]

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[186] See Susan C Morse, "Safe Harbors, Sure Shipwrecks" (2016) 49 UC Davis L Rev 1385 at 1428 [citations omitted].

[187] See *ibid*.

[188] See Wendy E Wagner, "Administrative Law, Filter Failure and Information Capture" (2010) Duke LJ 1322 at 1322-28.

[189] CMAJ, "MPs Call for Removal of Health Canada's Breast Implant Panel Members" (2005) 173:10 CMAJ 114.

[190] Salembier, *supra* note 179 at 38.

2.3.3.3. Health Canada's Interpretation is Parallel to the Disputed US 510(k) Clearance Process

One specific issue with the vague scientific evidence requirements under the *MDRs* and *ATPAs* is that their vagueness permits a manufacturer to base their medical device's safety and effectiveness by analogy to a similar medical device's safety and effectiveness. As discussed, under the mainstream market entry route (Part 1 of the *MDRs*), there is an absence of a requirement for scientific evidence to be based on testing that is conducted on the licensee medical device across all risk classes (Classes I-IV) except for NP-IVDDs. Similarly, under the *ATPAs*, which defines scientific evidence requirements even more open-endedly, the requirement to submit "sufficient evidence" that benefits outweigh risks does not bar this type of 'analogy' evidence.

Health Canada's Regulatory Decision Summary confirms the acceptance of this type of 'analogy' evidence: "[d]evice specific clinical evidence is therefore not required,"[191] and "[d]evice-specific clinical evidence is not required for this application as this device is sufficiently similar to currently licenced devices."[192] Penumbra's Jet 7 Xtra Flex was also not required to be clinically tested because its technology was considered to be "unchanged" by Health Canada: "[d]evice specific clinical studies were not required because the technology for the indicated use is unchanged, and safety and device effectiveness was fully supported by the evidence provided."[193] The Jet7 Xtra Flex catheter, however, was engineered to be more flexible than Penumbra's previous

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[191] Health Canada, "Regulatory Decision Summary – A.L.P.S. Clavicle Plating System" [Class III, date of decision: 2019-09-19], online: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10494>.

[192] Health Canada, "Regulatory Decision Summary – HIRES ULTRA 3D COCHLEAR IMPLANT" [Class III, date of decision: 2018-03-29], online: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10347>.

[193] Health Canada, RDS – PENUMBRA SYSTEM, *supra* note 99.

pioneering aspiration catheter so that it could compete with newer and more flexible catheters that enabled surgeries to be performed faster, which began eroding Penumbra's market share according to QCM.[194]

The reliance on a similar 'predicate' medical device's evidence of safety and effectiveness is substantially similar to a law in the US known as the "510(k) clearance process." The process permits a person to market a medical device if it can be deemed "substantially equivalent," including in respect to its clinical safety and effectiveness, to another legally marketed medical device in the US, which typically necessitates some preclinical scientific evidence to demonstrate substantial equivalency and general 'performance' equivalency (for e.g., "bench-testing" etc.).[195] While the 510(k) clearance process, enacted under the US *Medical Device Amendments of 1976*,[196] was meant as a temporary measure,[197] it became and continues to be the dominant market entry route in the US.[198] Thus, the PMA scheme, although serving as best practice-like law, is not the "mainstream" market entry route in the US.

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[194] QCM, *supra* note 96, slide 14.

[195] See US Food and Drug Administration, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (28 July 2014), online: <www.fda.gov/media/82395/download>; see also Institute of Medicine of the National Academies, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Committee on the Public Health Effectiveness of the FDA 510(k) Process: Board on Population Health and Public Health Practice (Washington, DC: National Academies Press, 2011) at 93 [IOM, *Report*].

[196] Pub L No 94-295, 90 Stat 539 (1976) [*MDAs*, 1976].

[197] See Jordan Bauman, "The 'Déjà vu Effect,' Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program" (2012) 67 Food & Drug LJ 337 at 361: ("[t]he 510(k) program originally was never intended by Congress to act as a 'Class II device approval pathway' - it has been forged into this state over many years of misuse by FDA, misappropriation of funds by Congress, and exploitation of weak statutory language by the medical device industry.").

[198] See Jonathan J Darrow, "FDA Regulation and Approval of Medical Devices: 1976-2020" (2021) 326:5 JAMA 420 at 420: ("[f]rom 1987 to 2020, the annual number of novel devices granted premarket approval (which excludes supplements) ranged from 8 to 56 (median, 32), and the number of clearances for 510(k) devices (those that are "substantially equivalent" to marketed devices) ranged from 2804 to 5762 (median, 3404).").

The 510(k) clearance process has been subject to criticism from a public health perspective. As Kushal T. Kadakia (Harvard Medical School), *et al* state: "[a]lthough the streamlined regulatory review under 510(k) offers advantages to device makers, the lower evidentiary standards compared with other FDA review pathways, such as premarket approval, have long been a cause for concern."[199] From the medical device industry's perspective, the streamlined process that imposes a lower evidentiary standard is itself overly burdensome and delays access to new treatments.[200]

In 2011, the US Institute of Medicine of the National Academies (renamed, the National Academy of Medicine)[201] recommended that the 510(k) clearance process be abolished rather than amended because it was found unable to provide reasonable assurance of a medical device's safety and effectiveness.[202] According to the Supreme Court of the United States ("USSC"), in the context of a federal preemption law that prohibits states from imposing different or additional (i.e., more rigorous) safety and effectiveness requirements onto manufacturers including at state common law,[203] the

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[199] Kadakia, *et al*, *supra* note 173 at 60.

[200] IOM, *Report*, *supra* note 195 at 4: ("[s]everal high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market.").

[201] National Academy of Medicine, "About the National Academy of Medicine", online: <https://nam.edu/about-the-nam/>:

> Founded in 1970 as the Institute of Medicine (IOM), the National Academy of Medicine (NAM) is one of three academies that make up the National Academies of Sciences, Engineering, and Medicine (the National Academies) in the United States. Operating under the 1863 Congressional charter of the National Academy of Sciences, the National Academies are private, nonprofit institutions that work outside of government to provide objective advice on matters of science, technology, and health.

[202] IOM, *Report*, *supra* note 195 at 7-8.

[203] See 21 USC s 360k(a); see *Cipollone v Leggett Group, Inc*, 505 US 504 (USSC 1992): (federal preemption of state 'requirements' includes requirements imposed within the state's common law and are not only legislative requirements).

federal 510(k) clearance process was found unable to provide reasonable assurance of safety and effectiveness and it was not ultimately found to be a safety and effectiveness "requirement."[204] Therefore, if a medical device was cleared onto the market under the 510(k) clearance process, i.e., by demonstrating "substantial equivalence," a manufacturer can be liable to more rigorous safety and effectiveness requirements under state law, for example to a more rigorous standard of care at common law in negligence.[205] In contrast, the PMA scheme (see Table 4) is considered by the USSC to be a safety and effectiveness "requirement,"[206] and therefore a person cannot hold a manufacturer liable under state law to more rigourous requirements beyond those imposed under the relatively "rigorous"[207] PMA scheme.[208]

In the context of product liability of pelvic mesh, the United States Court of Appeals for the Fourth Circuit[209] similarly found that the 510(k) clearance process does not adequately attest to a medical device's safety, which was described as a finding consistent with the "vast majority of courts."[210] Evidence of its clearance onto the market

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[204] *Medtronic, Inc v Lohr* (1996), 518 US 470 [*Lohr*]; see Chapter 5 for further discussion; see *Riegel v Medtronic, Inc* (2008), 552 US 312 [*Riegel*] affirming *Lohr*.

[205] Legislative Attorney (name redacted), "*Riegel v Medtronic, Inc*.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval" (Washington, DC: Congressional Research Service, 2012) at 8-9 (discussing *Lohr*, *ibid*).

[206] *Ibid*, at 13; *Riegel*, *supra* note 204 at 322-23.

[207] *Lohr*, *supra* note 204 at 477: ("Despite its relatively innocuous phrasing…the 'premarket approval' or 'PMA' process, is a rigorous one.").

[208] *Riegel*, *supra* note 204 at 330.

[209] The United States Court of Appeals for the Fourth Circuit, "About the Court", online: <www.ca4.uscourts.gov/about-the-court>: ("The court hears appeals from the nine federal district courts in Maryland, Virginia, West Virginia, North Carolina, and South Carolina and from federal administrative agencies.").

[210] *In re CR Bard, Inc, MDL No 2187, Pelvic Repair System Products Liability Litigation*, 810 F3d 913 at 922 (USCA 4th Cir 2016): ("While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several amici, we say so again today.").

under the 510(k) clearance process was barred because the Court found, affirming the lower court's finding, there would be "very substantial dangers of misleading the jury" abouts its safety if it were introduced as evidence to support the claim of its safety.[211] The Court further commented that "the 510(k) process has been repeatedly characterized as something less than a safety requirement, gaining the applicant an exemption from regulation rather than subjecting the applicant to regulation."[212]

To summarize, the ability of a manufacturer to rely on the clinical safety and effectiveness of a more vaguely "related" medical device (or in the US one that is "substantially equivalent" as specified in detail under primary legislation[213]) as evidence of a new 'licensee' medical device's safety and effectiveness has not been characterized as a sufficient method to evaluate a medical device's safety and effectiveness. Since 1996, the USSC has not legally characterized this type of evidence as imposing safety and effectiveness "requirements" onto a manufacturer,[214] which the Court reaffirmed in

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[211] *Ibid*.

[212] *Ibid*.

[213] 21 USC §360(i) [emphasis added]:

> (i) Substantial equivalence
>
> (1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means… that the device has the same intended use as the predicate device and that the Secretary by order has found that the device-
>
> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 360m of this title, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.
>
> (B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

[214] *Lohr*, *supra* note 204.

obiter dicta in 2008.[215] In Canada, apart from NP-IVDDs, this standard of scientific evidence that underlies the 510(k) clearance process is permitted under s. 32 of the *MDRs* and explicitly described in Health Canada's policy guidance document. The vagueness in these substantiation laws have also led to the standards being misunderstood by researchers. It has been stated, for example, that Canada does not have a market entry scheme akin to the 510(k) clearance process.[216] While the 510(k) clearance process is not explicit under Canadian law, the process is reflected in the administration of the vague scientific evidence requirements.

2.4. Conclusion

Chapter 2 sought to define medical device regulation and examine premarket regulation from a critical lens. As this chapter revealed, at the premarket stage, there is an absence of a requirement for explicit and reliable forms of scientific evidence to substantiate safety and effectiveness, which poses risks to the public. The underlying process governing market entry of medical devices is also characterized by inherent flexibility because regulations are considered a less 'stable' form of law compared to primary legislation. Preferably, licensing conditions that enumerate explicit requirements for reliable forms of scientific evidence would be vested in primary (Parliamentary)

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[215] *Riegel*, *supra* note 204.

[216] See Ghislaine Mathieu & Bryn Wiilliams-Jones, "Examining the National Regulatory Environment of Medical Devices: Major Issues in the Risk-Assessment of High-Risk Devices" (2016) 9:1 McGill JL & Health 17 at 40 (this article also does not explain clinical safety or effectiveness requirements in Canada. For example, it briefly defines 'pre-approval clinical regulatory requirements' according to four criteria at 30: 1) Risk assessment for Class IV; 2) Investigational testing authorization (new device); 3) Emergency use program (unapproved device); 4) FDA guidance may be used by Health Canada.).

legislation to add stability to methodologically rigourous scientific evidence requirements.

The following chapter seeks to broadly establish the federal government's constitutional power(s) to regulate medical device safety and effectiveness to gain a sense of how the federal government may lawfully regulate this sphere of activity to fall within federal jurisdiction.

CHAPTER 3 FEDERAL AUTHORITY OVER MEDICAL DEVICE SAFETY AND EFFECTIVENESS

3.1. Federalism: Introduction and Relevant Heads of Power

The *Constitution Act, 1867* enshrines Canada's structural arrangement of federalism predominantly under ss. 91 and 92 (the division of powers), which distribute subject matters between the federal (s. 91) and provincial governments (s. 92). In *Canadian Western Bank v. Alberta* (2007),[217] the SCC explained that the objectives of federalism were to "to reconcile unity with diversity, promote democratic participation by reserving meaningful powers to the local or regional level and to foster co-operation among governments and legislatures for the common good."[218] Federalism, outside of a doctrinal perspective, is described as a stable form of democratic governance.[219]

Federal and provincial governments may only enact laws, promulgate regulations, and act consistent with one or more of their listed subject matters under the *Constitution Act, 1867*:

> The Constitution binds all governments, both federal and provincial, including the executive branch (*Operation Dismantle Inc. v. The Queen*, [1985] 1 S.C.R. 441, at p. 455). They may not transgress its provisions: indeed, their sole claim to exercise lawful authority rests in the powers allocated to them under the Constitution, and can come from no other source.[220]

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[217] 2007 SCC 22 [*Canadian Western Bank*].

[218] *Ibid* at para 22.

[219] See e.g. Robert P Inman, "Federalism's Values and the Value of Federalism" Working Paper 13735 (Cambridge, MA: National Bureau of Economic Research, 2008) (discussing federalism in a non-US specific context).

[220] *Reference re Secession of Quebec*, [1998] 2 SCR 217 at para 72 (The Court) [*Reference re Secession*]:

Government laws or actions that are inconsistent with their enumerated powers, barring laws that are not "ancillary" to an otherwise valid legal scheme under the ancillary powers doctrine,[221] are deemed *ultra vires* ("without authority"[222]) under s. 52(1) of the *Constitution Act, 1982*, which means they are of no force or effect.[223]

Medical device safety and effectiveness is not a listed subject matter under the division of powers. This matter, however, broadly relates in part to 'health,' which is not itself enumerated under this division. Both federal and provincial governments may validly regulate in matters of health[224] if the specific aspect of the health matter in issue (i.e., licensing of medical devices in relation to safety and effectiveness) can stand "in relation to"[225] one or more of the enacting government's subject matters under the division of powers ("aspect theory").[226] For example, while the provinces have overriding control to regulate health professions, the federal government maintains power to 'regulate' health professions in a criminal law aspect, for example, in respect to matters of fraud.

Federal jurisdiction in health policy, in contrast to provincial jurisdiction, such as laws related to a medical device's safety and effectiveness, must relate to a subject matter

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[221] See Chapter 4 for further discussion of the ancillary powers doctrine.

[222] See generally Salembier, *supra* note 179.

[223] *Constitution Act 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982 c 11, s 52(1).

[224] *Carter v Canada (AG)*, 2015 SCC 5 at para 53; *RJR-MacDonald Inc v Canada (AG)*, [1995] 3 SCR 199 [*RJR-MacDonald*]; *Schneider v The Queen*, [1982] 2 SCR 112, at p 142 [*Schneider*].

[225] *Reference re Firearms* (SCC), *supra* note 50 at para 25.

[226] W R Lederman, "The Concurrent Operation of Federal and Provincial Laws in Canada" (1963) 9:3 McGill LJ at 186.

listed under s. 91. The federal government's criminal law power under s. 91(27) is recognized as the core constitutional basis for federal authority over health.[227]

Other potentially relevant federal powers that *prima facie* may support federal licensing of medical devices in relation to safety and effectiveness include, because of their plain text generality, the trade and commerce power (s. 91(2)), and the peace, order and good government power ("p.o.g.g.") (s. 91). In *Wetmore* (1983),[228] for example, which was the last SCC case to opine on the constitutionality of the *F&D Act* on federalism grounds, the majority in *obiter dicta* inferred that certain provisions under the *F&D Act* (RSC 1970) may be "subjoined" with the trade and commerce power, including those related to medical devices (the p.o.g.g. power was not considered by the majority). These provisions related to standard-setting, specifically "labelling and packaging, as well as the control of manufacture":[229]

> An examination of the various provisions of the *Food and Drugs Act* shows that it goes beyond mere prohibition to bring it solely within s. 91(27) but that it also involves a prescription of standards, including labelling and packaging as well as control of manufacture. The ramifications of the legislation, encompassing food, drugs, cosmetics and devices and the emphasis on marketing standards seem to me to subjoin a trade and commerce aspect beyond mere criminal law alone. There appear to be three categories of provisions in the *Food and Drugs Act*. Those that are in s. 8 are aimed at protecting the physical health and safety of the public. Those that are in s. 9 are aimed at marketing and those dealing with controlled drugs in Part III of the Act are aimed at

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[227] Glen Rivard, "Federal and Provincial Jurisdiction with Respect to Health: Struggles Amid Symbiosis" in Trudo Lemmens, *et al*, eds, *Regulating Creation: The Law, Ethics, and Policy of Assisted Human Reproduction* (Toronto: University of Toronto Press, Scholarly Publishing Division, 2017) 63 at 64: ("[t]he federal government's exclusive jurisdiction over criminal law serves as the primary head of power relied upon as the constitutional basis for federal health legislation."); *Canada (AG) v PHS Community Services Society*, 2011 SCC 44 at para 68 [*PHS Community Services*]: ("Parliament has power to legislate with respect to federal matters, notably criminal law, that touch on health. For instance, it has historic jurisdiction to prohibit medical treatments that are dangerous, or that it perceives as "socially undesirable" behaviour: R. v. Morgentaler, [1988] 1 S.C.R. 30; Morgentaler v. The Queen, [1976] 1 S.C.R. 616; R. v. Morgentaler, [1993] 3 S.C.R. 463.).").

[228] *Wetmore*, *supra* note 69.

[229] *Ibid* at 288.

> protecting the moral health of the public. One may properly characterize the first and third categories as falling under the criminal law power but the second category certainly invites the application of the trade and commerce power.
>
> However, it is unnecessary to pursue this issue and it has been well understood over many years that protection of food and other products against adulteration and to enforce standards of purity are properly assigned to the criminal law. *Standard Sausage Co. v. Lee*, [1933] 4 D.L.R. 501, supplemented by addendum at [1934] 1 D.L.R. 706 is a long standing application of these principles.[230]

Dickson J. (prior to CJ.) dissented and found the provisions in question (s. 8(a): prohibition on the unsanitary preparation, packaging, or manufacturing, etc. of drugs; s. 9(1): prohibition on deceptive marketing of drugs; and s. 26: penal sanctions for violation of ss. 8(a) and 9(1)) exclusively dependent on the criminal law power after consideration of the trade and commerce and p.o.g.g. powers: "the sections of the *Food and Drugs Act* in question are dependent and solely dependent on the federal criminal law power."[231]

The following section seeks to assess if the federal government may be dependent on the criminal law power to support, in a broad sense, licensing of medical devices in relation to safety and effectiveness by exploring the current scope of the trade and commerce and p.o.g.g. powers (see RQ2). If this matter is dependent on the criminal law power, then the dominant purpose of licensing in relation to safety and effectiveness must conform to standards of valid criminal law.

Based on the findings below that the federal government may be found dependent on the criminal law power, the last major section in this chapter defines the scope of valid criminal law to understand how federal authority over the licensing of medical devices in

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[230] *Ibid* [emphasis added].

[231] *Ibid* at Dickson J (prior to CJ) at 296-97 [emphasis in original], aff'm *Standard Sausage*, *supra* note 64, which dealt with the *F&D Act*, RSC 1927, *supra* note 67.

relation to safety and effectiveness may function. This discussion will be used to assess if the impugned laws assessed in Chapters 5 and 6 meet standards of valid criminal law.

3.2. Assessing the Dependency on the Criminal Law Power

As discussed above, the trade and commerce and p.o.g.g. powers must be assessed to determine if licensing of medical devices in relation to safety and effectiveness is dependent on the criminal law power. The scope of broadly worded powers, such as the trade and commerce power and the p.o.g.g. power, are said to be modified by other heads of powers, particularly those in the other order of government, through the principle of mutual modification.[232] The mutual modification principle helps to prevent powers "from being interpreted so expansively that the other power has no meaningful content."[233] Therefore, despite the broad wording of these powers, as the discussions below will reveal, they are generally narrow in relation to the matters they may support.

3.2.1. Trade and Commerce Power

3.2.1.1. Introduction

The federal government has jurisdiction over "The Regulation of Trade and Commerce," under s. 91(2), which potentially encompasses "almost any sphere of activity,"[234] including matters exclusive to provincial jurisdiction under "Property and

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[232] *Citizens' Insurance Co of Canada v Parsons* (1881), 7 App Cas 96 (PC) at 108-09 [*Citizens' Insurance*]: ("the two sections must be read together, and the language of one interpreted, and, where necessary, modified, by that of the other ... to arrive at a reasonable and practical construction of the language of the sections, so as to reconcile the respective powers they contain, and give effect to all of them.").

[233] Hoi L Kong, "Republicanism and the Division of Powers in Canada" (2014) 64:3 UTLJ 359 at 394.

[234] Halsbury's Laws of Canada, *Constitutional Law (Division of Powers)* "Meaning of matters within trade and commerce" (VII 1.) at HCL-127 (2019 Reissue) [Guy Régimbald & John J Wilson].

Civil Rights in the Province" (s. 92(13)) and "Generally all Matters of a merely local or private Nature in the Province." (s. 92(16)).[235] Because of the plain text breadth of the trade and commerce power, the SCC has stated that "courts should avoid making general pronouncements on the scope of the power,"[236] and that its ability to be used as a constitutional basis should be assessed on "a careful case by case analysis."[237]

With this background in mind, the trade and commerce power consists of two branches that include the interprovincial or international trade branch and the general regulation branch.[238] A law must fall under one of these branches to be upheld under this power. The following discusses these branches and examines the extent to which they may support federal licensing of medical devices in relation to safety and effectiveness.

3.2.1.2. Interprovincial and International Trade Branch

The SCC has not provided explicit criteria to guide a determination of whether a law falls under this branch, which contrasts with the general regulation branch discussed below. The modern basis of its scope begins in *Reference re Farm Products Marketing Act (Ontario)* (1957)[239] where the SCC established the following threshold basis to invoke it as a constitutional basis for a law:

> The concept of trade and commerce, the regulation of which is confided to Parliament, is entirely separate and distinct from the regulation of mere sale and purchaser agreements. Once an article enters into the flow of interprovincial or external trade, the subject matter and all of its attendant circumstances cease to be a mere matter of local concern.[240]

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[235] *Ibid*.

[236] *Ibid*, citing *John Deere Plow Co v Wharton*, [1915] AC 330 at 338-39 (PC).

[237] *General Motors of Canada Ltd v City National Leasing Ltd*, [1989] 1 SCR 641 at para 34 [*General Motors*].

[238] *Citizens' Insurance*, *supra* note 232.

[239] [1957] SCR 198 (SCC) [*Reference re Farm Products*]; see Guy Régimbald & Dwight Newman, *The Law of the Canadian Constitution*, 2nd ed, (Toronto: LexisNexis Canada, 2017) at 306.

[240] *Reference re Farm Products, ibid* at 205 [emphasis added].

Based on this broad statement alone, once commodities (such as medical devices) enter the "flow" of interprovincial or international trade, the federal government may regulate products for various federal policy objectives, such as the protection of a Canadian industry (Western oil) from less costly imported oil,[241] if effects on intraprovincial trade (for e.g., effects on property and civil rights) are incidental to achieve the federal policy objective.[242]

Commentary on the scope of this branch has explicitly suggested it may be used as a constitutional basis to support national commodity standards through national licensing schemes.[243] This suggests the branch could be used as a constitutional basis to support a national licensing scheme that establishes market entry requirements for medical device safety and effectiveness, and relatedly, standards for scientific evidence. For example, *Murphy v. C.P.R* (1958)[244] & *Caloil v. Canada (AG)* (1970)[245] are case examples wherein "the relevant federal legislation prohibited the international or interprovincial shipment of a product, subject to exceptions defined in federal regulations and/or to a requirement of federal licensing."[246] It has also been observed that "Parliament has used its authority to regulate international or interprovincial trade as a

[241] See *Caloil v Canada (AG)* (1970) [1971] SCR 543 [*Caloil*].
[242] *Ibid*.
[243] Mathen & Macklem, *et al*, eds, *supra* note 63 at 340.
[244] [1958] SCR 626.
[245] *Caloil*, *supra* note 241.
[246] Mathen & Macklem, *et al*, eds, *supra* note 63 at 340.

basis for imposing national product or marketing standards,"[247] for example, under the *Energy Efficiency Act*, s 4(1):[248]

> No dealer shall, for the purpose of sale or lease, ship an energy-using product from one province to another province, or import an energy-using product into Canada, unless
> (a) The product complies with the energy efficiency standard prescribed by the regulations, and
> (b) The product or its package is labelled in accordance with the regulations, if any

However, this provision and the *Act* have not been judicially reviewed on federalism grounds and are presumed constitutional.[249]

In *Saputo Inc. v. Canada (AG)*[250] (2011) the Federal Court of Appeal ("FCA") upheld commodity standards under the *Food and Drug Regulations*[251] for cheese products (Casein Ratio and Whey Ratio) under the interprovincial and international trade branch. These commodity standards established minimum casein content for various cheeses. For example, mozzarella was required to contain 63% casein from liquid milk, and for Cheddar, Brick and other enumerated cheeses, the minimum casein content was 83% from liquid milk.[252]

The FCA cited *Wetmore* (1983) for the proposition that the *F&D Act* was subjoined with the trade and commerce power (although *Wetmore* did not definitively conclude this[253]), although it found the *Act*'s principal basis was vested under the

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[247] *Ibid*.

[248] SC 1992, c 36.

[249] There is one cited case, *Rebuck v Ford Motor Company*, 2022 ONSC 2396.

[250] 2011 FCA 69 [*Saputo*].

[251] *Food and Drug Regulations and the Dairy Products Regulations, Regulations Amending the*, SOR/2007-302.

[252] *Ibid* at para 15.

[253] See *Wetmore*, *supra* note 69 at 288.

criminal law power.[254] The Court upheld both Casein and Whey Ratios because they amounted to objectively enforceable standards: "I find that the Casein Ratios and the Whey Ratio can be objectively enforced, the expert report of Dr. Goulet clearly concluding that there were a number of objective ways to ensure compliance (Appeal Book at pages 202 and ff.)."[255] The standards were therefore not "meaningless"[256] and their definitions under regulation did not vest "undue discretion"[257] in the administrative agency (the Canadian Food Inspection Agency) tasked with the enforcement of these regulations.[258]

Based on *Saputo*, if the federal government sought to licence medical devices in relation to safety and effectiveness under the interprovincial and international trade branch, the law (primary legislation or regulation) must likely devise methodologically rigourous scientific evidence requirements to objectively assess safety and effectiveness. Objective assessment criteria would likely include the principles of well-controlled investigations under model US laws in Chapter 2 (see Tables 3 and 4), such as a blinded, randomized and validly (i.e. placebo, if possible)-controlled clinical trial where feasible.

At the highest level of court, the SCC has however failed to uphold national commodity standards under this branch. In *Labatt Breweries of Canada Ltd. v. (AG)*

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[254] *Ibid*, at para 71:

> I acknowledge that the *Food and Drugs Act* is principally concerned with the protection of public heath and public safety in relation to food and drug products, and that its constitutional validity rests principally on the federal criminal law authority under subsection 91(27) of the *Constitution Act, 1867*: *Standard Sausage Co. v. Lee* (1933), [1934] 1 W.W.R. 81 (B.C. C.A.); *R. v. Kripps Pharmacy Ltd.*, [1983] 2 S.C.R. 284 (S.C.C.) [hereinafter R. v. Wetmore]; *C.E. Jamieson & Co. (Dominion) v. Canada (Attorney General)* (1987), 12 F.T.R. 167, 46 D.L.R. (4th) 582 (Fed. T.D.); *Canadian Generic Pharmaceutical Assn. v. Canada (Minister of Health)*, 2010 FCA 334 (F.C.A.).

[255] *Ibid* at para 75 [emphasis added].

[256] *Ibid* at para 74.

[257] *Ibid*.

[258] *Ibid*.

Canada (1979),[259] alcohol percentage ranges for "light" or "lite" beer could not be supported. The majority stated that the trade and commerce power in its entirety does not support the regulation of a single industry:

> the trade and commerce head cannot be applied to the regulation of a single trade, even though it be on a national basis, and in the *Board of Commerce* disposition, *supra*, the invocation of the trade and commerce head of federal jurisdiction is forbidden in the regulation of elements of commerce such as contracts, in an individual trade or concern even though the control was imposed in a series of separate regulatory codes each purporting to regulate a separate trade or industry.[260]

In *Dominion Stores Ltd. v. R.*[261] (1979), agricultural 'grade' standards for apples labelled as "Extra Fancy" were rejected by the SCC to the extent that they impeded on purely intraprovincial transactions.[262] Estey J. stated: "I approach the issue raised in this appeal on the basis that the Parliament of Canada may not, in the guise of regulating trade and commerce, reach into the fields allocated to the provinces by s. 92(13) and (16) and regulate trading transactions occurring entirely within the provinces."[263]

In secondary commentary, *Saputo* has also been cited as a more unique and notable case of "Parliament successfully regulating an industry" at the federal and provincial court of appeal level.[264] Generally, there is a hesitation with the interprovincial and international branch as a source of federal regulatory power.[265] For example, the

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[259] *Labatt Breweries of Canada Ltd v (AG) Canada*, [1980] 1 SCR 914 [*Labatt Breweries*].

[260] *Ibid* at 941-942.

[261] [1980] 1 SCR 844.

[262] *Ibid* at 845, 864-65.

[263] *Ibid* at 855 [emphasis added].

[264] See Régimbald & Newman, *supra* note 239 at 314.

[265] See e.g. *ibid* at 297: ("the courts have tended to give the trade and commerce power a relatively narrow scope, especially in early cases decided by the Privy Council. Although the Supreme Court of Canada has to some degree defined the boundaries of the trade and commerce power and allowed its scope to broaden

branch has been compared to the scope of the US Commerce Clause[266] for the proposition that the US clause is a "chief source of congressional regulatory power" in contrast to the interprovincial and international trade branch.[267] Hogg & Wright have also stated that:

> Whenever a market for a product is national (or international) in size, as opposed to local, there is a strong argument that effective regulation of the market can only be national; and this is the position which has been effectively established in the United States. The Canadian decisions do not yet go that far.[268]

In summary and resting on *Saputo* alone, the interprovincial and international trade branch provides a highly tangential basis to support licensing of medical devices in relation to safety and effectiveness.

3.2.1.3. General Regulation Branch

The general regulation branch of the trade and commerce power provides an unlikely basis to support laws governing licensing of medical devices in relation to safety and effectiveness. One significant factor used to assess if a law falls within the scope of this branch is to determine if it was aimed at regulating one industry, sector or commodity.[269] Although this factor is not determinative, it negates the law's ability to

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relative to the Privy Council decisions, it is still often criticized for being too narrowly defined in modern constitutional jurisprudence.").

[266] *US Constitution*, art 1, §8, cl 3.

[267] See Mathen & Macklem, *et al*, eds, *supra* note 63 at 342, citing Laurence Tribe, *American Constitutional Law*, 3rd ed, vol 1 (New York: Foundation Press, 2000) at 808; in the US, federal regulation of adulterated and misbranded medical devices is premised on the US Commerce Clause, see *To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes*, (1938) Pub L No 75-717, 52 Stat 1040 (titles amended 21 USC: Food and Drugs); see also Lainie Rutkow & Jon S Vernick, "The US Constitution's Commerce Clause, the Supreme Court, and Public Health" (2011) 126:5 Public Health Reports 750 (discussing the US Commerce Clause as a major source of legislative power for public health.).

[268] Hogg & Wright, *supra* note 51, §20:3.

[269] See *AG (Can) v Can Nat Transportation, Ltd*, [1983] 2 SCR 206 at 268 [*Can Nat Transportation*].

stand in relation to this second branch of general regulation.[270] The general regulation branch usually requires laws to be aimed at trade in a broader sense beyond the regulation of an industry or commodity[271] (for e.g. competition legislation) to demonstrate that the matter is of national economic concern, and therefore does not infringe provincial jurisdiction over property and civil rights.[272]

In the most recent case where the SCC has on an exceptional basis permitted one type of commodity to be regulated under this branch, which was the regulation of securities commodities, the policy rationale behind its federal regulation must have been relevant to national economic interests relative to controlling systemic risks to capital markets and material adverse consequences to the economy as a whole.[273] As the licensing of medical devices in relation to safety and effectiveness focuses on one type of commodity (medical devices), this strongly suggests and is effectively determinative that it could not be upheld under the general regulation branch of s. 91(2) because of its lack of connection to systemic risks and national economic stability.

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[270] *Ibid*: ("the presence of such factors [including "a concern with trade in general rather than with an aspect of a particular business"] does at least make it far more probable that what is being addressed in a federal enactment is genuinely a national economic concern and not just a collection of local ones.").

[271] See *Labatt Breweries*, *supra* note 259 at 941-942.

[272] See *General Motors*, *supra* note 237 at 662-663: (upholding the *Combines Investigation Act* within the general regulation branch).

[273] See *Reference re Pan-Canadian Securities Regulation*, 2018 SCC 48 at para 87: ("the pith and substance of the Draft Federal Act is 'to control systemic risks having the potential to create material adverse effects on the Canadian economy' (para. 124). Indeed, we find that the Draft Federal Act's purpose, its structure and the limits it imposes upon the exercise of the Authority's delegated power all support the conclusion that it has this narrow objective.").

3.2.2. Peace, Order and Good Government Power

3.2.2.1. Introduction

The federal government's residuary p.o.g.g. power is derived from the preamble under s. 91, which states, "[i[t shall be lawful for the Queen, by and with the Advice and Consent of the Senate and House of Commons, to make Laws for the Peace, Order and good Government of Canada, in relation to all Matters not coming within the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces."[274] This power is comprised of three branches, which include the: gap branch,[275] national concern branch,[276] and emergency branch.[277] The following discusses each of these branches and seeks to determine the extent they may support a licensing law respecting medical devices in relation to safety and effectiveness.

3.2.2.2. "Gap" Branch

The "gap" branch is said to imply federal authority over matters that were not explicitly enumerated under the division of powers.[278] Hogg & Wright have explained the nature of the gap branch as applying in:

> limited and unusual cases, where the application of the p.o.g.g. power is almost logically required. In most cases a 'new' or hitherto unrecognised kind of law does not have any necessary or logical claim to come within p.o.g.g.. It might come within property and civil rights in the province (s. 92(13)) or matters of a merely local or private nature in the province (s. 92(16)). Which head of power is appropriate depends on the nature of the 'new' matter, and the scope which is attributed to the various competing heads of power of which p.o.g.g. is only one.[279]

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[274] *Constitution Act, 1867*, *supra* note 50, s 91.

[275] Hogg & Wright, *supra* note 51 at §17:2.

[276] *References re GGPPA*, *supra* note 61.

[277] *Reference re Anti-Inflation Act, 1975 (Canada)*, [1976] 2 SCR 373 [*Reference re Anti-Inflation*].

[278] Mathen & Macklem, *et al*, eds, *supra* note 63 at 279.

[279] Hogg & Wright, *supra* note 51 at §17:2.

The gap branch could not be used as a basis to support licensing of medical devices in relation to safety and effectiveness because the 'aspect' of licensing (safety and effectiveness) is not 'orphaned' under the division of powers. This matter can clearly fall into the criminal law power domain if requirements of valid criminal law are met. This matter further has 'double aspects' in the sense that medical device safety and effectiveness could be regulated under a provincial tort-based scheme[280] (beyond the criminal realm), which falls into provincial jurisdiction under matters of a local or private nature (s. 92(16)). It is difficult to conceive of another "aspect" of licensing medical devices in relation to safety and effectiveness that would not fall within the criminal law power (federal jurisdiction), or in provincial jurisdiction under property or civil rights, or matters of a local or private nature. The gap branch therefore is not triggered.

3.2.2.3. National Concern Branch

The SCC commented in *References re GGPPA* (2021) that the national concern branch is rarely applicable as a constitutional basis to support laws.[281] The first 'threshold' question to invoke this branch is to examine if the matter (licensing medical devices in relation to safety and effectiveness) is "of concern to Canada as a whole." [282] Although this question appears open-ended, it is expressly meant to discourage the use of this branch to constrain and limit its application as opposed to "open[ing] the door" for its

[280] As noted in Chapter 2 under common law nuisance.

[281] *References re GGPPA*, *supra* note 61 at paras 4: ("National concern is a well-established but rarely applied doctrine of Canadian constitutional law. The application of this doctrine is strictly limited in order to maintain the autonomy of the provinces and respect the diversity of Confederation, as is required by the principle of federalism."); see also at para 142.

[282] *Ibid* at para 142-43.

use.[283] Even with this backstop principle in mind, one could argue that licensing medical devices in relation to safety and effectiveness is generally of concern to Canada given the importance that safe and effective medical devices play on population health. However, for context, even 'arms trafficking' was not described by the majority as dispositive as a matter of concern to Canada as a whole.[284]

Assuming the threshold question were to be answered positively to warrant further consideration, the analysis is highly unlikely to advance beyond the second stage of the inquiry, which necessitates that the matter meet the principle of "singleness, distinctiveness and indivisibility."[285] One of the core requirements is that the matter be "predominantly extraprovincial" in effect or nature,[286] such as marine pollution (distinguishable from freshwater pollution),[287] atomic energy that could pose "catastrophic interprovincial harm,"[288] or greenhouse gas emissions ("GHG") that contribute to climate change and pose systemic risks, including existential threats to human life.[289]

The federal government would also need to have evidence of "grave" extraprovincial consequences if one province failed to act on the matter, for example, a serious risk of harm.[290] If one province failed to act to provide assurance of medical device safety and effectiveness, any harm resulting because of one province's failure to

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[283] *Ibid* at para 144.

[284] *Ibid* at para 154 (the matter was described as having the "potential" to meet this threshold).

[285] *Ibid* at para 145.

[286] *Ibid* at para 148.

[287] *R v Crown Zellerbach Canada Ltd*, [1988] 1 SCR 401 at para 38.

[288] *Ontario Hydro v Ontario (Labour Relations Board)*, [1993] 3 SCR 327.

[289] *References re GGPPA*, *supra* note 61 at para 171.

[290] *Ibid* at para 153.

implement a licensing system is very unlikely to meet the threshold of "grave" extraprovincial consequences. Unsafe or ineffective medical devices is not a matter that could be described as having extraprovincial effects compared to marine pollution, atomic energy, or GHG emissions. Harms that stem from unsafe or ineffective medical devices occur within patients, and do not generally dispel interprovincially (or internationally).

To further satisfy the principle of 'singleness, distinctiveness and indivisibility,' evidence beyond "conjecture"[291] must demonstrate that one or more of the provinces (alone or together) are incapable of dealing with the matter of licensing medical devices in relation to safety and effectiveness, which is a high threshold to meet (the 'provincial inability' test).[292] The quantitative nature or sheer growth of a problem is considered insufficient to establish provincial inability.[293] In *References re GGPPA* (2021), Wagner CJ. for the majority expressly affirmed Dickson J.'s statement (prior to CJ.) in *Wetmore* (1983) (dissenting, but not on this point) that the regulation of the pharmaceutical industry[294] was not a matter of national concern because it failed on the 'provincial inability' test.[295] Wagner CJ. affirmed Dickson J.'s statement that logistical or financial difficulties do not meet the threshold of provincial inability.[296] The Court's most recent affirmation of Dickson J.'s analysis in *Wetmore* provides substantial support that the

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[291] *Ibid* at para 133.

[292] *Ibid* at para 146.

[293] *Ibid* at para 147.

[294] In *Wetmore*, *supra* note 69, the matter directly concerned the safety and effectiveness of drugs and their labelling rather than the 'pharmaceutical industry' at large.

[295] *References re GGPPA*, *supra* note 61 at para 104: "*R. v. Wetmore*, [1983] 2 S.C.R. 284, in which Dickson J., dissenting but not on this point, rejected regulation of the pharmaceutical industry as a matter of national concern. Dickson J. referred both to Beetz J.'s framework and to Professor Hogg's formulation of the provincial inability test, and concluded that the matter failed to meet both standards: p. 296.").

[296] *References re GGPPA*, *ibid* at para 155.

medical device industry, and by extension the licensing of medical devices in relation to safety and effectiveness, is not a matter of national concern because it would not pass the provincial inability test.

It is relevant to note that in the US, which is similar to Canada socioeconomically, Congress enacted a federal pre-emption clause as briefly discussed in Chapter 2 for purposes of replacing state premarket approval systems with one federal premarket approval system for medical devices.[297] These state law systems existed prior to federal regulation of medical devices in the US.[298] It seems unlikely therefore that the federal government would be able to provide evidence that provinces alone or together are incapable of implementing a market authorization scheme for medical device safety and effectiveness.

In sum, the national concern branch does not provide a realistic basis to support a market authorization scheme for medical device safety and effectiveness because of the high threshold that has been established to limit its use to exceptional matters that inherently transcend provincial jurisdiction,[299] such as marine pollution, atomic energy or GHG emissions.

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[297] *Riegel*, *supra* note 204 at 1018, n 14 [Ginsburg J dissenting]: ("Thus Congress sought not to terminate all state premarket approval systems, but rather to place those systems under the controlling authority of the FDA.").

[298] See *ibid* at 1018 [Ginsburg J dissenting, but not on this finding (quoting)]:

> "In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires pre-market approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices. Implementation of the Sherman Law has resulted in the *requirement* that intrauterine devices are subject to premarket clearance in California." H.R.Rep. No. 94–853, p. 45 (emphasis added).

[299] *References re GGPPA*, *supra* note 61 at para 166.

3.2.2.4. Emergency Branch

General licensing of medical devices in relation to safety and effectiveness could not be classified under the 'emergency branch' because laws must be temporary in nature.[300] General federal medical device laws related to the verification of a medical device's safety and effectiveness are not temporary. If a law, however, permitted medical devices to quickly enter the market through an emergency use authorization to control a pandemic, this law, or orders issued under it (an 'act') could be based under this branch,[301] and likely with substantial judicial deference on how federal authority governing emergency-use medical devices may operate. For example, less rigorous safety and effectiveness requirements to facilitate a medical device's rapid market entry to ameliorate an emergency is likely to be seen as reasonable.

3.2.3. Conclusion

Apart from the interprovincial and international trade branch of the trade and commerce power that in a highly tentative sense may support licensing of medical devices in relation to safety and effectiveness, all other federal powers and related branches are improbable as a constitutional basis to support this matter based on modern jurisprudence. If the interprovincial and international trade branch was accepted as a basis for this matter's support, the federal government would likely need to define objective criteria to evaluate safety and effectiveness in the licensing of medical devices based on *Saputo* (2011, FCA).

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[300] *Reference re Anti-Inflation*, *supra* note 277 at 427; see Hogg & Wright, *supra* note 51 at §17:11.

[301] See e.g. *F&D Act*, *supra* note 1 ss 30.1(1)-(2) (Interim Orders); see also *MDRs*, *supra* note 1 Part 2.

The federal government, however, is likely dependent on the criminal law power to support licensing of medical devices in relation to safety and effectiveness. The following section reviews the scope of the criminal law power to understand factors that a licensing scheme for medical devices in relation to safety and effectiveness would need to reflect to be upheld under this power.

3.3. Scope of the Criminal Law Power

3.3.1. Introduction

Laws that are valid under the criminal law power have three central components with limited exceptions:[302] 1) a prohibition, 2) backed with a penal sanction, and which is directed towards 3) a valid criminal law purpose.[303] The prohibition and penalty requirements are said to constitute the technical or formal components of valid criminal law, while the criminal law purpose requirement is considered the substantive component. These categories are, however, not watertight. As the discussion below will explain, fulfilling the 'prohibition' requirement is related to the substantive requirement (a valid criminal law purpose). Similarly, the severity of a penalty is also relevant to assess if the substantive requirement was met. Therefore, the criminal law purpose requirement acts as an 'umbrella' concern when analyzing the adequacy of the prohibition and penal sanction.[304] The valid criminal law purpose requirement is first

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[302] For example, a valid criminal law could repeal a criminal law, which would not have a prohibition backed with a penalty, see *Quebec (AG) v Canada (AG)*, 2015 SCC 14 at para 43 [*Quebec (AG)*]: ("the repeal of criminal provisions constitutes a valid exercise of the criminal law power").

[303] *Reference re Margarine*, *supra* note 52 at para 142.

[304] See generally *Morgentaler* (1993), *supra* note 62 at 489: ("The presence or absence of a criminal public purpose or object is thus pivotal"), citing *Lord's Day Alliance of Canada v Attorney General of British Columbia*, [1959] SCR 497 at 508-09; *Goodyear Tire and Rubber Co. of Canada v The Queen*, [1956] SCR 303 at 313; and *Boggs v The Queen*, [1981] 1 SCR 49) [*Boggs*].

discussed below, which is followed by an explanation of the prohibition and penal sanction requirements.

3.3.2. Criminal Law Purpose

Two requirements must be met for a court to find that an enacting body (a legislature or the executive branch of government) acted in relation to a valid criminal law purpose:[305] "target[ing] an evil, injurious or undesirable effect"[306] on a "public interest that can properly ground criminal law, or another similar public interest"[307] such as "peace, order, security, health and morality."[308] The key focus in determining whether a law is valid under the criminal law power revolves around assessing if the federal government enacted a law (or promulgated regulations, etc.), with the dominant purpose of targeting "evil, injurious or undesirable effect[s]," in the sense of "suppress[ing] the evil or… safeguard[ing] the interest threatened."[309]

A law that has a dominant purpose to promote health will not meet the criminal law purpose requirement. Health promotion can only amount to a secondary purpose or an incidental effect of an otherwise valid law that seeks to suppress threatened interests. As Karakatsanis J. explained in *Reference re GNDA*: "[t]he relevant question is whether the law meets the criminal law purpose test — whether, in pith and substance, it responds to a risk of harm to health. If it does, the possibility that the law will also produce

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[305] *Reference re GNDA*, *supra* note 60 at para 74 [Karakatsanis J].

[306] *Ibid*.

[307] *Ibid* at para 68.

[308] *Ibid* at para 74.

[309] *Reference re Margarine*, *supra* note 52 at 49.

beneficial health effects does not negate that conclusion."[310] The dissent written by Kasirer J. was also consistent with the forming majority's point: "The appellant argues that, in this case, the protection and promotion of health is a valid criminal law purpose….this Court has never accepted that it is sufficient for the impugned provisions' pith and substance to merely relate to health."[311]

In *R. v. Swain* (1991),[312] the majority similarly emphasized that the criminal law power does not permit the federal government to enact laws or promulgate regulations related to assuring access to medical treatment.[313] The majority stated that "[w]hile treatment or cure of the individual may be incidentally achieved, this consideration is secondary and simply a means to achieving the ends of protection and prevention."[314]

A market authorization scheme that attests to a medical device's safety and effectiveness with vague scientific evidence requirements, i.e., without explicit requirements for reliable scientific evidence, could be characterized as a law that promotes health by enabling faster market access through non-rigorous scientific evidence requirements. In the US, for example, it has been stated that: "[c]onsumers, manufacturers, and Congress constantly pressure the FDA to tip the scales in favor of permitting innovation and access, often at risk of compromising its mission of assuring device safety."[315]

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[310] *Reference re GNDA*, *supra* note 60 at para 101[emphasis added] (the contention that the criminal law power cannot be used to promote health, apart from secondary purposes/incidental effects, was fully unanimous; see paras 131 (Moldaver J), 238 (Kasirer J dissenting, but not on this point).

[311] *Ibid*, at para 238.

[312] [1991] 1 SCR 933 [*Swain*].

[313] *Ibid* at paras 112-13.

[314] *Ibid* at para 108.

[315] George Horvath, "Trading Safety for Innovation and Access: An Empirical Evaluation of the FDA's Premarket Approval Process" (2017) 5 BYU L Rev 991 at 1017; see relatedly Laura E Bothwell, *et al*, "Assessing the Gold Standard — Lessons from the History of RCTs" (2016) 374:22 New England J

Absence of explicit requirements for reliable scientific evidence may also be susceptible to a colourable characterization, which refers to a situation where a "legislature [or regulator] attempts to enact a law outside the scope of its authority but frames the statute in such a way that it appears to fall under one of the legislature's designated heads of power."[316] A law therefore appears superficially to adhere to a government's enumerated powers.[317] For example, the absence of explicit requirements for reliable scientific evidence increases the probability that a licensing scheme is meant to promote economic interests of the medical device industry. This objective may be achieved by reducing explicit expectations and requirements for rigorous scientific evidence that impose greater costs on the industry, while at the same time providing the industry with a "certificate" (licence or order) that attests to a medical device's purported safety and effectiveness.[318] This characterization appears to advance industry interests by promoting consumer confidence in the safety and effectiveness of medical devices at the expense of suppressing harm from threatened interests caused by unreliably tested medical devices. To define the dominant purpose of vague scientific evidence requirements for safety and effectiveness as laws that are meant to suppress harm from threatened interests may be facile.

Medicine 2175 at 2177 ("rapid" developments in technology are used to justify less rigorous and time-intensive methodological standards; however as Bothwell *et al* point out, this rationale assumes changes in technology are superior to existing products comparable to the "Red Queen" effect in evolutionary biology where things are in a race to keep mutating, but not in a way that necessarily yields an evolutionary advantage.).

[316] Régimbald & Newman, *supra* note 239 at 185.

[317] *Ibid*.

[318] See generally Horvath, *supra* note 315; ICIJ, "Medical Devices Harm Patients Worldwide", *supra* note 4: ("A global investigation reveals the rising human toll of lax controls and testing standards pushed by a booming industry."); see also Larry Husten, "WSJ Attack on Sham Surgery is About Healthy Profits, Not Patients" *Forbes* (20 February 2014), online: <https://www.forbes.com/sites/larry husten/2014/02/20/wall-street-journal-op-ed-on-sham-surgery-gets-it-wrong/?sh=47bcc6a74eb2>.

In summary, if the federal government seeks to issue licences for medical devices in relation to safety and effectiveness, there must be objective methodological criteria to attest to safety and effectiveness, otherwise the law is open to a dominant purpose characterization that does not relate to a valid criminal law purpose. The integration of rigorous methodological safety and effectiveness requirements may be necessary to demonstrate a valid criminal law purpose by conveying assurances that substantial efforts to accurately assess safety and effectiveness were made to suppress public harm.

3.3.3. Requirement for a Valid Prohibition

3.3.3.1. Introduction

Conventionally, a valid criminal law is one that prohibits conduct in absolute form (without exceptions), such as prohibiting gun ownership in its entirety. However, courts have recognized that a law may still be valid under the criminal law power if it departs from an absolute prohibition, and instead regulates conduct. For example, a government could control gun ownership through a market authorization scheme whereby a person must obtain a licence and meet certain terms and conditions to own a gun.[319] As long as the criminal law purpose is evident, the form of the law (controlling conduct rather than absolute prohibitions) is likely to be valid.

However, the more a legal scheme departs from the conventional 'absolute prohibition' standard, and instead controls or 'regulates' conduct through various terms, conditions and exceptions, especially through highly discretionary schemes, the more

[319] See *Reference re Firearms* (SCC), *supra* note 50 (controlling gun ownership through a licensing regime rather than absolutely prohibiting gun ownership); see also, for e.g. *RJR-MacDonald*, *supra* note 224 (controlling tobacco use through restrictions on tobacco advertising rather than absolutely prohibiting tobacco) use; *Canada (Procureure générale) c Hydro-Québec*, [1997] 3 SCR 213 [*Hydro-Québec*] (controlling toxic substances rather than absolutely prohibiting toxic substances).

vulnerable it is to being scrutinized on the basis of failing to meet the valid criminal law prohibition (and effectively purpose) requirement.[320]

In these more 'regulatory' environments (licensing of firearms[321] or controlling the release of toxic substances into the environment,[322] and, in this case, the licensing of medical devices in relation to safety and effectiveness), courts will often use the language of determining whether the legal scheme is sufficiently "criminal" or more "regulatory" in nature, and hence invalid under the criminal law power. Given that detailed and complex legal regimes may still be valid as criminal law, this section explains the SCC's concerns with controlled and/or discretionary licensing schemes as it affects their validity under the criminal law power.

The jurisprudence reveals two distinct concerns regarding whether a provision will be characterized as 'criminal' or more 'regulatory' in nature. First, a law may be 'regulatory' rather than 'criminal' because it imposes a licensing scheme for an aim unrelated to a valid criminal law purpose, which means that courts are concerned that the law's dominant purpose is not definable as the suppression of harmful conduct (targeting evil, injurious or undesirable effects on public interests, such as health, safety, or economic interests). In this case, Parliament is using the technical form of the criminal law to regulate a matter without the rationale of the law being premised on a valid criminal law purpose.

Second, a law may be deemed 'regulatory' as opposed to 'criminal' if Parliament permits the executive branch of government to substantially define all terms, conditions

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[320] See *infra*.

[321] See *Reference re Firearms* (SCC), *supra* note 50.

[322] See *Hydro-Québec*, *supra* note 319.

and exemptions for licensing, which could enable unconstitutional effects in the making of regulations or administrative actions, i.e., it is overly discretionary. The concern in this second category is not necessarily that Parliament does not have a valid criminal law purpose, but instead appears to be about the concern of enabling *ultra vires* actions that fail to be premised on a valid criminal law purpose. The following sections elaborate on each of these streams relevant to the 'prohibition' requirement and analysis.

3.3.3.2. Prohibitions with "Regulatory" Rather than Criminal Objectives

In respect to the first category of concern that relates to Parliament having regulatory objectives is that a law that controls conduct (for e.g. with licences) does not in its dominant purpose necessarily suppress harmful conduct, i.e., target evil, injurious or undesirable effects on a public interest.[323] The valid criminal law purpose requirement is therefore carried over to the analysis of a valid prohibition requirement. The following cases illustrate where controlled conduct was found to have regulatory rather than criminal objectives: *Ontario (AG) v. Reciprocal Insurers* (1924),[324] *Labatt Breweries of Canada Ltd. v. Canada (AG)* (1979),[325] and *Reference re Assisted Human Reproduction Act* (2010).[326]

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[323] See Chapter 6 for a potential example of this issue related to the dominant purpose of the *ATPAs*.

[324] [1924] AC 328 (PC) [*Reciprocal Insurers*].

[325] *Labatt Breweries*, *supra* note 259.

[326] *Reference Re Assisted Human Reproduction* Act*,* 2010 SCC 61 [*Reference re AHRA*]: (these cases comprised the discussion of the 'regulatory' question concerning the scope of s 91(27), barring *Boggs*, *supra* note 304, which is not relevant in respect to licensing, in *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17 (Factum of the Appellant at paras 42-45 [FOA]), online: <www.scc-csc.ca/WebDocuments-DocumentsWeb/38478 /FM010_Appellant_Canadian-Coalition-for-Genetic-Fairness.pdf>).

In *Reciprocal Insurers* (1924), the Court found that the pith and substance of the then-s. 508 of the *Criminal Code*[327] was to ensure compulsory compliance with a federal statutory-based licensing scheme that broadly regulated the insurance industry.[328] The Court concluded that while s. 508 was valid in technical form under s. 91(27) because it imposed an indictable penalty for the failure to seek a licence in carrying on the business of insurance, it was invalid in substance because the licensing scheme had not demonstrated a clear connection to a valid criminal law purpose.[329]

In *Labatt Breweries* (1979), Estey J., writing for the majority, found that regulations enabled under the *Food & Drugs Act*, RSC 1970 that required beer labelled as "light" to contain a maximum alcohol content was unsupported by a valid criminal law purpose. The "main purpose [of the required alcohol content] is the regulation of the brewing process itself by means of a 'legal recipe.'"[330] The regulation for this alcohol content could not be construed on its face to relate to health,[331] and could not be connected with the criminally valid concept of preventing "adulteration" in beer.[332] The regulations were framed as relevant only to the "the detailed regulation of the brewing industry in the production and sale of its product [and were not a] proper exercise of the federal authority in criminal law."[333]

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[327] *Criminal Code*, RSC 1985, c C-46.

[328] *Reciprocal Insurers*, *supra* note 324.

[329] *Ibid* at 792, 797.

[330] *Labatt Breweries*, *supra* note 259 at 916.

[331] *Ibid*, at 934-35.

[332] *Ibid* at 934.

[333] *Ibid*.

In *Reference re AHRA* (2010),[334] LeBel and Deschamps JJ. (Abella & Rothstein JJ. concurring) characterized controlled prohibitions over research and the clinical application of assisted human reproductive technologies under the *Assisted Human Reproduction Act*[335] as "a specious attempt to exercise its criminal law power by merely juxtaposing provisions falling within provincial jurisdiction with others that in fact relate to the criminal law."[336] They further noted that: "the recourse to a regulatory scheme with penalties appears to suggest that Parliament chose to emphasize the form of the Act, in full knowledge of the weakness of its position as regards the substance."[337]

Cromwell J. alone characterized the controlled 'regulatory' activities as the "regulation of virtually all aspects of research and clinical practice in relation to assisted human reproduction."[338] Cromwell's J. found that the text of the law conferred "sweep[ing]" powers to the Governor in Council under s. 65,[339] and to the Assisted Human Reproduction Agency of Canada under s. 40 to issue licences at its discretion for the controlled activities, and with any terms and conditions it sought to attach. Cromwell J. noted that:

> the essence of the legislation goes beyond that proposed by Justices LeBel and Deschamps. As I see it, the purpose and effects of the challenged provisions are not limited, as they would hold, to 'the regulation of assisted human reproduction as a health service' (para. 227); the regulation authorized by the impugned provisions goes far beyond that.[340]

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[334] *Reference re AHRA*, *supra* note 326.

[335] *Assisted Human Reproduction Act*, SC 2004, c 2.

[336] *Reference re AHRA, supra* note 326 at para 278, citing *Scowby v Glendinning*, [1986] 2 SCR 226.

[337] *Reference re AHRA*, *ibid*; see also at para 271.

[338] *Ibid* at para 283.

[339] *Ibid* at para 285.

[340] *Ibid* at para 286.

Courts have therefore raised questions about whether Parliament's objective for controlling conduct was premised on a criminal law purpose. If conduct is 'controlled' by Parliament, such as the licensing of medical devices in relation to their safety and effectiveness, the courts may scrutinize the scientific evidence requirements to determine if this 'control' sufficiently addresses a criminal law purpose. If scientific evidence requirements ('controls') are unreliable to validate safety and effectiveness (expectations or requirements for methodologically reliable forms of scientific evidence are absent), this may compromise the ability of these laws to be perceived as being premised on a valid criminal law purpose. In other words, scientific evidence requirements that are lenient may amount to a "legal recipe" to obtain a market entry authorization, or relatedly they may be perceived as *pro forma*-like requirements to obtain market entry regardless of the evidentiary reliability of the safety and effectiveness evidence.

3.3.3.3. Broad Delegations of Power and Unconstitutional Effects

A law that extends a broad delegation of power to the executive branch of government (Governor in Council or relevant Minister) that permits it to discretionarily define controlled or prohibited conduct without Parliamentary oversight could be invalid because it may enable *ultra vires* laws (or actions) that are not for the purpose of suppressing harm. As Dickson CJ. and Lamer J. (prior to CJ.) noted for the majority in *R. v. Morgentaler* (1988),"[e]ven if the purpose of legislation is unobjectionable, the administrative procedures created by law to bring that purpose into operation may produce unconstitutional effects, and the legislation should then be struck down."[341] For example, a broad delegation of power to the executive branch of government that permits

[341] *R v Morgentaler*, [1988] 1 SCR 30 at 62.

it to define controlled conduct in relation to the market entry of medical devices could enable what may be *ultra vires* vague and lax scientific evidence requirements assuming their dependency on the criminal law power.

The following criminal law power cases, *Labatt Breweries* (1979), *Canada (Procureure générale) c. Hydro-Québec* (1998)[342] and *Reference re Firearms Act (Canada)* (2000),[343] support the position that Parliament may be limited, if acting under the criminal law power, from delegating the responsibility to define prohibitions to the executive branch of government because of concerns over enabling *ultra vires* effects.

The concern over broad delegations of power that could enable *ultra vires* effects (actions or regulations) seemed to have been implied first in *Labatt Breweries* (1979). Estey J., for the majority, found s. 25(1)(c) of the *F&D Act*, which authorized the executive branch of government to promulgate regulations and permitted them to define standards over light beer, *ultra vires* insofar as it applied to malt liquor because the delegation of law-making power (equivalent to "regulation-enabling" power) was untailored to a valid criminal law purpose.[344] In respect to the law-making power under the *F&D Act*, Estey J. observed:

> Under the authority of s. 25(1)(c), there has been produced an elaborate set of regulations…We are here concerned principally with Pt. B of the Food and Drug Regulations…. It may be observed that s. 6 was introduced into the Act in 1953 [1952-53, c. 38] and s. 25(1)(c) was expanded at the same time to its present form. Prior to that time, the statute was concerned with the adulteration of food, misbranding, the offering of food or drugs for sale as treatment for specified diseases,… Regulation B.01.042 illustrates the detailed reach of this regulatory pattern.[345]

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[342] *Hydro-Québec*, *supra* note 319.

[343] *Reference re Firearms* (SCC), *supra* note 50.

[344] *Labatt Breweries*, *supra* note 259 at 947.

[345] *Ibid* at 931-32 [emphasis added].

Laskin CJ. in dissent similarly observed a "complete revamping of the Food and Drugs Act, 1920 (Can.), c. 27."[346] He pointed out that the removal of the adulteration and misbranding offences under the *Food and Drugs Act* 1952-53 affected the characterization of the *Act* as being in relation to protecting the public from injurious or deceptive products: "[w]hereas the predecessor Act was limited to protection of the public against adulteration and misbranding, the new Act more clearly addressed itself, by the regulation-making power conferred under s. 25 upon the Governor in Council, to standards of strength and quality as well as labelling."[347] Both Estey J. for the majority and Laskin CJ. implied that broad delegations of law-making power may be unconnected to a valid criminal law purpose (suppression of harm, i.e., the targeting of evil, injurious or undesirable effects).

Concerns over broad delegations of power to the executive branch of government under the criminal law power arose again more clearly in *Hydro-Québec* (1998).[348] The case began with the dissenting decision followed by the majority judgment. As this concern was originally raised by the dissent and was affirmed by the majority, the dissenting opinion is first discussed. Specifically, the majority addressed the dissent's concerns and affirmed them in principle while ultimately departing in the application of these 'unconstitutional effects concerns' based on the facts. The majority's departure from the dissent was based on the finding of fact that the executive branch of government's discretion was sufficiently tailored under the impugned statute.

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[346] *Ibid* at 920.

[347] *Ibid*.

[348] *Hydro-Québec*, *supra* note 319.

At issue in *Hydro-Québec* was the constitutionality of the *Canadian Environmental Protection Act*[349] in its entirety. One issue was whether the legislation was valid under s. 91(27). The dissent noted that while the *Act* had a valid criminal law purpose,[350] it faltered under s. 91(27) because of an insufficient "prohibition." The four-party dissent, written by Lamer CJ. and Iacobucci J., stated this was caused by ss. 34 and 35 that extended significant discretion to the Governor in Council and Ministers of the Environment and Health that permitted them to determine prohibitions related to the control of toxic substances.[351] While the dissent acknowledged that a scheme may still be valid under s. 91(27) if it "confer[s] a measure of discretionary authority",[352] the entirety of the *Act* crossed over into the "essential regulatory" category through what was perceived as extensive discretion and delegation that permitted the executive branch of government to define prohibitions:

> In this case, there is no offence until an administrative agency "intervenes". Sections 34 and 35 do not define an offence at all: which, if any, substances will be placed on the List of Toxic Substances, as well as the norms of conduct regarding these substances, are to be defined on an on-going basis by the Ministers of Health and the Environment. It would be an odd crime whose definition was made entirely dependent on the discretion of the Executive. This further suggests that the Act's true nature is regulatory, not criminal,…[353]

The majority written by La Forest J. agreed in principle that if legislation provided the Governor in Council or federal Ministers with extensive discretion to define the scope of the criminal prohibition, then broad discretionary language could make a law

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[349] *Canadian Environmental Protection Act*, RSC, 1985, c 16 (4th Supp).

[350] *Hydro-Québec*, *supra* note 319 at para 44: (the broad ecological protection of the environment).

[351] *Ibid* at paras 34 and 35.

[352] *Ibid* at para 47.

[353] *Ibid* at para 55.

invalid based on it enabling *ultra vires* effects: "the attack here ultimately is that the impugned provisions grant such a broad discretion to the Governor in Council as to permit orders that go beyond federal power. I can imagine very nice issues being raised concerning this matter under certain types of legislation."[354]

The majority was therefore receptive to the concerns raised by the dissent in respect to the compatibility of broad enabling-powers in primary legislation that may enable *ultra vires* decision-making. The majority explicitly affirmed: "tailoring [of discretion] is obviously necessary in defining the scope of a criminal prohibition."[355] Applying this reasoning to the facts of the *Act*, La Forest J. found the executive branch of government's discretion was "carefully tailor[ed]."[356] For example, one of the factors that helped to validate the *Act* under the criminal law power was that it had a primary legislative (Parliament-defined) procedure to test for toxic substances: "[i]t is important to underline that what Part II of the Act provides for is a procedure to control toxic substances generally by subjecting the many chemical substances in use in Canada to testing."[357] This case generally stands for the proposition that tailoring of the executive branch of government's discretion is "necessary"[358] for laws to conform to requirements under the criminal law power.

In *Reference re Firearms Act (Canada)*, (2000) (ABCA), the Attorney General of Alberta argued that a federal statute attempted to regulate all aspects of firearm usage.[359]

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[354] *Ibid* at para 130.

[355] *Ibid* at para 151.

[356] *Ibid*; see also paras 141-42.

[357] *Ibid* at para 144.

[358] *Ibid* at para 151.

[359] *Reference re Firearms Act*, 1998 ABCA 306 at para 251 [*Reference re Firearms* (ABCA)].

At the Court of Appeal of Alberta, Fraser CJ. addressed the submission that the federal government had "crossed the legislative divide by imposing a discretionary regulatory scheme."[360] However, Fraser CJ. did not perceive the scheme as extending undue discretion to the executive branch of government or a public administrator: "[m]ore significantly, Parliament has clearly defined the scope and content of the offences here. No administrative officer has been delegated this responsibility."[361] Moreover, the duties and prohibitions were clearly defined by Parliamentarians in primary legislation: "having a firearm in one's possession knowingly without a licence and without a registration certificate is an indictable offence."[362] The exemptions from licensing were also provided substantively in the statute with significant detail:

> Moreover, there are precise and limited exemptions from the general prohibitions, both in substance and time. The exemptions are carefully designed so as not to undercut the seriousness, scope and effect of the prohibitions.[363]
>
> There are two exceptions to the general overall requirements that warrant mention. One is for hunters from other countries. The licensing and registration requirements do not apply to them. However, there are still limits imposed. A person in this situation cannot remain in the country with his guns for more than 60 days (s. 36 of the Act).[364]

While the comment was made that Parliament can further delegate the prohibitions or exemptions related to licensing to "refine and define"[365] them through the regulatory process, this remark was made in the context of the prohibitions and the exemptions related to licensing already being considerably precise in primary legislation. Fraser CJ.

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[360] *Ibid* at para 249.

[361] *Ibid* at para 264.

[362] *Ibid* at para 258.

[363] *Ibid* at para 260.

[364] *Ibid* at para 261.

[365] *Ibid* at para 265.

further remarked that "the regulatory requirements are also designed to ensure that the general prohibitions can be, and will be, effectively enforced."[366]

The concerns raised at the ABCA were reflected at the SCC. The unanimous decision written by the "The Court" also found that the executive branch of government's discretion was substantially limited by various controls in primary legislation: the prohibition was explicitly clear;[367] the statute itself provided the eligibility criteria to hold a licence; an administrative refusal to register a firearm must have been based on a standard of a "good and sufficient reason";[368] and ultimately the discretion was explicitly subject to judicial review, which emphasized a concern by Parliament for accountability within the executive branch of government:

> [t]he offences are not defined by an administrative body, avoiding the difficulty identified in the dissenting judgment in *Hydro-Québec*, *supra*. They are clearly stated in the Act and the Criminal Code….Eligibility to hold a licence is delineated in the rest of the Act….These provisions demonstrate that the Act does not give the chief firearms officer or the Registrar undue discretion. Furthermore, the chief firearms officer and the Registrar are explicitly subject to the supervision of the courts.[369]

For further context, ss. 5 to 16 and 54 to 73 of the impugned *Firearms Act* (point-in-time)[370] described the process for the issuance of "licences, registration certificates and authorizations under which persons may possess firearms in circumstances that would otherwise constitute an offence under subsection 91(1), 92(1), 93(1) or 95(1) of the

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[366] *Ibid* at para 263.

[367] *Reference re Firearms* (SCC), *supra* note 50 at para 37.

[368] *Ibid*.

[369] *Ibid* [emphasis added].

[370] *An act respecting firearms and other weapons*, SC 1995, c 39 online: https://heinonline-org.ezproxy.library.dal.ca/HOL/Page?handle=hein.ssl/sscan0017&id=145&collection=caotp&index=ssl/sscan> [*Firearms Act*].

Criminal Code"[371] as well as licences or authorizations respecting weapons and cross-bows.[372]

Eligibility to hold a licence (i.e., terms and conditions) was detailed extensively in primary legislation. For example, the *Act* established criteria to guide the chief firearms officer to assess a person's behavioural eligibility to hold a licence (regard to whether a person was convicted or discharged of certain criminal offences under the *Criminal Code*[373] and regard to a history of mental illness).[374] Beyond this specific criteria to guide the chief firearms officer's discretion, the *Act* established detailed requirements necessary to obtain a licence, such as the successful completion of a Canadian Firearms Safety Course.[375]

As Keyes states, "the firearms provisions came within the criminal law power because the main elements of the prohibited conduct were stated in the enabling legislation (i.e., primary legislation)."[376] While the *Act* incorporated some degree of administrative discretion (assessment of behaviour as eligibility criteria), as noted non-discretionary criteria was also delineated. Keyes states that the "*Firearms Reference* test for regulatory provisions leaves scope for debate about where the line is to be drawn in distinguishing them from prohibitive provisions."[377] As a basic principle, however, it appears that licensing conditions must generally be defined in primary legislation as

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[371] *Ibid*, s 4(a)(i).
[372] *Ibid*, ss 4(a)(ii)-(iii).
[373] *Ibid*, ss 5(2)(a)(i)-(iv).
[374] *Ibid*, ss 5(2)(b).
[375] *Ibid*, ss 7(1)(a).
[376] Keyes, 3rd ed (2021), *supra* note 53 at 95.
[377] *Ibid* at 96.

opposed to licensing or major conditions of licensing being delegated in their near totality to the discretion of the executive branch of government.

Keyes cites the factors or "test"[378] in *Reference re Firearms* (SCC) (2000) as 'good law' that has not been overruled in the two major subsequent criminal law power cases, *Reference re AHRA* (2010) and *Reference re GNDA* (2021).[379] In sum, *Labatt Breweries* (1979), *Hydro-Québec* (1998), *Reference re Firearms* (SCC) (2000) demonstrate that extensive discretion to define the scope of a prohibition (such as prohibitions in relation to licensing) can result in a provision that is invalid because its effects can enable *ultra vires* actions in the executive branch of government.

Recognizing limitations on delegation and discretion to define prohibitions under s. 91(27) also integrates unwritten constitutional principles that inform the scope of powers, which are the rule of law and constitutionalism.[380] The rule of law conveys, among other things, "a sense of orderliness, of subjection to known legal rules and of executive accountability to legal authority."[381] Constitutionalism, like the rule of law, requires that all government actions including the actions of the executive branch of government, comply with the Constitution.[382]

3.3.4. Requirement for a Penal Sanction

A valid penal sanction (backing the prohibition) requires a fine or imprisonment to meet the technical components of valid criminal law. The severity of the fine or the

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[378] *Ibid*.

[379] *Reference re GNDA*, *supra* note 60.

[380] *Reference re Secession*, *supra* note 220 at para 52: ("[t]he principles assist in the interpretation of the text and the delineation of spheres of jurisdiction, the scope of rights and obligations, and the role of our political institutions.").

[381] *Ibid* at para 70, citation omitted [emphasis added].

[382] *Ibid* at para 72.

maximum imprisonment terms can be of weight in the overall evidence to determine if a law targets a valid criminal law purpose.[383] However, severe penalties cannot transform a law that does not have a valid criminal law purpose into a valid criminal law.[384]

3.4. Conclusion

Chapter 3 examined the extent to which the federal government may be dependent on the criminal law power to support licensing of medical devices in relation to their safety and effectiveness. The trade and commerce and p.o.g.g. powers were analyzed to understand if their scopes may support this type of licensing scheme at a broad conceptual level. The only relevant power that may support this type of licensing scheme is the interprovincial and international trade branch under the trade and commerce power. However, this branch remains highly tangential based on presiding SCC case law and secondary commentary.

This chapter also described the requirements of valid criminal law. These requirements include the need for a law's dominant purpose to clearly relate to targeting evil, injurious or undesirable effects (suppression of harm). Scientific evidence requirements that are highly discretionary may not meet this threshold. Additionally, there is a likely need for Parliament to limit the extent of delegation and discretion to the executive branch of government in respect to defining conditions of licensing for medical devices in relation to safety and effectiveness. These two broad factors define the core scope of federal authority over licensing of medical devices in relation to safety and effectiveness.

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[383] See *Morgentaler* (1993), *supra* note 62 at 511-12.

[384] *Reference re Firearms* (ABCA), *supra* note 359 at para 258.

Chapter 4 will describe the legal process (methodology) to examine the dominant purpose of an impugned law and will explain how the dominant purpose of a law is classified under a subject matter under the division of powers (ss. 91 and 92). The framework in Chapter 4 centers the analysis in Chapters 5 and 6, which attempt to determine the constitutional validity of the impugned laws, including the scientific evidence requirements under Part 1 of the *MDRs* as well as its law-making (or regulation-enabling) authority (Chapter 5), and the *ATPAs* as a whole (Chapter 6). The focus of these chapters will be on determining whether their dominant purpose is classifiable under the criminal law power as the presiding basis for licensing of medical devices in relation to safety and effectiveness.

CHAPTER 4 PROCESS TO ASSESS A LAW'S CONSTITUTIONAL VALIDITY

4.1. Introduction

This chapter describes the legal process to assess a law's constitutional validity on federalism grounds that will be applied to the medical device market entry laws in Chapter 5 (scientific evidence requirements under Part 1 of the *MDRs*) and Chapter 6 (the non-mainstream, "agile" market entry route under the *ATPAs*). This framework is split into two main steps. The first step requires a law's dominant purpose to be characterized ("characterization process"). The second step requires this dominant purpose to be classified "in relation to"[385] the enacting government's enumerated powers under ss. 91 and 92 of the *Constitution Act, 1867* ("classification process"). If a law is found invalid (meaning that the dominant purpose is not classifiable under the enacting government's power(s)), then a third residuary step may arise under the ancillary powers doctrine. This doctrine may save an otherwise invalid law from an *ultra vires* declaration, which would otherwise render it of no force or effect under s. 52(1) of the *Constitution Act, 1982*.

4.2. First Step: Characterization of a Law's Dominant Purpose

The first step in a federalism analysis "is to determine 'the matter'…in relation to which the impugned law is enacted. What is the essence of what the law does and how does it do it?"[386] The "matter" of a law is synonymous with the terms "dominant purpose" or "pith and substance." Other terms interchangeable with "dominant purpose"

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[385] *Reference re Firearms* (SCC), *supra* note 50 at para 25.

[386] *Chatterjee v Ontario (AG)*, 2009 SCC 19 at para 16.

include "pith and substance," "true character;"[387] "dominant or most important characteristic;"[388] "leading feature or true character;"[389] and "true subject matter."[390] However, the term "dominant purpose"[391] was specifically favoured by LeBel & Deschamps JJ. (Abella & Rothstein JJ.) in *Reference re AHRA* (2010) where it was said to consolidate the term's nuances.[392]

A law's dominant purpose, as the term has consistently been used, is determined on the basis of 1) the purpose the enacting body had in enacting a law, which is the legislature or other enacting body, and; 2) the law's legal and practical effects.[393] While this inquiry into a law's dominant purpose is flexible and non-technical nor formalistic,[394] there are "overarching principles."[395] These principles can be divided into three sections as described below.

The first section below explains the basic principles and rules that determine an enacting body's purpose for the enactment of a law. The second section defines the importance of a law's legal and practical effects in influencing the dominant purpose characterization. The third section details the weight and validity of two categories of evidence divided into textual sources of intrinsic evidence (impugned provisions and

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[387] *RJR-MacDonald*, *supra* note 224 at para 29.

[388] *Friends of the Oldman River Society v Canada (Minister of Transport)*, [1992] 1 SCR 3 at 62-63.

[389] *Morgentaler* (1993), *supra* note 62 at 481-82.

[390] *Reference re Pan-Canadian*, *supra* note 273 at para 86.

[391] *RJR-MacDonald*, *supra* note 224 at para 29.

[392] *Reference re AHRA*, *supra* note 326 at para 184.

[393] *Kitkatla Band v British Columbia (Minister of Small Business, Tourism and Culture)*, 2002 SCC 31 at paras 53-54.

[394] *Morgentaler* (1993), *supra* note 62 at 482.

[395] *References re GGPPA*, *supra* note 61 at para 51.

legal scheme) and extrinsic sources that refers to any contextual evidence relevant to the dominant purpose that exists outside the intrinsic text.

4.2.1. Overview of Principles

The general principle applied to interpret a law's (dominant) purpose is expressed in Dreidger's 'modern principle' of statutory construction: "the words of an Act are to be read in their entire context in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament."[396] This overarching principle applies to all types of statutory and non-statutory interpretation, including criminal law;[397] non-constitutional statutes for purposes of constitutional compliancy on the basis of both *Charter* and federalism (ss. 91 and 92 of the *Constitution Act, 1867*);[398] and to the interpretation of constitutional statutes, including ss. 91 and 92 of the *Constitution Act, 1867*.[399] However, rules governing the determination of the dominant purpose are more specific than this general principle of statutory construction.

Under a constitutional "dominant purpose" inquiry, courts emphasize that the dominant purpose characterization is an objective inquiry that is not dependent on the subjective intent expressed by the enacting body.[400] Further, an enacting body is also very

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[396] Elmer A Driedger, *The Construction of Statutes*, 2nd ed (Toronto: Butterworths, 1983) at 87.

[397] Stéphane Beaulac & Pierre-André Côté, "Dreiedger's 'Modern Principle' at the Supreme Court of Canada: Interpretation, Justification, Legitimization" (2006) 40 RJT 131 at 137.

[398] *Ibid* at 137.

[399] *Ibid* at 137-38.

[400] *Canadian Western Bank*, *supra* note 217 at para 27 (emphasis in original), citing *Reciprocal Insurers*, *supra* note 324 at 337 (a court "seek[s] to ascertain the *true* purpose of the legislation, as opposed to its mere stated or apparent purpose." [emphasis in original]); *Reference re Margarine*, *supra* note 52 at para 139 (Rand J emphasized that in determining the "real character" of a provision, "legislation cannot conclude the question by a declaration in a preamble: at most it is a fact to be taken into account.").

likely to have multiple purposes in enacting a law, [401] but the focus of the inquiry must be stated as a singular dominant purpose. Incidental effects, purposes that are secondary to the dominant purpose, or overly narrow descriptions of a law's dominant purpose—even if within the power of the enacting government (*intra vires*)—cannot be used as substitutes to uphold an *ultra vires* dominant purpose. In *Canadian Western Bank v. Alberta* (2007),[402] the majority emphasized this point:

> [i]ts secondary objectives and effects have no impact on its constitutionality: "merely incidental effects will not disturb the constitutionality of an otherwise *intra vires* law"[[403]]…. By "incidental" is meant effects that may be of significant practical importance but are collateral and secondary to the mandate of the enacting legislature…[[404]][405]

If a provision has multiple purposes, which is common, then each purpose must be ranked to determine the singular 'dominant' purpose.[406]

The dominant purpose of a provision must also be stated with a high degree of precision.[407] In *References re GGPPA* (2021), the majority described the standard of precision as "as precisely as possible."[408] Precision has also recently been said to "encourag[e] courts to take a close look at the evidence of the law's purpose and effects,

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[401] Ruth Sullivan, *Sullivan on the Construction of Statutes*, 6th ed (Markham, ON: LexisNexis Canada 2014) at 270 [Sullivan, *Construction of Statutes*].

[402] *Canadian Western Bank*, *supra* note 217.

[403] *Global Securities Corp v British Columbia (Securities Commission)*, 2000 SCC 21 at para 23.

[404] *British Columbia v Imperial Tobacco Canada Ltd*, 2005 SCC 49 at para 28.

[405] *Canadian Western Bank*, *supra* note 217 at para 28.

[406] Sullivan, *Construction of Statutes*, *supra* note 401 at 272: ("the court must consider whether those purposes are compatible or competing and what sort of ranking or balance (if any) the legislature had in mind.").

[407] *Reference re GNDA*, *supra* note 60 at para 32.

[408] *References re GGPPA*, *supra* note 61 at para 52: ("as precisely as possible"); *Reference re AHRA*, *supra* note 326 at para 190; see also *Desgagnés Transport Inc v Wärtsilä Canada Inc*, 2019 SCC 58 at para 161 [*Wärtsilä*]: ("sufficiently precise").

and discourages characterization that is overly influenced by classification. The focus is on the law itself and what it is really about."[409] In *Desgagnés Transport Inc. v. Wärtsilä Canada Inc*.[410] (2019), the Court reiterated the emphasis on precision and then provided an example of a precisely stated dominant purpose:

> Vague and general characterizations are unhelpful in that they can be superficially assigned to various heads of powers….the matter should be "spelled out sufficiently to inform anyone asking, 'What's it all about?'" (p. 490).[411] For example, the Court in *ITO*[412] identified the matter at issue as "the negligence of a stevedore-terminal operator in the short-term storing of goods within the port area pending delivery to the consignee" (pp. 774-75).[413]

The dominant purpose of a law also exists prior to its enactment.[414] Therefore, it is the purpose of the enacting body that is relevant in the characterization of the dominant purpose and not to a legislature in the future. In *R. v. Big M Drug Mart Ltd.* (1985) Dickson J. (prior to CJ.) emphasized this point by stating that: "the theory of a shifting purpose stands in stark contrast to fundamental notions developed in our law concerning the nature of 'Parliamentary intention'. Purpose is a function of the intent of those who drafted and enacted the legislation at the time, and not of any shifting variable."[415] The purpose of a law therefore cannot be "repurposed" once enacted; it is a historical fact that exists prior to its enactment. Only in the interpretation of constitutional legislation, i.e.,

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[409] *Reference re GNDA*, *supra* note 60 at para 31.

[410] *Wärtsilä*, *supra* note 408.

[411] Albert S Abel, "The Neglected Logic of 91 and 92" (1969) 19:4 UTLJ 487 at 490.

[412] *ITO-International Terminal Operators Ltd v Miida Electronics Inc*, [1986] 1 SCR 752.

[413] *Wärtsilä*, *supra* note 408 at para 35.

[414] Sullivan, *Construction of Statutes*, *supra* note 401 at 286.

[415] *R v Big M Drug Mart Ltd*, [1985] 1 SCR 295 at para 91 [*Big M Drug Mart*].

the division of powers, does a flexible approach to interpretation apply that is not restricted to the intention of the founders of the *Constitution Act, 1867*.[416]

Although the dominant purpose is a historical fact that 'rests' in the enacting body, legal and practical effects (elaborated below) whether forecasted or whether they occurred after a law's enactment, are objective indicia of the enacting body's dominant purpose:

> either an unconstitutional purpose or an unconstitutional effect can invalidate legislation. All legislation is animated by an object the legislature intends to achieve. This object is realized through the impact produced by the operation and application of the legislation. Purpose and effect respectively, in the sense of the legislation's object and its ultimate impact, are clearly linked, if not indivisible. Intended and actual effects have often been looked to for guidance in assessing the legislation's object and thus, its validity.[417]

Legal and practical effects are therefore important considerations in the process to determine a law's dominant purpose. The following section describes the kinds of legal and practical effects that will be considered by a court in the characterization of a law's dominant purpose.

4.2.2. Legal and Practical Effects Influence a Law's Dominant Purpose

A law's legal effects, or "strict legal operation,"[418] stems from the rights and liabilities created under the law, particularly the rights and liabilities of those who are subject to the law.[419] In *Morgentaler* (1993), Sopinka J. stated that legal effects can be

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[416] *Ibid* at para 92 [emphasis added]: ("[a]s Laskin C.J. has suggested in *R. v. Zelensky*, [1978] 2 S.C.R. 940, at p. 951, "new appreciations" and "re-assessments" may justify a re-interpretation of the scope of legislative power. While this may alter over time the breadth of the various heads of power and thereby affect the classification of legislation, it does not affect the characterization of the purpose of legislation,").

[417] *Ibid* at para 80.

[418] *Morgentaler* (1993), *supra* note 62 at 482.

[419] *Ibid*.

indicative of a law's dominant purpose even if unintended nor appreciated by the legislative or regulatory body.[420] This point was also emphasized in *Reference re Employment Insurance Act (Can.), ss. 22 and 23* (2005), where it was stated that effects going beyond a law's aim ("preponderant effect[s]") are valid evidence of a law's dominant purpose and "cannot be disregarded."[421]

Legal effects further include the legal rights or powers conveyed to a person or administrative body tasked with the law's administration. As Hogg & Wright state, "[t]here have been cases in which the court has examined the administration of a statute as an aid to classifying it for constitutional purposes."[422] For example, in *Saumur v. Quebec (City of)*[423] (1953), the Court noted that the way the legislation was administered, and what the text of the law was "apt to authorize" an administrator to do, were relevant to a provision's dominant purpose.[424]

Practical effects are divided into two categories. The first category relates to the economic or social ends sought to be achieved by the law.[425] The second category relates to "the actual or predicted practical effect[[426]]," which can include the effects over long

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[420] *Ibid* at 483.

[421] 2005 SCC 56 at para 27.

[422] Hogg & Wright, *supra* note 51 at §15:9 ("Effect"): ("it is obvious that the judges were influenced by the actual use of the by-law, and it is even more obvious that they regarded the facts as to the actual use of the by-law as relevant and admissible on the question of classification." [footnote 10: "In A.-G. B.C. v. McDonald Murphy Lumber, [1930] A.C. 357, 363, the Privy Council reinforced its conclusion that the challenged provincial tax was an invalid export tax with the fact that the portion of the tax purportedly payable on timber used locally was not actually collected. In R. v. Hydro-Québec, [1997] 3 S.C.R. 213, para. 147, the majority of the Court looked at the administration of the Canadian Environmental Protection Act (finding only a small number of toxic substances under regulation) to reinforce the conclusion that it was a criminal law.").

[423] [1953] 2 SCR 299 [*Saumur*].

[424] Hogg & Wright, *supra* note 51 at §15:9, citing *Saumur*, *ibid*.

[425] *Morgentaler* (1993), *supra* note 62 at 483.

[426] *Ibid*, citing *Reference re Alberta Legislation*, [1938] SCR 100 at 130.

periods of time.[427] Practical effects are not always relevant to a dominant purpose determination. As explained in *Morgentaler* (1993) by Sopinka J.: "in one context practical effect[s] may reveal the true purpose of the legislation…, in another context it may be incidental and entirely irrelevant even though it is drastic."[428]

In the most recent SCC statement on the scope of the criminal law power, *Reference re GNDA* (2020), the effects of a law, both legal and practical, became a driving focus in the characterization analysis. Different kinds of effects, however, were weighed differently among the justices, which ultimately led to three different conclusions of the impugned law's dominant purpose. The following three decisions reiterate that effects remain highly relevant, if not pivotal, in the characterization of a law's dominant purpose, and thus are described in greater detail below to further explain and emphasize this point. The decisions also demonstrate that legal and practical effects may be weighed differently, which makes a law's dominant purpose potentially difficult to predict.

First, Karakatsanis' J. (Abella and Martin JJ. concurring) declared the "crucial" role of effects in the characterization of the law's dominant purpose:

> Crucially, Parliament's purpose in enacting the provisions in question is borne out in the provisions' effects. The most direct and significant practical effect of the prohibitions is to give individuals control over the decision of whether to undergo genetic testing and over access to the results of genetic testing. This practical effect is a direct result of the prohibitions' legal effects.[429]

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[427] See *Morgentaler* (1993), *supra* note 62 at 483, citing *Reference re Anti-Inflation*, *supra* note 277 at 389.

[428] *Morgentaler* (1993), *ibid* at 486 [citations omitted].

[429] *Reference re GNDA, supra* note 60 at para 64.

However, Karakatsanis J. did not ultimately conclude that the dominant purpose was about providing people with control over their genetic information to protect health, as Moldaver J. (Côté J. concurring) concluded.[430] Rather, given the text of the law (e.g., its title) along with Parliamentary debates, Karakatsanis J. concluded that the dominant purpose of the law was "to combat genetic discrimination and the fear of genetic discrimination based on the results of genetic tests by prohibiting conduct that makes individuals vulnerable to genetic discrimination in the areas of contracting and the provision of goods and services."[431]

Second, Moldaver J.'s opinion (Côté J. concurring) generally agreed with Karakatsanis J.'s determination of the provision's effects.[432] However, Moldaver J.'s conclusion on the dominant purpose turned more directly on the law's effects rather than the text of the law that emphasized the phrase 'genetic discrimination.' Moldaver J. concluded that the provisions' effects gave people control over their genetic information, mitigated their fears over the information being misused, and ultimately aimed to protect (not promote) health.[433] By giving individuals control over sensitive genetic information,

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[430] See *infra*.

[431] *Reference re GNDA, supra* note 60 at para 49.

[432] *Ibid* at para 133:

> I substantially agree with how Justice Karakatsanis has characterized the effects of the challenged provisions. In particular, I agree with her observation that, while the challenged provisions reduce the opportunities for genetic discrimination, '[t]he most significant practical effect of the *Act* is that it gives individuals control over the decision of whether to undergo genetic testing and over access to the results of any genetic testing they choose to undergo'.

[433] In its full context, see *ibid* at para 136 [Moldaver J (Côté J concurring); emphasis added]:

> I conclude that the pith and substance of ss. 1 to 7 of the *Act* is to protect health *by* prohibiting conduct that undermines individuals' control over the intimate information revealed by genetic testing. These provisions prohibit compulsory genetic testing, compulsory disclosure of genetic test results, and the non-consensual collection, disclosure and use of those results in a wide array of contexts that govern how people interact with society. *By giving people control over this information, ss. 1 to 7 of the Act mitigate their fears that it will be used against them.* Such fears lead many to forego genetic testing, to the detriment of their own health, the health of their families, and the public healthcare system as a whole.

fears about its misuse would be mitigated because a lack of control discouraged individuals from undergoing genetic testing to the detriment of their health.[434] Forgoing testing would have cascading effects that would compromise the health of their families and the "public healthcare system as a whole."[435] In sum, Moldaver J. concluded that the provisions' dominant purpose was to protect health by giving people control over their genetic information, which was a direct reflection of how the provisions' effects were framed by Moldaver J..[436] Preventing genetic discrimination was, for Moldaver J., only one potential effect of the law, and thus, it was not characterized solely in this regard.

In determining practical and legal effects, Moldaver J. relied on both contextual (extrinsic) evidence, i.e. Parliamentary commentary, and textual (intrinsic) evidence of the impugned provisions:

> I recognize, as Justice Karakatsanis does, that discussions of genetic discrimination figure prominently in the parliamentary record. However, I believe that when the parliamentary record [extrinsic evidence] is considered together with what ss. 1 to 7 of the Act actually do [effects /intrinsic evidence], it is clear that in enacting these provisions Parliament sought to address individuals' fears that their information would be subject to compulsory disclosure and used without their consent — including, potentially, in discriminatory ways — because of the deleterious effects those fears had on health. Therefore, while reducing the opportunities for discrimination is an important feature of the legislation, I am of the view that preventing discrimination is not the dominant purpose of the provisions in issue.[437]

Moldaver J., seemed to place greater weight on the effects derived from the text of the provisions than had Karakatsanis J.. Consequently, this affected Moldaver J.'s conclusion on the dominant purpose.

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[434] *Ibid.*

[435] *Ibid.*

[436] *Ibid.*

[437] *Ibid* at para 129 [emphasis added].

Third, Justice Kasirer's dissenting opinion (Wagner CJ., Rowe and Brown JJ. concurring) did not view the control over genetic information as a primary effect of the impugned provisions, in contrast to Karakatsanis and Moldaver JJ. Rather, Kasirer J stated: "[i]n my view, the dominant effects of the impugned provisions concern the regulation of insurance and the promotion of health rather than the protection of privacy and autonomy or the prevention of genetic discrimination."[438] Kasirer J. ultimately concluded that: "the pith and substance [dominant purpose] of ss. 1 to 7 of the *Act* is to regulate contracts and the provision of goods and services, in particular contracts of insurance and employment, by prohibiting some perceived misuses of one category of genetic tests, the whole with a view to promoting the health of Canadians."[439] This decision was therefore also heavily reliant on the perceived dominant effects of the legislation. Kasirer J. argued that the granting of individual control over genetic information, which would prevent some forms of discrimination, was an incidental effect,[440] and therefore, Kasirer J. declined to characterize it in relation to genetic discrimination.

In critiquing Kasirer's J. view, Karakatsanis J. stated that the effects on the insurance industry as one of the primary means to characterize the pith and substance presented an overly narrow approach: "[a] characterization narrowly focused on insurance reflects an impoverished view of the *Act* and fails to capture the broad purpose and effects of the legislation."[441] Moldaver J.'s opinion concurred on this specific point

[438] *Ibid* at para 205.
[439] *Ibid* at para 227.
[440] *Ibid* at para 214.
[441] *Ibid* at para 62.

and noted that the effects on insurance contracts, employment agreements and generally the exchange of goods and services merely amounted to "incidental effects," in contrast to its characterization as a dominant effect by Kasirer J. that was highly influential to this dissenting judgment.[442]

Reference re GNDA (2020) is the most up-to-date statement on the criminal law power that discusses the characterization process of a law's dominant purpose (i.e., the pith and substance doctrine). Significant emphasis on the legal and practical effects of the law were taken in each of the three judgments. An increased focus on effects is therefore taken in Chapters 5 and 6 to assess if the effects of the impugned laws demonstrate effective measures to ensure medical device safety and effectiveness of medical devices. If the laws do not, this will affect their characterization as laws that suppress harm against threatened interests as required under the criminal law power.

4.2.3. Sources of Evidence: Intrinsic (Text of the Law) and Extrinsic (Context of the Law)

The type of evidence in a characterization analysis is separated into intrinsic and extrinsic categories. Intrinsic evidence, also known as textual evidence, refers to the text of the law.[443] It includes anything within the four-corners[444] of the law, including the text of the impugned provisions, titles, preambular statements, definitions of terms, headings,

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[442] *Ibid* at para 130:

> I acknowledge that the record contains references to contracts such as insurance contracts and employment agreements, and the provision of goods and services. While these references demonstrate that Parliament was aware of the incidental effects the impugned provisions may have on certain areas, that was not its focus. Rather, those references served to explain and give examples of the contexts in which individuals' fears regarding control over their genetic test results were leading them to make harmful health decisions.

[443] *Reference re AHRA*, *supra* note 326 at para 202.

[444] *Morgentaler* (1993), *supra* note 62 at 483.

and divisions.[445] The text of a provision must also be interpreted in light of its overall scheme as it may play an important role in determining its dominant purpose.[446] As the Court has noted: "a provision may take on a valid constitutional cast by the context and association in which it is fixed as complementary provision serving to reinforce other admittedly valid provisions."[447]

Part of intrinsic evidence consists of the "legislative [or regulatory] choice of means,"[448] which are the substantive provisions that enable a purpose. It has been previously emphasized by the SCC that judges are not democratically elected and are not best suited to determine if the means used by Parliament are efficacious in relation to the policy objectives.[449] Therefore, jurists should not "express disapproval of either the policy of the statute or the means by which the legislation seeks to carry it out."[450] This statement, however, requires qualification based on modern pith and substance jurisprudence. Most recently, the majority in *References re GGPPA* (2021) (Wagner CJ.; Abella, Moldaver, Karakatsanis, Martin and Kasirer JJ. concurring) affirmed that the law's 'means' implemented to obtain a policy objective are valid as evidence of a law's dominant purpose: "there may be cases in which an impugned statute's dominant characteristic or main thrust is so closely tied to its means that treating the means as irrelevant to the identification of the pith and substance would make it difficult to define

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[445] Pierre-André Côté, Stéphane Beaulac & Mathieu Devinat, *The Interpretation of Legislation in Canada*, translated by Steven Sacks (Toronto: Carswell, 2011) at 62-79.

[446] *Quebec (AG)*, *supra* note 302 at para 30.

[447] *Kirkbi AG v Ritvik Holdings Inc*, 2005 SCC 65 at para 20.

[448] *References re GGPPA*, *supra* note 61 at para 53.

[449] See generally *Morgentaler* (1993), *supra* note 62 at 488.

[450] *Quebec (AG)*, *supra* note 302 at para 31.

the matter of a statute or a provision precisely."[451] As the majority noted in *References re GGPPA* (2021), "as long as [a court] does not lose sight of the fact that the goal of the analysis is to identify the true subject matter of the challenged statute or provision" consideration of the legislative choice of means is indeed valid.[452]

The "means" to obtain the policy objective is also integral to identify laws that are colourable or specious. Colourable laws refer to those that have an *intra vires* (within the authority of the enacting government) appearance, but the government instead has an ulterior purpose that is *ultra vires*.[453] As Hogg & Wright state: "[i]n *Morgentaler*, Sopinka J. stated that '[i]f the means employed by a legislature to achieve its purported objectives do not logically advance those objectives, this may indicate that the purported purpose masks the legislation's true purpose.'"[454] Again however, colourable or specious purposes do not need to be in issue for a law's "means" to influence the dominant purpose as discussed by the majority in *References re GGPPA*: "there is nothing impermissible about defining a matter with reference to the legislative means."[455] Similarly, Sopinka J. stated, "the colourability doctrine really just restates the basic rule, applicable in this case as much as any other, that form alone is not controlling in the determination of constitutional character, and that the court will examine the substance of the legislation to determine what the legislature is really doing."[456]

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[451] *References re GGPPA*, *supra* note 61 at para 53.

[452] *Ibid*.

[453] *Quebec (AG)*, *supra* note 302 at para 31.

[454] *Morgentaler* (1993), *supra* note 62 at 511.

[455] *References re GGPPA, supra* note 61 at para 54.

[456] *Ibid* at para 51; see *Reciprocal Insurers*, *supra* note 324 at para 12: ("it may be necessary to examine with some strictness the substance of the legislation for the purpose of determining what it is that the Legislature is really doing.").

Extrinsic evidence refers to a much greater breadth of evidence than intrinsic evidence. It includes any material existing outside the "four corners" of the impugned law and its scheme, that may be relevant to its dominant purpose such as "background and circumstances."[457] Extrinsic evidence is useful to help define the mischief that Parliament sought to address and it is admitted on the standard of a "rational basis" in relation to a contended dominant purpose: "extrinsic evidence material need only go so far as to persuade the Court that there is a rational basis for the legislation which it is attributing to the head of power invoked in this case in support of its validity."[458] Generally, the weight accorded to different types of extrinsic evidence is context-specific, which makes it difficult to make a generalized statement about the weight that different types of extrinsic evidence will have.

Sources of extratextual evidence include: legislative history; legislative evolution;[459] 'binding' precedents (the principle of *stare decisis*),[460] and non-binding precedents; predecessors to the impugned statutes or law (i.e., repealed/replacement versions of an impugned statute); foreign legislation and its case law/interpretation;[461] social science evidence;[462] and scholarly articles.[463] Historical information about a law is

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[457] *References re GGPPA*, *ibid* note 61 at para 51, citing *Ward v Canada (AG)*, 2002 SCC 17.

[458] *Reference re Anti-Inflation*, *supra* note 277 at 423.

[459] Sullivan, *Construction of Statutes*, *supra* note 401 at 660: ("[t]he evolution of a legislative provision consists of the successive enacted versions of the provision from its inception to the version in place when the relevant facts occur. Some provisions are rooted in common law, so that it is necessary to look to pre-enactment case law to establish the initial rule.").

[460] Precedents that establish a provision's dominant purpose form part of extrinsic evidence because it is information that exists outside the 'four-corners' of the legislation. The weight of a 'binding' precedent will vary according to the similarities between the cases and the intrinsic and extrinsic evidence that was considered in each case.

[461] Ruth Sullivan, *Statutory Interpretation*, 3ed (Toronto: Irwin Law, 2016) at 271.

[462]Sullivan, *Construction of Statutes*, *supra* note 401 at 655, §22.24.

[463] *Ibid* at 701, §23.100.

often used to provide context into its dominant purpose, which can be undertaken by tracing prior statutes that the law has repealed or amended.[464] Tracing the evolution of an enactment, for example, "may reveal past decisions by the legislature to adopt a new policy or strike out in a new direction; it may reveal a gradual trend or evolution in legislative policy, or it may reveal the original purpose of legislation and show that this purpose has remained constant."[465]

Legislative history refers to "everything that relates to [a law's] conception, preparation and passage, from the earliest proposals for legislative change to royal assent".[466] This is a narrower category than legislative evolution because an 'evolution' relates more to identifying legislative trends over time. Legislative history includes Parliamentary materials including all bill versions of the enactment, Parliamentary debates (known as Hansard), legislative testimony, committee hearings and reports, minutes of proceedings, and commissioned reports. For example, in *Reference re GNDA*, Karakatsanis J. noted that the statute as passed excluded an exception for "high-value insurance contracts" that was originally present in a bill version and that had meant to serve as a concession to the insurance industry.[467] The removal of this exception in the final statute "underline[d] the importance of the *general* prohibitions,"[468] which influenced the law's characterization.

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[464] Côté, Beaulac & Devinat, *supra* note 445 at 457.

[465]Sullivan, *Construction of Statutes*, *supra* note 401 at 286-87 [case citations omitted].

[466] *Ibid* at 679, §23.53.

[467] *References re GNDA*, *supra* note 60 at para 61.

[468] *Ibid* [emphasis in original].

Legislative debates or discussions could be of low weight and must be analyzed for reliability,[469] in part because they may not be representative of the dominant purpose. In *Reference re GNDA*, Karakatsanis J. emphasized caution: "I would note that this Court has historically urged caution in relying too heavily on statements made in the course of parliamentary debates…. With that caution in mind, I proceed to examining statements suggestive of purpose…."[470] Certain judges may place greater weight on the text of the law (intrinsic evidence) to characterize the dominant purpose if Parliamentary statements are not viewed as reliable.[471] As discussed above, Sopinka J. in *Morgentaler* (1993) pointed out that a law's stated purpose (whether it be in extrinsic or intrinsic sources of evidence) can be different from what the law is "really doing,"[472] and to determine this, the law's substantive provisions including the means used to achieve an objective, must be examined.

Scholarly articles may also be helpful as context and can be used to set out relevant facts[473] in relation to the law's "historical, social, political, economic or institutional context…"[474] These above sources consist of the major forms of extrinsic evidence and comprise a significant breadth of evidentiary sources that can be used to characterize a law's dominant purpose.

In summary, the characterization process must be focused on defining an impugned law's singular dominant purpose, which is generally an objective inquiry that

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[469] See Edward Heath, "How Federal Judges Use Legislative History" 25:1 J Legis 95 at 103.

[470] *Reference re GNDA*, *supra* note 60 at paras 40-41.

[471] Heath, *supra* note 469.

[472] *Morgentaler* (1993), *supra* note 62 at 496.

[473] Sullivan, *Construction of Statutes*, *supra* note 401 at 701, §23.100.

[474] *Ibid*.

includes the assessment of a law's legal and practical effects. Various sources of evidence must be taken into consideration when determining a law's dominant purpose, including both intrinsic (textual) sources, and extrinsic (contextual) sources that give meaning to the impugned law's dominant purpose.

4.3. Second Step: Classification of a Law's Dominant Purpose

After the dominant purpose of a law is characterized, the second step is to classify the dominant purpose under a head of power that it stands "in relation to."[475] The law must be classified under one or more of the enacting government's head of power(s) for it to be valid. This classification analysis is not "an exact science."[476] This second step requires a court to interpret the breadth or scope of the head of power. As discussed, courts avoid interpreting the scope of a relevant classification power, such as the criminal law power, the trade and commerce power or p.o.g.g., in overly broad definitions to preserve the structural arrangement of federalism in Canada.[477] As discussed in Chapter 3, the federal government is likely dependent on the criminal law power to support the constitutional validity of a medical device scheme in relation to safety and effectiveness. The criminal law power is therefore the primary focus of the constitutional analysis in Chapters 5 and 6.

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[475] *Reference re Firearms* (SCC), *supra* note 50 at para 25.

[476] *Ibid* at para 26.

[477] *Citizens' Insurance*, *supra* note 232.

4.4. Third Step: Ancillary Powers Consideration for Invalid Laws

Laws that cannot be classified under one of the enacting body's powers may be upheld if they are "ancillary" to an otherwise valid scheme. To determine whether an impugned law(s) is ancillary, a court will assess an invalid law's necessary degree of integration in an otherwise valid legal scheme according to its degree of intrusion on the other order of government's powers.

The more serious the intrusion the invalid law is on the other government's powers, the more the law will have to be 'strictly necessary' to advance the otherwise valid scheme (the necessarily incidental/strict necessity threshold).[478] If the invalid law represents a less serious intrusion on the other government's power, the provision will be upheld if it 'rationally and in function' furthers the purpose of the otherwise valid scheme (the rational and functional connection threshold).[479]

There are two justifications for permitting infringements on another order of government's powers. First, courts recognize that some degree of overlap in federal and provincial jurisdiction is inevitable, which is associated with modern federalism where provincial and federal jurisdictions are not held to be exclusive 'watertight' zones.[480] Second, courts recognize that laws that fall outside an enacting government's powers can be important to an otherwise overall valid scheme.[481] However, as McLachlin CJ. emphasized in *Quebec (AG) v. Lacombe*[482] (2010): "the availability of ancillary powers is limited to situations in which the intrusion on the powers of the other level of government

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[478] *Quebec (AG) v Lacombe,* 2010 SCC 38 at para 42 [*Lacombe*], citing *General Motors*, *supra* note 237.

[479] *Lacombe*, *ibid*.

[480] *Ibid* at para 35.

[481] *Ibid*: ("the invocation of ancillary powers runs contrary to the notion that Parliament and the legislatures have sole authority to legislate within the jurisdiction allocated to them by the *Constitution Act, 1867*.").

[482] *Ibid*.

is justified by the important role that the extrajurisdictional provision [invalid law] plays in a valid legislative scheme."[483] Therefore, if a law has a specious dominant purpose, the ancillary powers doctrine would not apply because it establishes an ulterior purpose unrelated to the valid scheme. A specious law may foreclose the ability to raise the ancillary powers doctrine.

It is also unclear that the ancillary powers doctrine is logical. Given that the dominant purpose of a provision is to be informed by the legislative scheme to which it belongs, if an impugned law's effect(s) has a rational-functional connection (a minimum requirement) to the otherwise valid legal scheme, then the law could have been characterized as valid given that a law's legal and practical effects influence a law's dominant purpose, as discussed in reference to the three judgments in *Reference re GNDA*. Similarly, if a law was first found to have an invalid dominant purpose in the first step of the inquiry, but then the law was found, under the ancillary powers test, to be "strictly necessary" to advance the otherwise valid scheme, this indicates that the invalid dominant purpose of the law was not a correct characterization. The Court noted in *Lacombe* that the ancillary powers test has been criticized on the basis of whether it represents a "logical synthesis" of past case law,[484] although they did not further

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[483] *Ibid*.

[484] *Ibid* at para 43:

> The General Motors test has been applied…in all subsequent decisions of this Court in which the possibility of ancillary jurisdiction was canvassed…It has been criticized on the basis that it involves a difficult distinction between serious and less serious intrusions (one's view of the seriousness of an intrusion may vary depending on whether one is intruding or being intruded upon, for example), and on the basis that it is not really a logical synthesis of the *Attorney-General for Canada v. Attorney-General for the Province of Quebec* and *Papp* lines of authority.

elaborate, ultimately noting in the context of the case that it was unnecessary to "address the merits of these criticisms."[485]

In summary, the ancillary powers doctrine does not appear relevant if the characterization process correctly weighed the law's legal and practical effects into the equation of the law's dominant purpose as required under modern pith and substance jurisprudence. Although the ancillary powers doctrine will still be considered in Chapters 5 and 6 if there is a finding of invalidity, this doctrine could unlikely be invoked to save a colourable law because its dominant purpose would be disconnected from the otherwise valid legal scheme, and thus would not meet the minimum 'rational-connection' standard.

4.5. Conclusion

This chapter described the legal process to examine a law's constitutional validity on federalism grounds. This process is divided into three steps. The first step requires a law's dominant purpose to be characterized, the second step involves classifying this dominant purpose under the enacting government's power(s), and the third step requires identifying whether the law is "ancillary" to an otherwise valid legal scheme if its dominant purpose is unclassifiable under the second step.

Chapter 5 applies this process to determine if the scientific evidence requirements for the market entry of medical devices under Part 1 of the *MDRs* is constitutionally valid on federalism grounds. Chapter 5 also applies this validity framework to determine if the law-making authority under the *F&D Act* that authorizes the executive branch of government to determine all market entry conditions for most medical devices, including

[485] *Ibid* at para 44.

scientific evidence requirements, is valid. Chapter 6 applies the same framework to determine if the 'agile' market entry route under the *ATPAs* for medical devices deemed 'advanced therapeutic products' is constitutionally valid on federalism grounds.

CHAPTER 5 VALIDITY: SCIENTIFIC EVIDENCE REQUIREMENTS UNDER PART 1 OF THE MEDICAL DEVICES REGULATIONS AND ENABLING POWERS

5.1. Introduction

This chapter examines the constitutional validity of the scientific evidence requirements under the mainstream market entry route (ss. 9(2) and 32 under Part 1 of the *MDRs*). It then analyses the constitutional validity of its enabling power under s. 30(1) of the *F&D Act* that permits the executive branch of government to determine all market entry requirements (licensing conditions) for medical devices, including the scientific evidence requirements.

5.2. Scientific Evidence Requirements under Part 1 of the *MDRs*

5.2.1. Characterization

5.2.1.1. Intrinsic Evidence: Text of the Scientific Evidence Requirements

Under Part 1 of the *MDRs,* a person is required to obtain some form of a licence to legally import or sell most medical devices. Part 2 of the *MDRs* consists of the "exceptional" market entry routes meant for a person that wishes to sell or import a custom-made medical device or those who seek access to medical devices for "special access" reasons.[486]

[486] See *MDRs*, *supra* note 1, s 69(2): ("[i]n this Part, ***special access*** means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable." [emphasis in original]).

As discussed in Chapter 2, under Part 1 of the *MDRs* every person is required to obtain a licence before they import or sell a medical device. There are two types of licences: 1) a Medical Device Establishment Licence ("MDEL") and 2) a Medical Device Licence ("MDL"). For lowest risk devices (Class I), a person is generally required to obtain an MDEL with certain exceptions.[487] For medium to highest risk medical devices (Class II-IV), a person is required to hold an MDL. Selling or importing a medical device without the required licence is a prohibited offence.[488] These prohibited offences are backed with serious penal sanctions (a summary or indictable offence) that include high maximum fines or imprisonment, or both as detailed in Chapter 2, and are based in a public welfare 'strict liability' scheme.[489] If a person, however, knowingly or recklessly causes serious risk of injury to human health in contravention of any provision under the *Act* or regulations, the maximum penal sanction is potentially higher.[490]

Issuance of an MDL (for Class II-IV) by the Minister of Health turns on a person's ability to meet ss. 10-20 (entitled "Safety and Effectiveness Requirements") under the *MDRs*:

> **Medical Device Licence**
> **Issuance**
> **36 (1)** If the Minister determines that a medical device in respect of which an application is submitted meets the applicable requirements of sections 10 to 20 the Minister shall
> **(a)** issue to the manufacturer of the device a medical device licence, in the case of an application for a medical device licence; [emphasis added]

[487] *Ibid*, s 44(2).

[488] *Ibid*, s 26 (for Class II-IV); s 44 (for Class I).

[489] *F&D* Act, *supra* note 1, s 31.2; see s 31.3 establishing due diligence as a defence.

[490] *Ibid*, s 31.4.

The Minister's issuance of an MDEL (Class I) also turns on a person's ability to demonstrate due diligence procedures within their establishment, such as the requirement to maintain distribution procedures and other record-keeping responsibilities.[491] The Minister of Health can also refuse to issue an MDEL if they believe that it would harm the "health or safety of patients, users or other persons."[492] *Prima facie*, protecting the public is the core focus of medical device licensing based on the rationale behind the issuance of licensing and the corresponding 'default' strict liability (public welfare) offence. Issuance of licences under the *MDRs* is for the *prima facie* purpose of protecting the public.

While the *prima facie* purpose of medical device licensing turns on public protection, the scientific evidence requirements (the means used to ensure that medical devices are safe and effective) is in tension with this objective from a practical effects perspective.[493] As stated in Chapter 4, '[i]f the means employed by a legislature [or enacting body] to achieve its purported objectives do not logically advance those objectives, this may indicate that the purported purpose masks the legislation's true purpose."[494] The following discussion elaborates on the absence of rigour in the scientific evidence requirements (distinguishable from 'safety and effectiveness' requirements), which represent the pivotal means to substantiate the high level of safety and effectiveness required upon market entry.

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[491] *MDRs, supra* note 1, s 45.

[492] *Ibid*, s 47.

[493] See *infra*.

[494] *Morgentaler* (1993), *supra* note 62 at 511; see also discussion of *Reference re GNDA*, *supra* note 60 in Chapter 4 (the effects of the law was central to defining the dominant purpose in each of the three judgments).

To first recap and further elaborate on the discussion in Chapter 2, every medical device subject to Part 1 regardless of its risk class must meet the same safety and effectiveness requirements under ss. 10-20 of the *MDRs*. For example, s.10 requires that a medical device "shall be designed and manufactured to be safe,"[495] and that "reasonable measures"[496] be taken to identify risks, and generally eliminate the risks as much as possible.[497] Similarly, s. 11(1) is the risk-benefit clause that states that a medical device shall not adversely affect health or safety when used according to its "manufactured, sold or represented" use, except to the extent that any adverse effect (risk) will be outweighed by its benefits and is generally still compatible "with a high level of protection of health and safety."[498] Section 12(1) is the effectiveness requirement clause that states that a medical device "shall perform as intended by the manufacturer and shall be effective" for its "manufactured, represented or sold for uses."[499] Sections 13-20 further establish more context-specific criteria for safety and effectiveness related to storage, transportation, biocompatibility, and software functionality, among others. These requirements, *prima facie*, convey an impression that only medical devices that are safe and effective will gain lawful market entry.

While ss. 10-20 do convey the impression that all medical devices are to be safe and effective, the scientific evidence 'substantiation' requirements (the "means" used to validate these requirements) are potentially inconsistent with the *prima facie* purpose of licensing (public protection) because of the absence of emphasis on reliable forms of

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[495] *MDRs*, *supra* note 1, s 10.

[496] *Ibid*.

[497] *Ibid*.

[498] *Ibid*, s 11(1).

[499] *Ibid*, s 12(1).

scientific evidence. These laws are vague compared to the detailed model US laws (see Tables 3 and 4) which list requirements for scientific evidence that are able, in practical effect, to validate a medical device's safety and effectiveness. These scientific evidence requirements are found under ss. 9(2) and ss. 32 of the *MDRs*. The following explains the relationship between these two critical sections under Part 1 of the *MDRs*.

First, s. 9(1) of the *MDRs* requires a manufacturer to meet the safety and effectiveness requirements under ss. 10-20 of the *MDRs*, entitled "Safety and Effectiveness Requirements." Section 9(2) establishes a scientific evidence "standard" that requires a manufacturer to "keep objective evidence to establish that the medical device meets those requirements."[500] The term "objective evidence" is defined under the *MDRs* under s. 1:

> ***objective evidence*** means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition ***objective evidence*** in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time.

As discussed in Chapter 2, IS0 8402:1994 has been withdrawn, but the current ISO (2015) definition remains substantially unchanged and is vague as conveyed through terms such as "objective evidence," defined as "data…supporting the existence or verity of something"[501] or "objective evidence" that is "obtained through observation, measurement, test, or by other means."[502] This definition does not list explicit requirements for methodologically rigorous forms of scientific evidence.

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[500] *Ibid*, s 9(2).

[501] See ISO, "evidence", *supra* note 130.

[502] *Ibid*.

Methodologically sound types of evidence is critical to evaluate safety and effectiveness: "[p]oorly designed or conducted clinical trials or observational studies can readily overstate benefits or minimize risks."[503] The current scientific evidence requirements may facilitate market access to medical devices based on methodologically unsound scientific evidence, which was the case with Medtronic Inc.'s RDS.

Second, s. 32, entitled "Application for a Medical Device Licence" imposes additional scientific evidence 'substantiation' requirements beyond the requirement to hold "objective evidence" in proof of ss. 10-20. These additional requirements apply only to medical devices in Class II-IV. Class I medical devices are not subject to an MDL, and no additional requirements exist beyond the requirement to hold "objective evidence," a vaguely defined standard even as currently defined under the ISO's 2015 definition.[504]

Under s. 32, scientific evidence requirements vary according to the risk class of a medical device. The higher the risk class, the more specific the scientific evidence requirements become. As detailed in Table 1, only a person that imports or sells an NP-IVDD is required to submit at least one clinical test that is "conducted on the device."[505] For all other medical devices that are not NP-IVDDs—again, the vast majority—there is an express absence for studies to be "conducted on the device", including those of the highest risk (Class IV). Further, the scientific evidence requirements are vague, for e.g., "all studies on which the manufacturer relies…."[506] While for Class IV (highest risk) medical devices this requires pre-clinical and clinical evidence, this is not a requirement

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[503] See Jerry Avorn *et al*, "Forbidden and Permitted Statements about Medications — Loosening the Rules" (2015) 373 New England J Medicine 967.

[504] See *MDRs*, *supra* note 1, ss 44-51.1.

[505] See *ibid*, s 32(2)(e) for Class II; s 32(3)(h) for Class III; s 32(4)(k) for Class IV.

[506] See *ibid* at s 32(3)(f) for Class III; s 32(4)(i) for Class IV.

for Class III (high risk) medical devices under s. 32(3) in contrast to s. 32(4) (compare Class III and IV columns in Table 1). The omission for clinical evidence of safety and effectiveness for Class III medical devices would unlikely be considered an oversight. The only apparent reason for distinguishing a Class III (high risk) medical device from a Class IV (highest risk) medical device is to not impose clinical evidence requirements for Class III (high risk) medical devices.

Overall, the scientific evidence requirements lack objective concreteness, in contrast to the scientific evidence requirements considered "essential" by the scientific community under the model US law described in Chapter 2. This finding weighs against the *prima facie* dominant purpose of ss. 9(2) and 32 as being defined in terms of public protection because the requirements ("the means") do not predictably advance the public protection rationale of medical device licensing. To further understand the dominant purpose of the licensing scheme, and ss. 9(2) and 32 as the specific impugned laws, the following section examines extrinsic sources of evidence.

5.2.1.2. Extrinsic Evidence: Context of the Scientific Evidence Requirements

The following extrinsic evidence consists of three types of contextual sources relevant to the scientific evidence requirements and to the *MDRs* more broadly. First, Health Canada's policy guidance on scientific evidence requirements for most types of medical devices where there is a requirement to submit scientific evidence to the government will be discussed (i.e., Class III and IV). Health Canada's interpretation will be shown to run parallel to the US 510(k) clearance process as briefly introduced in Chapter 2. Treatment of the 510(k) clearance process by US courts and a non-governmental organization will be elaborated beyond the initial discussion in Chapter 2,

which will provide evidence of the impugned scientific evidence requirements' practical and legal effects. Second, this section will then review reports of the Office of the Auditor General that assess Health Canada's administration of the *MDRs*, which provides further evidence of the practical effects of medical device licensing more broadly. Third and last, the legislative history of the *MDRs* will be reviewed.

5.2.1.2.1. Health Canada's Interpretation of the Scientific Evidence Requirements

Health Canada has issued policy guidance for the administration of the *MDRs* as it respects the scientific evidence requirements for medical devices in Class III and IV that are not *in vitro* diagnostic devices (IVDDs).[507] This guidance document elaborates on the scientific evidence requirements in s. 9(2) ("objective evidence") and s. 32 (risk-class specific scientific evidence requirements). For clarity, this guidance document does not elaborate on the scientific evidence requirements for Class I or II because scientific evidence is not required to be submitted to the government in a licence application (see Table 1).

The guidance document was adopted and made effective in 2012 and it appears to be the first time a guidance document was issued for purposes of explaining the scientific evidence requirements.[508] While this guidance document states that preclinical and clinical studies is a requirement for Class III medical devices, it is not legally binding. As this document states: "[g]uidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach."[509] This guidance document

[507] Health Canada, "Guidance on Supporting Evidence," *supra* note 142.

[508] See *ibid* at 2 (the "Background" section does not refer to any prior document).

[509] *Ibid*, at i "Foreword".

also affirms that evidence of a medical device's safety and effectiveness, particularly clinical evidence, does not need to derive from the licensee medical device. Accepted types of clinical evidence can derive from "relevant clinical data from published sources, or device-related investigations:"[510]

> An evaluation of clinical evidence is necessary to help establish the clinical safety and effectiveness of a medical device for each claimed indication for use. A clinical evaluation considers available, relevant clinical data from published sources, or device-related investigations. It may be necessary to generate additional clinical data to address specific issues for certain medical devices.[511]

The guidance document further explains that clinical evidence from a "device-related" medical device can be used as the basis to inform the clinical evidence of the licensee device if that device has a "well established" clinical history:

> If a clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review of relevant publications in the peer-reviewed scientific literature. Reference to devices other than the subject device in support of safety or effectiveness requires a thorough comparison to the subject device design, features and performance capabilities to demonstrate relevance. This may be provided in a table format. Leveraged publications should be referenced but copies only need to be provided if pivotal in supporting safety or effectiveness.[512]

The comparison must therefore be thorough in relation to "design, features and performance capabilities to demonstrate relevance."[513] This "relevance" standard, however, still remains generally vague.

If the manufacturer cannot "demonstrate relevance" to a related medical device, or when it chooses to undertake an investigational test to gather clinical evidence based

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[510] *Ibid* at 14 (Class III); at 31 (Class IV).

[511] *Ibid* at 14 (Class III); at 31 (Class IV) [emphasis added].

[512] *Ibid* [emphasis added].

[513] *Ibid*.

on the exact licensee medical device, Health Canada only requires the information to be "summarized" for medical devices in Class III, whereas information must be provided in a clinical report for Class IV medical devices:[514]

> [c]linical evidence in the form of device-specific clinical investigations conducted in Canada or other countries should be summarized [but, for Class IV: "…should be provided"]. Summaries [for Class IV: "Reports should…"] should cover the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical investigations should be preceded by a discussion in context with the published literature. Both statistical and clinical significance should be considered and critically analyzed [substantively equivalent for Class IV].[515]

The guidance document still, however, does not emphasize requirements for well-controlled investigations (this is neither emphasized under any other section of the *MDRs*), such as requirements for blinding, randomization, or valid control groups that reduce bias in respect to conclusions drawn about a medical device's purported safety and effectiveness.

Overall, the scientific evidence requirements to support a medical device's safety and effectiveness are not methodologically rigorous based on the absence of emphasis on reliable forms of scientific evidence with the exception of NP-IVDDs. Health Canada has also acknowledged this flexibility: "under the current process for reviewing and approving medical devices, there is flexibility on the type of clinical evidence that can be provided to demonstrate medical device safety and effectiveness."[516]

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[514] In contrast, a new drug submission requires "detailed reports of the tests made to establish the safety of the new drug…" see *FDRs*, *supra* note 181 at C.08.002(2)(g).

[515] Health Canada, "Guidance on Supporting Evidence" *supra* note 142 at 14 (Class III) & 31 (Class IV).

[516] Health Canada, "Health Canada's Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness and Quality" (Ottawa: Health Canada, December 2018) at 3, online: <www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/medical-devices-action-plan/medical-devices-action-plan-eng.pdf>.

5.2.1.2.2. Judicial Treatment of Health Canada's Interpretation

This section reviews how US courts have treated the use of scientific evidence requirements that permit medical devices to enter the market based on a similar medical device's clinical evidence of safety and effectiveness. There is an absence of case law in Canada that considers the impugned scientific evidence requirements in respect to how Health Canada has interpreted them (i.e., permitting reliance on the clinical evidence of a similar medical device). This findings from US case law will be used to predict how Canadian courts may interpret this form of safety and effectiveness substantiation.

In the US a manufacturer can base a medical device's safety and effectiveness on a "substantially equivalent" medical device's clinical evidence of safety and effectiveness under the 510(k) clearance process, which is akin to how Health Canada interprets the scientific evidence requirements under ss. 9(2) and 32. The Supreme Court of the United States ("USSC") has described the 510(k) clearance process as an exception to the rigorous premarket approval ("PMA") scheme, which unlike that PMA scheme, permits certain medical devices to be "rapidly introduced into the market."[517] The 510(k) clearance process has not been characterized by the USSC as a law that can provide reasonable assurance of a medical device's safety and effectiveness.[518] The USSC has stated that the practical effect of this type of substantiation provides "'little protection to the public.'"[519]

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[517] *Lohr*, *supra* note 204 at 2247.

[518] See *infra*, *ibid*.

[519] *Ibid* at 2254 [citation omitted].

In *Medtronic Inc., v. Lohr*, (1996),[520] the USSC rejected Medtronic, Inc.'s argument that Congress' purpose for enacting the 510(k) clearance process was to ensure that medical devices were safe and effective:

> even though FDA may well examine §510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device, [citing brief], it did not "require" Medtronics' pacemaker to take any particular form for any particular reasons; the agency simply allowed the peacemaker, as a device substantially equivalent to one that existed before 1976 to be marketed without running the gauntlet of the PMA process. In providing for this exemption to PMA review, Congress intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976.[521]

The USSC remarked that Medtronic Inc.'s characterization of the 510(k) clearance process as a standard to evaluate a medical device's safety overstated its importance and its ability to evaluate safety:

> [t]he company's defense exaggerates the importance of the § 510(k) process and the FDA letter to the company regarding the pacemaker's substantial equivalence to a grandfathered device. As the court below noted, ''[t]he 510(k) process is focused on *equivalence*, not safety.'' 56 F.3d, at 1348. As a result, ''substantial equivalence determinations provide little protection to the public[…].'' The design of the Model 4011, as with the design of pre–1976 and other ''substantially equivalent'' devices, has never been formally reviewed under the MDA [*Medical Device Amendments* (1976)] for safety or efficacy."[522]

The USSC, citing the lower court, further stated that the standards were not "sufficiently concrete"[523] to reflect scientific evidence requirements meant to evaluate medical device

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[520] *Ibid*.

[521] *Ibid* at 2254-55.

[522] *Ibid* at 2254.

[523] *Ibid*.

safety and effectiveness.[524] The finding of this case was also upheld in *obiter dicta* in *Riegel v. Medtronic, Inc.* (2008).[525]

In 2011 the Institute of Medicine of the National Academies ("IOM") published a report on the ability of the 510(k) clearance process to protect public health through its twelve-member Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process.[526] Like the consensus at the USSC, the IOM unanimously concluded that the 510(k) clearance process was not intended, with limited exceptions, to assess the safety and effectiveness of medical devices, and that in function it could not serve as a premarket scheme to provide reasonable assurance of safety and effectiveness.[527]

The IOM recommended that any investment to amend the 510(k) scheme would not be a 'wise" use of resources.[528] Instead, it suggested Congress abandon the 510(k) scheme and replace it with a new "integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device lifecycle."[529] Its recommendations for a new scheme were described by the Chair, David R. Challoner, to be "focused on strengthening the science base needed to make better-informed regulatory decisions and on giving the FDA the tools that it needs to identify and remove problematic devices from the market."[530] Before the report was published, it received substantial resistance from allies within the medical

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[524] *Ibid*.

[525] *Riegel*, *supra* note 204.

[526] IOM "Report", *supra* note 195 at 139: (the committee consisted of various representatives generally from legal and medical backgrounds, and all members reached unanimous consensus on the conclusions and recommendations, *ibid* at v, xiii).

[527] *Ibid* at 5 [Conclusion 7-1].

[528] *Ibid* at 7.

[529] *Ibid* at 8.

[530] *Ibid* at xii.

device industry, as reported by the *New York Times,* in anticipation that the committee would likely recommend a "tougher approval process."[531] They reported that medical device industry allies were "waging an extraordinary campaign in Washington to discredit [the] coming report by one of the country's pre-eminent scientific groups that examines possible new regulations on the industry."[532]

The 510(k) clearance process that is based on permitting medical devices to enter the market if a person can demonstrate substantial equivalence to a previous medical device (including substantial equivalence of safety and effectiveness), is implied, if not nearly explicit, under s. 32 of the *MDRs*. As discussed, only for NP-IVDDs, a highly narrow category of medical devices, is there a requirement for clinical evidence to derive from testing "conducted on the device" (see Table 1). Even for highest risk medical devices (Class IV), there is an absence of a requirement that the clinical evidence be "conducted on the device." The practical effect of the scientific evidence requirements under s. 32 of the *MDRs* do not provide significant assurance that a medical device is safe and effective upon its market entry based on the text of the law that does not require evidence of safety and effectiveness to derive from the licensee medical device. In legal effect, the scientific evidence requirements do not hold manufacturers liable to a high standard of methodological rigour.

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[531] Barry Meier "Study of Medical Device Rules Is Attacked, Unseen" *New York Times* (27 July 2011), online: <www.nytimes.com/2011/07/28/health/28institute.html>.

[532] *Ibid*.

5.2.1.2.3. Regulatory History

The regulatory history of the *MDRs* must also be examined to shed light on the dominant purpose of the scientific evidence requirements.[533] The *MDRs* were promulgated in 1998 and were prompted by a 1991-1992 report of the Medical Devices Review Committee known as the Hearn Committee.[534] The Hearn Committee was established by a former Minister of National Health and Welfare in February 1991, Ambrose M. Hearn,[535] and its purpose was to make recommendations to the existing medical device scheme in view of the increased "volume and complexity" of the medical device market and "the need for timely availability of safe and efficacious devices in the next decade."[536]

The Hearn Committee was part of a broad initiative to evaluate federal regulatory programs.[537] The Hearn Committee's report did not discuss specific safety incident(s) that prompted a political will to change federal medical device regulation. The Committee remarked that while Canadians have been exposed to "dramatic" medical device issues, "these are not common occurrences."[538] The overall thrust of the Report was that a new regulatory model should address safety "flaws" while also being adaptable to "rapidly changing technology" by being "efficient and effective."[539]

The Committee consisted of nine members including the chairman who worked in health facilities accreditation, the committee advisor who was a biomaterials professor,

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[533] As discussed in Chapter 4.

[534] Canada, Regulatory Impact Analysis Statement, SOR/98-282, (1998) C Gaz II 1680 at 1680-81 [RIAS].

[535] Canada, Medical Devices Review Committee, "Direction for Change: Report of the Medical Devices Review Committee" (Ottawa: The Committee, 1992) at 16 [Hearn Committee].

[536] *Ibid* at 85; see also RIAS, *supra* note 534 at 1689-90.

[537] Hearn Committee, *ibid* at 2.

[538] *Ibid* at 1.

[539] *Ibid*.

and seven representatives from various bodies: the Canadian Hospital Association, Medical Devices Canada, Canadian Dental Association, Consumer's Association of Canada, Canadian Coordinating Office for Health Technology Assessment, Canadian Nurses Association, and Canadian Medical Association.[540] Various other consultations were held with industry, government, academia, health care professionals and consumers, after this report was published and leading up to the final promulgation of the 1998 *MDRs*.[541]

The *MDRs* were said to be consistent with the recommendations made by the Hearn Committee.[542] Since their enactment in 1998, the scientific evidence requirements (ss. 9(2) and 32) have not been substantially amended. Only minor and non-substantive sentence re-phrasing has occurred; for example, substituting "the safety and effectiveness requirements" for "ss. 10-20" (the provisions of which are entitled "Safety and Effectiveness Requirements."[543]

Besides the Hearn Committee's report as relevant background to the *MDRs*, the 1998 "Regulatory Impact Analysis Statement" ("RIAS") for the *MDRs* (SOR/98-282) stated that the purpose of the regulations was "to ensure that medical devices distributed in Canada are both safe and effective."[544] The RIAS also emphasized that the regulatory initiative was to assure those in the health care community that medical devices have

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[540] *Ibid* at 86-87.

[541] RIAS, *supra* note 534 at 1690.

[542] *Ibid* at 1681.

[543] See *Medical Devices Regulations*, SOR/98-282, (1998) C Gazette II beginning at 164, s. 1 "objective evidence; ss. 9(2), 32, online:<https://www.gazette.gc.ca/rp-pr/p2/1998/1998-05-27/pdf/g2-13211.pdf> (original date-in-time regulations).

[544] RIAS, *supra* note 534 at 1680.

undergone appropriate degrees of premarket scrutiny proportional to the risk of the medical device:

> [there is a need to] provide assurance to the health care institutions that the devices they purchase have undergone the appropriate pre-market scrutiny for the risk that the device presents. The licensee will be provided with physical evidence of compliance by means of the medical device licence and therefore will allow health care institutions to be assured that the devices they use are safe, effective and of high quality. The licensee may then respond to any purchasers (hospitals) requests for certification of compliance with the requirements of the Medical Devices Regulations without delay.[545]

Another practical effect of the 1998 *MDRs* described in the RIAS was that the regulations would provide greater assurance to the Canadian public that medical devices would be safe and effective:

> Canadians must have confidence in the regulatory measures undertaken by the TPP [Therapeutic Products Programme, the responsible authority under Health Canada] to provide safe and effective medical devices. This regulatory initiative impacts positively on the Canadian public as increased safety assurances will result from the introduction of pre-market scrutiny….[546]

Therefore, the need to maintain public confidence in medical device safety and effectiveness within the health care community and the general public was highlighted as a practical effect of the *MDRs*. Overall, the RIAS statement suggests that the purpose of the *MDRs* was to help maintain public confidence in the market entry of medical devices to assure the public of their safety and effectiveness.

5.2.1.2.4. Audits of the Administration of the MDRs

As discussed in Chapter 4, how laws or regulations have been administered by those tasked with administering a scheme has been accepted by courts as valid extrinsic

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[545] *Ibid* at 1687-88.

[546] *Ibid* at 1688.

evidence of a provision's dominant purpose.[547] Audits of a law's administration similarly supplies reliable evidence of a law's administration. Health Canada's administration of the *MDRs* has been subject to three Auditor General of Canada investigations that occurred in 2004, 2006, and 2011.

The 2004 report was undertaken to examine Health Canada's management of a medical device's risks and benefits across its lifecycle (premarket and postmarket as discussed in Chapter 2).[548] In terms of Health Canada's oversight of medical devices prior to market entry, the 2004 report highlighted inadequacies in Health Canada's inspections of manufacturing facilities and observed that there was insufficient oversight of investigational testing. The report stated that "Health Canada is aware of the gaps and weaknesses in the Program but has made limited efforts to address them."[549] The report stated that the *MDRs*, in legal and practical effect, placed "significant responsibility on the industry to do all it can to protect the health and safety of the public"[550] and "to a lesser degree, on health care professionals."[551] The report noted that Health Canada did not inspect the data from investigational tests and therefore could not "verify the quality or integrity of the results of the investigational tests when making its decision on whether

[547] Hogg & Wright, *supra* note 51 at §15:9 ("Effect"): ("[t]here have been cases in which the court has examined the administration of a statute as an aid to classifying it for constitutional purposes.").

[548] Canada, OAGC, 2004 *supra* note 3 at 2.

[549] *Ibid* at 2.

[550] *Ibid* at 5.

[551] *Ibid* at 9.

or not to authorize the sale of devices."[552] It also observed that Health Canada generally devotes fewer than ten days in the review of medical device licence applications.[553]

The report highlighted several deficiencies in the postmarket phase of medical device regulation: "Health Canada does not engage in any inspection activity at the post-market phase and does not know the extent to which the *Regulations* are being respected."[554] In sum, the report concluded:

> Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk—risk of both injury and liability.[555]

The 2006 report was broader in its focus, examining the adequacy of how Health Canada allocates funding in relation to its regulatory responsibilities in three programs: product safety, drugs, and medical devices.[556] The report determined that Health Canada needed a coherent funding plan to ensure that funding reflects public health needs.[557] The report repeated several of the concerns raised in the 2004 report, and it emphasized that it was not clear what Health Canada was "trying to achieve."[558]

The 2006 report further noted that program managers were concerned that its own

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[552] *Ibid* at 3.

[553] *Ibid* at 17 (in contrast, the US FDA takes on average 1,200 hours to review a device that has undergone investigational testing, and 20 hours on a device that uses the 510(k) clearance process, see IOM, *Report*, *supra* note 130 at 229).

[554] *Ibid* at 19.

[555] *Ibid* at 1.

[556] Canada, OAGC 2006, *supra* note 3 at 1.

[557] *Ibid* at 1-2.

[558] *Ibid* at 3: ("the Department needs to decide what it is trying to achieve, what its priorities are, and direct resources toward programs and services that help Canadians. It then needs to monitor its programs to ensure that they are achieving the intended results.").

programs were insufficiently funded to protect the public.[559] For example, the program or department that oversaw medical device clinical radiation protection for products including x-rays, lasers, and sunlamps believed that the public was exposed to health risks; though its managers requested funding to better observe this area, the funding fell short.[560] The 2006 report stated that "the budget for core funding for the three programs audited has significantly decreased over three years: 10 percent for the Product Safety program…, and 50 percent for [the] Medical Devices program."[561] However, it also noted that "[u]nfulfilled regulatory responsibilities are not systematically reported to the Departmental Executive Committee."[562]

The 2011 report primarily observed Health Canada's practices in the postmarket phase of risk management, along with review timelines.[563] This thesis only focuses on the premarket (market entry) stage; however, it is significant that the Office made the following overall core conclusion:

> [o]verall, we concluded that Health Canada has not made satisfactory progress in acting on commitments it made in response to recommendations from our 2004 and 2006 reports. <u>While overall program funding has increased and program capacity has been enhanced, primarily at the post-market stage, the Department is not fully meeting its obligations in relation to medical devices.</u>[564]

These reports, as evidence of the *MDRs* effects, rebut the *prima facie* objective of the overall licensing scheme as having a dominant purpose of public protection. Public

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[559] *Ibid* at 8.

[560] *Ibid* at 8.

[561] *Ibid* at 14.

[562] *Ibid* at 21.

[563] Canada, OAGC 2011, *supra* note 3.

[564] *Ibid* at 31 [emphasis added].

protection is not reflected in how the law is administered by Health Canada at least across the timeframe these audits occurred (2004-2011).

5.2.1.2.5. Case Law Consideration: ss. 9(2), 10-20, and 32 of the MDRs

The impugned sections under Part 1 of the *MDRs* (ss. 9(2) and 32; but also ss. 10-20) have not been questioned on constitutional grounds, nor have the *MDRs*. However, how courts have come across these provisions may provide extrinsic evidence into the dominant purpose of the impugned laws (ss. 9(2) and 32). The only listed case that cites s. 9 (ss. 9(1)-(2)) is *Klein v. American Medical Systems Inc.* (2005) in relation to whether a class action could proceed against Health Canada/Attorney General of Canada ("AG") in a case of alleged negligence in the licensing of "a silicon-coated sling-mesh with 'InhibiZone'" [pelvic mesh] for female incontinence.[565] The class action alleged that Health Canada:

> (a) …failed to take the necessary steps to approve the Device…
> (b) …failed to test or adequately test the Device when it approved it for sale, supply and use in Canada…
> (c) …relied on skewed tests submitted by the manufacturer …
> (d) It knew or ought to have know[n] the Device was unsafe, untested or inadequately tested…
> (e)…showed a reckless disregard for the lives and safety of Canadians into whose body the untested or inadequately tested Device would be inserted, in particular the Plaintiff Lorraine Klein…
> (f) …misrepresented that the Device had been tested or adequately tested and was safe for its purpose and use…
> (g)… was complicit in supplying the Device without warning and without knowledge as to whether the Device was safe...[566]

Specifically, the case was an unsuccessful motion by the Crown to dismiss the class action against it on grounds that it did not owe a private duty of care. While the

[565] *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ) at para 2 [*Klein*, 4910].
[566] *Ibid* at para 3.

allegations made against Health Canada in the above were not verified,[567] the AG did not explicitly deny the claims; instead, the AG argued that it did not owe a private duty of the care, which is assessed prior to determinations of standard of care assessments. The Court also referenced the AG's claim that the *MDRs* do not specify how medical device safety and effectiveness is assessed, which demonstrates that Health Canada maintains, in legal effect, complete discretion over the type of scientific evidence required prior to the issuance a medical device licence: "Counsel for the AG submits that the Department of Health and the Food and Drug Acts and the Medical Devices Regulations do not impose any duty on the Minister to test medical devices, nor do they specify how the Minister is to determine whether a device meets safety and effectiveness requirements."[568] As noted in the intrinsic evidence, there is largely no requirement under the *MDRs* to test a medical device to verify its safety and effectiveness prior to the issuance of a licence, even though licences are issued upon the core condition that the safety and effectiveness requirements under ss. 10-20 were met.

The decision was reversed in *Klein v. American Medical Systems Inc.* (2006),[569] where it was determined that it would be unwise for policy reasons to impose a private law duty of care on the federal government in this context,[570] partially because the

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[567] Regulatory decision summaries are published selectively by Health Canada, and there is an absence of public information respecting the scientific evidence used in support of this device's market entry. For example, currently, there are no Regulatory Decision Summaries for any of the four intragastric balloons that have been available in Canada. These include: 1) Endball – Systeme de Ballon Intra-gastrique manufactured by Endalis (licence was revoked as of February 2019); 2) Reshape Medical Intragastric Balloon manufactured by Reshape Medica (licence was revoked as of February 2019); 3) Orbera System Intragastric Balloon manufactured by Apollo Endosurgery Inc, and; 4) Spatz3 Adjustable Balloon System Insertion Kit manufactured by Spatz Fgia (Israel) Ltd.).

[568] *Klein*, 4910, *supra* note 565 at para 27 [emphasis added].

[569] [2006] OJ No 5181 (Ont Div Ct).

[570] *Ibid* at paras 37-39.

"spectrum of unlimited liability to an unlimited class" would be large.[571] The only cases citing s. 32 in relation to the contents required in a licence application for Class II-IV medical devices were also these two cases. There are no relevant cases that cite ss. 10-20.[572]

The case series appears to affirm that Health Canada maintains significant discretion in allowing a medical device onto the market with little constraint over the scientific rigour of scientific evidence requirements for safety and effectiveness.

5.2.1.3. Conclusion: Dominant Purpose

As discussed in Chapter 4, the dominant purpose of ss. 9(2), and 32 of the *MDRs* is informed by the law's text (intrinsic evidence), its context (extrinsic evidence) and its legal and practical effects. The characterization process is an objective determination in the sense that it is not dependent on how Health Canada or other party defines its purpose.

To define the dominant purpose of the scientific evidence requirements as a law that is aimed at public protection, specifically laws that are meant to verify the safety and effectiveness of medical devices to prevent unsafe and ineffective medical devices from market entry though a licensing scheme, is overly simplistic. The exceptions are the scientific evidence requirements for NP-IVDDs, which are more likely to be defined as laws that are meant to protect the public by providing assurance of safety and effectiveness by means of a requirement for clinical evidence based on testing of the licensee medical device.

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[571] *Ibid* at para 37.

[572] See Appendix A for detailed section-by-section note-up, and summary of outstanding cases.

The absence of emphasis under the *MDRs* for reliable forms of scientific evidence to substantiate safety and effectiveness under ss. 9(2) and 32 weighs against the characterization of the licensing scheme as having a dominant purpose centred around the protection of the public from unsafe or ineffective medical devices. There does not appear to be empirical evidence to determine if Part 1 of the *MDRs* have any practical effect on ensuring safety and effectiveness.

One of the purposes of the scientific evidence requirements, and *MDRs* more broadly, was to increase confidence among consumers, as explained in the RIAS, that medical devices imported or sold in Canada are safe and effective. However, fostering consumer trust in medical device safety and effectiveness may be more precisely for the dominant purpose of health promotion by means of non-rigorous scientific evidence requirements to facilitate faster market access to medical devices.

These non-rigorous scientific evidence requirements may, in the alternative, be for the dominant purpose of supporting the medical device industry through less costly substantiation (scientific evidence) requirements to facilitate access to the market with a licence that facially attests to safety and effectiveness, which regulates the informed consent process for medical device-related trade by fostering consumer confidence in these products. These dominant purposes characterizations are further explored in Chapter 6 in the context of the *ATPAs*.

5.2.2. Classification

Assuming that the criminal law power is the only available constitutional basis to support the scientific evidence requirements as described in Chapter 3, the dominant purpose characterizations would not fall within requirements for valid criminal law. To

meet the requirements of valid criminal law, a provision must generally have: 1) a valid criminal law purpose; 2) (typically) in the form of a prohibition; 3) that is backed by a penal sanction. If a law's dominant purpose, however, does not fulfill the substantive criminal law purpose requirement (to suppress harm from threatened interests) then it cannot be supported by the criminal law power.

The dominant purpose of the scientific evidence requirements does not fulfill the valid criminal law purpose requirement. Regulating contracts or commercial transactions in an industry or business falls into provincial jurisdiction under property and civil rights, s. 92(13).[573] Similarly, regulating medical devices for purposes of health promotion is not a valid criminal law purpose as described in Chapter 3.[574]

The ancillary powers doctrine could unlikely be invoked to support the validity of the scientific evidence requirements under the criminal law power. The scientific evidence requirements under ss. 9(2) and 32 are the most pivotal aspects of medical device licensing to the extent they affect the characterization and validity of the entire mainstream market entry scheme under Part 1 of the *MDRs* against a public protection characterization.

5.2.3. Conclusion

The federal government is constrained under s. 91 of the *Constitution Act, 1867* in the sphere of regulating medical devices in relation to safety and effectiveness. The dominant purpose of regulating the safety and effectiveness of medical devices must likely be premised on objectives in relation to the criminal law power.

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[573] See *Can Nat Transportation*, *supra* note 269 at 258.

[574] See *Reference re GNDA*, *supra* note 60; *Swain*, *supra* note 312.

To meet requirements of valid criminal law, a licensing scheme must be found to have a dominant purpose, a relatively rigorous threshold, in relation to suppressing harm from threatened interests. A federal licensing scheme for medical devices cannot, in its dominant purpose, turn on promoting health or promoting economic objectives in a regulated industry through licences that facially attest to safety and effectiveness because it would not meet the "suppression of harm" requirement. If laws do not prevent harm in their practical effect, this is also likely to weigh against the ability of a law's dominant purpose as being in relation to the suppression of harm. The existing scientific evidence requirements do not predictably prevent harm because of the absence of reliable scientific evidence requirements.

As discussed in Chapter 4, in *Reference re GNDA*, the practical effects of the law significantly weighed into the dominant purpose determination in all three judgments. To reiterate Karakatsanis J.'s statement: "[c]rucially, Parliament's purpose in enacting the provisions in question is borne out in the provisions' effects."[575] A law that does not in practical effect require a high scientific evidentiary bar while issuing licences that attest to a high standard of safety and effectiveness may not be characterized as meeting the core criminal law purpose requirement of suppressing harm.

Challenging the scientific evidence requirements on federalism grounds has the potential to help compel and create expectations for explicit and reliable forms of scientific evidence that are more likely to provide reasonable assurance of a medical device's safety and effectiveness. Methodologically rigorous scientific evidence

[575] *Reference re GNDA supra* note 60 at para 64.

requirements will further help ensure that the suppression of harm is "borne out"[576] in the law's practical effects.

5.3. Validity of Law-Making Authority for Part 1 of the *MDRs*

This section analyzes the constitutional validity of the law-making authority under s. 30(1) of the *F&D Act* that permits the executive branch of government to determine all aspects of medical device licensing, including scientific evidence requirements, and therefore all conditions governing their market entry.

5.3.1. Characterization

5.3.1.1. Intrinsic Evidence: Text of the Law-Making Authority

Under s. 30(1) of the *F&D Act* Parliament had delegated broad law-making authority to the executive branch of government, namely the Governor in Council (in effect Health Canada as discussed in Chapter 2) respecting an array of matters related to the marketing of medical devices, as well as drugs and cosmetics.

The substantive scope of law-making authority granted to the executive branch of government is by its explicit wording non-exhaustive because the law in legal effect authorizes the executive branch of government to make regulations "for carrying the purposes and provisions of this Act into effect…but without restricting the generality of the foregoing."[577] Examples of major substantive law-making authority governing the marketing of medical devices include, but are not limited to: labelling and advertising;[578]

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[576] *Ibid*.

[577] *F&D Act*, *supra* note 1, s 30(1).

[578] *Ibid*, s 30(1)(b)(i).

conditions of sale to prevent a person from being deceived in terms of quality/value;[579] and testing "in the interest of, or for the prevention of injury to, the health of the purchaser or consumer."[580] The executive branch of government is therefore provided with substantial discretion under this enabling law, and they are not legally compelled to enact laws (i.e., 'promulgate regulations') in respect to these non-exhaustive enumerated matters.

Any regulation promulgated by the Governor in Council (Health Canada) is backed with serious penal sanctions as discussed in Chapter 2, which connotes the seriousness of any violation of a regulation made by Health Canada. This law-making authority further enables Health Canada to define standards of prohibited conduct on a broad discretionary basis for a vast array of matters (licensing, testing, etc.). For example, all requirements for licensing of medical devices under Part 1 of the *MDRs*, as well as custom use or 'special access' market entry pathways, have been defined by Health Canada.

5.3.1.2. Extrinsic Evidence: Context of the Law-Making Authority

5.3.1.2.1. Legislative History and Other Parliamentary Commentary

This section reviews the legislative history of s. 30(1) of the *F&D Act*, which was enacted under *An Act respecting Food, Drugs, Cosmetics and Therapeutic Devices* (1952-53).[581] Although the section numbers have been changed since their original enactment under the 1952-53 *Act*, the impugned provisions under s. 30(1), as delineated

[579] *Ibid*, s 30(1)(b)(iii).

[580] *Ibid*, s 30(1)(e).

[581] *Food and Drugs Act*, 1952-53, *supra* note 67.

above, are substantively unchanged.[582] For these reasons, the enacting legislature in 1952-53 is the relevant Parliament to ground the discussion of the legislative history of s. 30(1).[583]

The legislative history of s. 30(1) reveals concerns over the scope of law-making authority to the executive branch of government from a government accountability perspective. The discussions arose in the *Votes and Proceedings: Senate Committee on Public Health and Welfare* where the bill-form of the 1952-53 *Act* was considered clause-by-clause.[584] The following passage demonstrates the regulator's desire to maintain control over defining prohibitions related to the offence of "adulteration" (a broad term for unsafe, ineffective or 'unpure' products) with flexibility to avoid being confined to specific and detailed primary legislative requirements:

> Hon Mr. Hayden [Senator]: You [the Regulatory Official] are creating a lot of problems if you take complete power in the Governor in Council to define generally or in relation to a particular food or drug what shall constitute adulteration. You are just taking away from us any authority to say what we think about your definitions.[585]…once the statute is passed it will endure for some time and we do not know who will be writing the definition in [the] future.[586]
> …
> Mr. Curran [Regulatory Official]: …the purpose of delegating to the Governor in Council the authority to define 'adulteration' by regulation is that we recognize the difficulty of coining at the present time a definition which would be all-inclusive…The object was to give the flexibility which we think is desirable if we are going to make 'adulteration' apply to those foods which are regarded as adulterated.[587]

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[582] Gary P Rodriguez, "Legislative Histories, Food and Drugs Act" in *Crankshaw's Criminal Code of Canada,* s 30; see *Food and Drugs Act*, 1952-53*, supra* note 67, s 24(1).

[583] *Big M Drug Mart*, *supra* note 415.

[584] Senate, *Votes and Proceedings: Senate Committee on Public Health and Welfare*, 21st Parl, 7th Sess, vol 1 at 14, online: <https://parl.canadiana.ca/view/oop.com_SOC_2107_2_1/18?r=0&s=1> [*Senate Committee Public Health*].

[585] *Ibid* at 56.

[586] *Ibid* at 57.

[587] *Ibid* at 58.

> …
> Hon. Mr. Roebuck [Senator]:…there is another viewpoint, and it is that the general public should be able to read in the statue what is prohibited and what is not prohibited, and that this matter should not be decided in little pieces behind closed doors. I think that is the substance of Senator Hayden's objection, that parliament should determine what is meant by 'adulteration', rather than that the question should be left in flux from time to time as you gentlemen of the department come to the conclusion that you should take another step forward or backward.[588]

The Honourable Mr. Hayden expressed concern about the potential for an absence of general public knowledge if the prohibited offence of 'adulteration' was left to the executive branch of government to discretionarily define on an ex post basis.[589] The Senator broadly advocated against delegating matters to the Governor in Council under the *Act*: "I object on principle to delegating our powers to the Governor in Council…I have protested against the delegation every time I had an opportunity…"[590] These concerns were reiterated by the Honourable Mr. Roebuck. Both Senators expressed disapproval over the scope of law-making authority to the executive branch of government from the general perspective of government accountability.

Committees in the House of Commons have also discussed the scope of law-making authority under s. 30(1) of the *F&D Act* post-1952-53.[591] In Parliamentary statements from the *Minutes of Proceedings and Evidence of the Special Committee on Regulatory Reform* (1980), Health Canada (previously the Department of National Health and Welfare) has described their approach to promulgating or deleting regulations as one

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[588] *Ibid* at 59 [emphasis added].

[589] *Ibid* at 57: ("…whether we are going to have some knowledge of what the definition is or whether the definition is to be made by the Governor in Council. My choice would be for a statutory definition.").

[590] *Ibid*.

[591] See Canada, House of Commons, *Minutes of Proceedings and Evidence of the Special Committee on Regulatory Reform* (6 November 1980) at 24:6 online: <https://parl.canadiana.ca/view/oop.com _HOC _3201_41_3/466?r=0&s=1> [*Special Committee on Regulatory Reform*].

where they work "very closely and deeply to involve the private sector"[592] based on "elaborate and extensive consultation and communications procedures" with industry.[593] Dr. A. B. Morrison, (Assistant Deputy Minister, Health Protection Branch, Department of National Health and Welfare) stated:

> we have long held the view and articulated it on numerous occasions with, for instance, the drug industry, that the best relationship which we can have with them is one taken from the eighteenth verse of the first chapter of Isaiah in the Old Testament: 'Come now and let us reason together'. We really believe that it is in reasoning together and in avoiding the atmosphere of confrontation and a kind of Mexican stand-off which characterizes too much of the relationship between the regulator and the regulate in other countries that we have been able to achieve the kind of a profitable interaction with the regulated sector that we have.[594]

Section 30(1) creates a rulemaking procedure that in legal and practical effect likely enables the industry on the "rational basis" standard[595] to influence requirements for the market entry of medical devices, including scientific evidence requirements, in a way that is favourable to private rather than public interests.

Section 30(1) also authorizes the executive branch of government to rely on voluntary standards of conduct as described in the *Special Committee on Regulatory Reform* (1980) because it does not require the promulgation of any regulation:

> Dr. Morrison: In a number of instances we have moved away from formal regulations to the production of guidelines, which are guidance for the industry but are not legally binding upon the industry. This has been widely accepted by the industry and has, I suppose, de facto, the ultimate effect in terms of regulatory control of regulations, yet it reduces the legal burden on the industry and it has been invoked by voluntary collaboration and co-operation with the industry.

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[592] *Ibid* at 24:7.

[593] *Ibid* at 24:9.

[594] *Ibid* at 24:9.

[595] See *Reference re Anti-Inflation*, *supra* note 277 at 423.

> The Chairman (James Peterson, MP): Could I just interrupt you here, Doctor Morrison?
>
> Dr. Morrison. Please.
>
> The Chairman: Why is there any difference between a legal requirement and a guideline? You are getting the same type of compliance
>
> Dr. Morrison: One is invoked by law; the other is invoked by voluntary co-operation. The end result is, of course, the same.
>
> The Chairman: The end result is the very same?
>
> Dr. Morrison: That is right.
>
> The Chairman: Are you going more and more to that voluntary type?
>
> Dr. Morrison: I see us going more and more to voluntary compliance by the industries.
>
> The Chairman: Voluntary compliance—you will still set the standards in the same fashion as you have in the past?
>
> Dr. Morrison: Yes, we will, by extensive consultation and by mutual agreement that this is an acceptable standard.
>
> The Chairman: Why do you feel voluntary compliance is better than compliance with some form of positive law?
>
> Dr. Morrison: It seems to be that there is a kind of atmosphere of mind that is involved, and that is that those who voluntarily comply and do not do so by reason of legal obligation are perhaps more committed themselves to carrying out the requirements. There has clearly to be a mix of regulation and voluntary compliance, and there has to be a willingness and a perceived ability to move to regulation when regulation is required, but regulation is not necessarily the only way.[596]

The approach of forming cooperative relationships with industry and establishing voluntary standards by issuing guidelines rather than objective requirements is consistent with the approach taken under the *MDRs*. Although the *MDRs* are a form of binding law rather than a guidance document, reliable forms of scientific evidence in legal effect remain voluntary because of the vagueness of these scientific evidence requirements.

Section 30(1) in practical effect further facilitates conditions for regulatory capture, which occurs "when regulated entities have substantial influence over

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[596] *Special Committee on Regulatory Reform*, *supra* note 591 at 24:12.

policymaking."[597] The term is invoked in the context of an agency that has allegedly "failed to serve the public interest, as Congress [or Parliament, in Canada] intended."[598] Facilitating regulatory capture may be a practical effect of s. 30(1), and in some ways a legal effect of s. 30(1), because it creates conditions for rulemaking where the industry is well-funded to influence the executive branch of government over the content of the law with relatively little oversight from Parliament.[599]

In the context of regulatory reform discussed in the House of Commons' *Sub-Committee on Regulations and Competitiveness of the Standing Committee on Finance*[600] (1992), it has been pointed out that the purpose of delegating matters to the Governor in Council or to permit Ministerial discretion is to ensure the flexibility of legal schemes.[601] This purpose is consistent with the SCC's interpretation of the modern statute in *Labatt Breweries* (1979), where the *F&D Act* was characterized by its regulatory nature by way of the law-making authority (regulation-enabling power).[602] In the discussions of this *Sub-Committee* (1992), the Director of Regulatory Affairs (Treasury Board of Canada) stated that delegated law-making authority that is overly flexible can enable actions, or

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[597] Shapiro, Sidney A. "The Complexity of Regulatory Capture: Diagnosis, Causality, and Remediation" (2012) 17:1 Roger Williams U L Rev 221 at 223.

[598] *Ibid*.

[599] See e.g. Graeme G Mitchell, "Not a General Regulatory Power: A Comment on Reference re Assisted Human Reproduction Act" (2011) 54:22 SCLR 633 at 640 ("[t]ypically, regulations are promulgated with little, if any, prior public scrutiny").

[600] Canada, House of Commons, *Minutes of Proceedings and Evidence, Sub-Committee on Regulations and Competitiveness of the Standing Committee on Finance*, 34th Leg, 3rd Sess, Vol 1 (7 May 1992) (Mr. James K Martin, Director of Regulatory Affairs, Treasury Board of Canada) [*Sub-Committee on Regulations and Competitiveness*], online: <https://parl.canadiana.ca/view/oop.com_HOC_3403_94_1/11?r=0&s=1>.

[601] See *infra*.

[602] *Labatt Breweries*, *supra* note 259.

enable regulations, that could be inconsistent with the parameters intended by Parliament, or within the authority of Parliament under s. 91 of the *Constitution Act, 1867*:

> The difficulty in getting hold of a regulatory framework, which is going to be useful for any particular industry is extraordinarily complicated, because of the many special interests in there... A lot of things have been put in place by the governor in counsel or a minister. The main reason for that is obviously to try to introduce more flexibility into the legislative frameworks. Legislation, as we all know, is very difficult to achieve. There is this balance between flexibility and what's at a minister['s] discretion versus parliamentary authority[,] at getting hold of the philosophy and the laying out the objective. How does one balance that in a reasonable sort of way so one structure[s] the minister['s] discretion properly to be able to respond to these changing conditions, yet still act within the parameters set by Parliament? It's a very complicated problem.[603]

As the Director stated, balancing "ministerial discretion versus parliamentary authority" was a "complicated problem."[604]

Another practical effect of s. 30(1) is that it may erode federalism as a governance structure if discretion is substantially untailored. For example, laws that delegate significant flexibility to the executive branch of government, such as s. 30(1), can result as inferred from this passage in unconstitutional actions taken by executive branch of government. If it is assumed that the current scientific evidence requirements under Part 1 of the *MDRs* as enabled under s. 30(1) are *ultra vires*, then these requirements would be an unconstitutional effect that flows from this broad enabling law-making power.

5.3.1.2.2. Case Law Consideration

The scope of enabling powers to make regulations under the *F&D Act* was also discussed in the only appellate case to determine the constitutional validity of enabling

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[603] *Sub-Committee on Regulations and Competitiveness*, *supra* note 600 1:30-31 [emphasis added].
[604] *Ibid*.

powers under s. 30(1), which was *Labatt Breweries* (1979).[605] The case specifically determined the validity of s. 30(1)(c) that permitted the Governor in Council to enact regulations for purposes of "prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device."[606] The impugned provision was then enacted as s. 25(1)(c) under the *Food and Drugs Act*, RSC 1970.[607] Estey J. writing for the majority (Martland, Dickson [prior to CJ.], Beetz and Pratte JJ. concurring) found the enabling power under s. 25(1)(c) *ultra vires* as it applied to the product in issue, malt liquor.[608] Regulations made under s. 25(1)(c) were also *ultra vires* in relation to malt liquor.[609]

Both the majority and the dissenting opinions defined the *F&D Act* in "regulatory" terms. Estey J. for the majority implied that the law-making powers were a core characteristic of the *F&D Act* that differentiated it from the predecessor statute, which was the *Food and Drugs Act*, RSC 1927. This previous statute was found to have a clearer focus on preventing adulteration and misbranding of food and drugs:

> Under the authority of s. 25(1)(*c*), there has been produced an elaborate set of regulations…We are here concerned principally with Pt. B of the Food and Drug Regulations…. It may be observed that s. 6 was introduced into the Act in 1953 [1952-53, c. 38] and s. 25(1)(*c*) was expanded at the same time to its present form. Prior to that time, the statute was concerned with the adulteration of food, misbranding, the offering of food or drugs for sale as treatment for specified diseases,…[610]

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[605] See Gary P Rodrigues, *Crankshaw's Criminal Code of Canada*, "FDA 30§1 — Constitutionality" (online: Westlaw Edge Canada).

[606] *Food and Drugs Act*, RSC 1970, c F-27, see *supra* note 67.

[607] *Ibid*.

[608] *Labatt Breweries*, *supra* note 259 at para 38: ("I…declare that ss. B.02.130.[S] to B.02.136[S] of the Food and Drug Regulations are invalid and that ss. 6 and 25(1)(c) of the Food and Drugs Act are ultra vires Parliament insofar as they relate to malt liquors.").

[609] *Ibid*.

[610] *Ibid* at para 13 [emphasis added].

> Regulation B.01.042 illustrates the detailed reach of this regulatory pattern.[611]

This passage implies that the public welfare purpose of the new *F&D Act* lost focus under its 'regulatory' nature because of the expansion of law-making authority to the executive branch of government.

As previously cited above, Laskin CJ. in dissent also noticed a "complete revamping of the Food and Drugs Act, 1920 (Can.), c. 27:"[612] "[w]hereas the predecessor Act was limited to protection of the public against adulteration and misbranding, the new Act more clearly addressed itself, by the regulation-making power conferred under s. 25 upon the Governor in Council, to standards of strength and quality as well as labelling."[613] The law-making authority (or 'regulation-making' authority) served as the basis to characterize the *F&D Act* as regulatory as opposed to a 'neutral' law-making tool to advance the objectives of public protection.

5.3.1.3. Conclusion: Dominant Purpose

Insofar as s. 30(1) applies to the licensing of medical devices, the provision may be characterized as enabling flexible policies for their market entry (labelling, testing, scientific evidence requirements, etc.). While protecting the public from unsafe or ineffective medical devices may have been one type of policy objective under s. 30(1) insofar as it relates to medical devices, it is not clear that this objective is its dominant purpose.

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[611] *Ibid* at para 14.

[612] *Ibid* at para 72.

[613] *Ibid* [emphasis added].

Under a dominant purpose analysis, the legal and practical effects of a public welfare scheme must reasonably help advance the public welfare objective. If the legal and practical effects are inconsistent with the scheme's apparent objective (harm prevention), such as administrative tools that are overly discretionary (non-obligatory), it may weigh against the impugned characterization (s. 30(1) of the *F&D Act*) to be held consistent with a public welfare objective. Parliament could be seen to abdicate its responsibility under s. 30(1) to ensure medical device safety and effectiveness by using broad grants of power that do not obligate regulators to enact any regulations.

Permitting the regulator to work cooperatively with industry, a "side-effect",[614] of s. 30(1), may have had and continue to have, a practical effect of institutionalizing regulatory capture in the substance of requirements for the market entry of medical devices. These legal and practical effects weigh against the conclusion that the dominant purpose of s. 30(1) is about preventing public protection based on the public welfare nature of the *F&D Act*.

5.3.2. Classification

It is unclear whether the dominant purpose of s. 30(1) is classifiable under the criminal law power assuming that this is the predominant power that can be used to enable a licensing scheme for medical devices in relation to safety and effectiveness. As elaborated in Chapter 3, laws that must stand in relation to the criminal law power must meet three requirements: 1) a valid criminal law purpose; 2) (typically) in the form of a prohibition; 3) that is backed with a penal sanction. The characterization of the

[614] *References re GGPPA*, *supra* note 61 at para 77: ("A law's practical effects are "'side' effects flow[ing] from the application of the statute which are not direct effects of the provisions of the statute itself": *Kitkatla*, at para. 54.").

dominant purpose of s. 30(1), as being a hosting platform to enable flexible policies by means of significant delegation and discretion to the executive branch of government, does not clearly meet the requirements for a valid criminal law purpose (suppression of harm from threatened interests).

The requirement for a law to meet a valid "prohibition" requirement may also be absent under s. 30(1). As discussed in Chapter 3, in *Hydro-Québec* (1998), the majority found that the impugned statute was valid as criminal law because the control of toxic substances was substantially controlled in primary legislation rather than delegated to the discretion of the executive branch of government: "[i]t is important to underline that what Part II of the Act provides for is a procedure to control toxic substances generally by subjecting the many chemical substances in use in Canada to testing."[615] Under the *F&D Act*, there is an absence of a primary legislative requirement to test medical devices for their safety and effectiveness. Instead, licensing and testing requirements have been established, under the enabling law-making authority of s. 30(1) at the discretion of the executive branch of government. Section 30(1) does not compel any requirements for licensing or testing. Similarly, in *Reference re Firearms* (SCC) (2000), the licensing process to control firearms was substantially defined in the statute and was not delegated to the discretion of the regulator as described in Chapter 3.[616] The Court noted that statutory exceptions to licensing were narrow, limited and defined by Parliament:

> The offences are not defined by an administrative body, avoiding the difficulty identified in the dissenting judgment in *Hydro-Québec*, *supra*. They are clearly stated in the Act and the Criminal Code….Eligibility to hold a licence is delineated in the rest of the Act….These provisions demonstrate that the Act does not give the chief firearms officer or the

[615] *Hydro-Quebec*, *supra* note 319 at para 144.

[616] As discussed in Chapter 3.

> Registrar undue discretion. Furthermore, the chief firearms officer and the Registrar are explicitly subject to the supervision of the courts.[617]

Assuming that s. 30(1) was held dependent on the criminal law power, and may be invalid, invalid provisions may still be saved under the ancillary powers doctrine.[618] Section 30(1) should not be considered an ancillary part of an otherwise valid scheme. The regulation-enabling powers have been held as the defining core feature of the *F&D Act* in *Labatt Breweries* (1979), and not as ancillary to advance a public welfare objective that was more apparent under the previous *F&D Act* considered in *Standard Sausage*.[619] As it relates to medical devices, the impugned provisions under s. 30(1), as far as they enable Part 1 of the *MDRs*, and apply to medical devices, could be held *ultra vires*.

5.3.3. Conclusion

Assuming that s. 30(1) of the *F&D Act* was held dependent on the criminal law power,[620] core provisions for licensing, including scientific evidence requirements, may require a basis in primary legislation to be valid under federal authority. A challenge to the constitutional validity of s. 30(1) on public interest grounds may facilitate this process, and potentially help stabilize methodologically rigorous forms of scientific evidence in medical device licensing under primary legislation. This conclusion rests on the assumption that the federal government could be held to a higher standard of scientific evidentiary rigour when licensing medical devices in relation to safety and effectiveness.

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[617] *Reference re Firearms* (SCC), *supra* note 50 at para 37.

[618] See *Lacombe*, *supra* note 478.

[619] *Labatt Breweries*, *supra* note 259; (*Wetmore*, *supra* note 69 did not consider the enabling powers under the *F&D Act*, and did not review the legislative evolution of the *F&D Act* as had the court in *Labatt Breweries*.).

[620] As discussed in Chapter 3.

CHAPTER 6 VALIDITY: ADVANCED THERAPEUTIC PRODUCTS AMENDMENTS (ATPAS)

6.1. Introduction

This chapter seeks to characterize the dominant purpose of the *Advanced Therapeutic Products Amendments* (*ATPAs*) by reference to intrinsic and extrinsic sources of evidence, and with regard to the *ATPAs*' legal and practical effects. It then seeks to determine whether the dominant purpose characterization is classifiable under federal jurisdiction.

6.2. Characterization

6.2.1. Intrinsic Evidence: Text of the *ATPAs*

Advanced therapeutic products ("ATPs") are "therapeutic products"[621] (including medical devices) that the Minister of Health ("the Minister") believes "represents an emerging or innovative technological, scientific or medical development."[622] The Minister is required to describe the product under Schedule G of the *F&D Act* upon determining that the product is an ATP. The Minister is granted wide discretion to determine if a medical device will meet the definition of an ATP, but is required to consider four broad factors: the known risks and benefits of the medical device; whether there are "measures" to control risks; how similar or different the medical device is from other medical devices; the existence of legal frameworks to prevent physical injury or

[621] *F&D Act*, *supra* note 1, s 2: ("therapeutic product means a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the Natural Health Products Regulations").

[622] *Ibid*, s 21.91(1).

misleading information; and any prescribed factor promulgated by regulation.[623] These factors, along with the definition of an ATP, could in effect enable a broad range of medical devices to be defined as an ATP at the Minister's discretion.

Under the *ATPAs*, it is a prohibited offence for a person to "import, sell, advertise, manufacture, prepare, preserve, package, label, store or test" an ATP medical device without a licence or an order.[624] As discussed in Chapter 2, and referenced in Chapter 5, this prohibited offence is backed with serious penal sanctions.[625]

Licensing is premised on oversight of a product (an ATP medical device), whereas orders are premised on authorizations that permit a pre-vetted person within a "class of persons" to market a product (an ATP medical device) without direct product oversight. Both market authorizations (licences and orders) are further examined below.

Section 21.92 authorizes the Minister to issue a licence to a person with or without terms and conditions if the Minister believes on a broad scientific evidence standard that a person has provided "sufficient evidence" to make two conclusions: (a) that the benefits outweigh its risks, and (b) that risks would be "adequately managed and controlled" (see Table 2). The Minister is provided with full discretion to determine the type of evidence that would be deemed sufficient. There are no specific rules that require a person to undertake "well-controlled investigations" consistent with recognized standards of evidence-based medicine (see Tables 3 and 4). Section 21.93 permits the Minister, subject to any regulations, to suspend or revoke a licence if the Minister believes that the risk of the product outweighs its benefits, that any risks are not being

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[623] *Ibid*, s 21.91(2).

[624] *Ibid*, s 21.9.

[625] See *ibid*, ss 31.2, 31.4

adequately managed or controlled, or for any other prescribed factor defined in regulation. In legal effect, the licensing scheme under the *ATPAs* falls under the near exclusive control of the executive branch of government through the use of flexible and broad standards of enabling powers respecting conditions of licensing.

Section 21.95(1) permits the Minister to make orders with or without terms and conditions to authorize "any person within a class of persons" to legally market an ATP medical device.[626] Factors the Minister must consider in defining "classes of persons" are not defined under the *F&D Act*. Like the licence stream under the *ATPAs*, the executive branch of government is in legal effect provided with broad discretion to define an appropriate "class of persons" and therefore has exclusive discretion to determine if an order can be made that permits a person to market an ATP medical device.

The cornerstone function of the *ATPAs* is vested in ss. 21.94 and 21.96. These sections by default exempt a person who wishes to sell an ATP medical device from all regulations enabled by the *F&D* Act, which include the *MDRs*.[627] Regulations may be prescribed by the Governor in Council (in effect, Health Canada as discussed in Chapter 2) on an 'opt-in' basis as enabled under s. 30 (1.2)(b.2). Section 30(1.2)(b.2) provides the Governor in Council with wide discretion to maintain or make regulations on any matter in respect to the marketing of an ATP medical device.[628] In legal effect, the *ATPAs* appear to be an 'agile' market entry route that a person can take to market a medical device if they are seeking to avoid conformity to the *MDRs*.[629]

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[626] *Ibid*, s 21.95.

[627] See *ibid*, s 21.94 (licence); s 21.96 (order).

[628] *Ibid*, ss 30(1.2)(b.2).

[629] *Ibid*, s 21.9(1).

This agile market entry route is in legal and practical effect under the near complete control of the executive branch of government because it enables this branch to determine the conditions of sale for an ATP medical device through terms and conditions for licences and orders determined on a case-by-case basis. In legal effect, the *ATPAs*' cornerstone function is to exempt a person from regulations they would otherwise be subject to, including the mainstream market entry pathway under Part 1 of the *MDRs*, if seeking to market a medical device.

The legislative history of the *ATPAs* is explored below to further understand the dominant purpose from a policy-centred perspective beyond the intrinsic text. The legislative history is summarized in Figure 1 at the end of the following section.

6.2.2. Extrinsic Evidence: Context of the *ATPAs* (Legislative History)

The *ATPAs*, which amended the *F&D Act*, were part of a budget bill (Bill C-97) to implement various policies described in the executive branch of government's March 2019 budgetary publication, Budget 2019: Investing in the Middle Class.[630] The bill was titled, *An Act to implement certain provisions of the budget tabled in Parliament on March 19, 2019 and other measures*,[631] and was described as an over 350-page omnibus law—a law that seeks to repeal, amend, or enact several acts geared to various policy initiatives.[632] The *ATPAs* fall within Part 4 of Bill C-97 (Various Measures: Division 9

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[630] Canada, *Budget 2019*, *Investing in the Middle Class*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 19 March 2019, online: <www.budget.gc.ca/2019/docs/plan/toc-tdm-en.html> [*Budget 2019*].

[631] Bill C-97, *An Act to implement certain provisions of the budget tabled in Parliament on March 19, 2019 and other measures*, SC c 29 [Bill C-97, assented to June 21, 2019].

[632] See Marc Bosc & André Gagnon, ed, *House of Commons Procedure and Practice*, 3rd ed (Ottawa: 2017) at 730.

Regulatory Modernization: Subdivision C). Four predominant policy amendments to the *F&D Act* occurred under Bill C-97 "to improve safety and enable innovation:"[633]

> Subdivision C of Division 9 of Part 4 amends the Food and Drugs Act to improve safety and enable innovation by introducing measures to, among other things,
> (a) allow the Minister of Health to classify certain products exclusively as foods, drugs, cosmetics or devices;
> (b) provide oversight over the conduct of clinical trials for drugs, devices and certain foods for special dietary purposes;
> (c) provide a regulatory framework for advanced therapeutic products; and
> (d) modernize inspection powers.[634]

The *ATPAs* are the basis of "(c)", which is to "provide a regulatory framework for advanced therapeutic products," and are derived directly from the policy recommendations made in Health Canada's *Health and Biosciences Sector Regulatory Review Roadmap* ("*HBSR*").[635] The *HBSR*, however, is not a policy that stemmed from the administrative agency (Health Canada) but is part of a federal cabinet policy that stems from several budgetary agendas. The policy of the *HBSR* was generated from the seeds of Budget 2017: Building a Strong Middle Class, specifically its Innovation and Skills Plan (ISP).[636] Budget 2017's ISP gained further traction with additions made to it in Budget 2018: Equality + Growth: A Strong Middle Class,[637] and in Budget 2019: Investing in the Middle Class,[638] which culminated in the *ATPAs*.

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[633] Bill-C-97, *supra* note 631, "Summary."

[634] *Ibid* [emphasis added].

[635] Canada, Health Canada, *Health and Biosciences Sector Regulatory Review Roadmap* (Ottawa: Health Canada 2019) (date modified: 7 June 2019; date accessed: 15 December 2019) [Health Canada, *Roadmap*].

[636] Canada, *Budget 2017: Building a Strong Middle Class: #Budget2017*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 22 March 2017, online: <www.budget.gc.ca/2017/docs/plan/budget-2017-en.pdf> [*Budget 2017*].

[637] Canada, *Budget 2018: Equality + Growth: A Strong Middle Class*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 27 February 2018, online: <https://budget.gc.ca/2018/docs/plan/budget-2018-en.pdf> [*Budget 2018*].

[638] *Budget 2019*, *supra* note 630.

The legislative history below begins by explaining the ISP in Budget 2017 and follows the core additions to the ISP relevant to the *ATPAs*, which include Budget 2018's Modernizing Canada's Regulatory Frameworks sub-ISP policy. This sub-ISP policy was the basis of the *ATPAs*.

6.2.2.1. Budget 2017: Policy Seeds of the ATPAs

Budget 2017: Building a Strong Middle Class launched the Innovation and Skills Plan ("ISP"), under "Chapter 1—Skills, Innovation and Middle Class Jobs." The purpose of the ISP is described as "an ambitious effort to make Canada a world-leading centre for innovation, to help create more good, well-paying jobs and help strengthen and grow the middle class."[639] This ISP targets six industries "focus[ed] on expanding growth and creating jobs:"[640] One of these targeted industries was the health/biosciences sector, which is the core industry relevant to the *ATPAs*.[641]

6.2.2.2. Budget 2018: Modernizing Regulatory Frameworks

Budget 2018 developed the same themes presented in Budget 2017 with its focus on job creation, economic growth, and growth of the middle class. The ISP was expanded in Budget 2018 consistent with these core themes.[642] For example, Budget 2018 defined an explicit and more active role of the federal government as a major partner for innovative sectors under the ISP as described under the Innovation and Skills Plan—A

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[639] *Budget 2017*, *supra* note 636 at 44.

[640] *Ibid* at 95.

[641] *Ibid*.

[642] See *Budget 2018, supra* note 637 at 81-82*:* ("[t]his spirit of innovation that Canadians share helped to create the industries and jobs that created and grew Canada's middle class.. we can build a forward-looking economy for Canada, one that our children and grandchildren will want to be a part of, in jobs they are qualified for, and excited to have.").

More Client-Focused Federal Partner for Business.[643] This specific ISP sub-policy, with its focus on the government as a client of industry, has two purposes: creating high-quality jobs, and ensuring the competitiveness of Canadian businesses in a globally competitive marketplace.[644]

A central aspect of this ISP sub-policy is a subheading titled Making it Easier for Entrepreneurs and Companies to Do Business.[645] It consists of three components: A New Intellectual Property Strategy;[646] Modernizing Canada's Regulatory Frameworks;[647] and Simple and Better Procurement.[648] The *ATPAs* are rooted in the Modernizing Canada's Regulatory Frameworks component. This component is described as "an ambitious regulatory agenda," and it was provided with $11.5 million in federal funding over a three-year period that began in 2018-2019.[649] The goal of the regulatory agenda was "to make the Canadian regulatory system more agile, transparent and responsive, so that businesses across the country can explore and act on new opportunities, resulting in benefits for all Canadians."[650]

To advance this goal, the Government of Canada created six Economic Strategy Tables "where there is great potential for Canadian businesses to grow and create high-quality jobs:…digital industries, health/bio-sciences…".[651] The Economic Strategy

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[643] *Ibid* at 100.
[644] *Ibid* [emphasis added].
[645] *Ibid* at 115.
[646] *Ibid* at 116.
[647] *Ibid* at 118.
[648] *Ibid* at 119.
[649] *Ibid* at 115, 118.
[650] *Ibid* at 118 [emphasis added].
[651] *Ibid* at 84.

Tables identified several areas to "drive economic growth and create jobs,"[652] and it identified needed supports to "[c]atalyze innovation" and "[p]romote efficient and predictable regulation."[653]

The Modernizing Canada's Regulatory Frameworks component was, in part, influenced by background recommendations made by the Advisory Council on Economic Growth ("ACEG") *Investing in a Resilient Canadian Economy* (December 2017).[654] The ACEG's report cited the need to adopt a regulatory system that is "open, flexible, and quick to adapt,"[655] to "keep pace with sectors undergoing rapid evolution."[656] Canada's Economic Strategy Tables: Health and Biosciences similarly concluded that the regulatory process in Canada "present[s] significant hurdles for the rapid adoption of Canadian innovations. This may reduce patient access to leading-edge therapeutic products and harm the international competitiveness of Canadian health and biosciences firms."[657]

6.2.2.2.1. Treasury Board of Canada Secretariat

The Treasury Board of Canada Secretariat ("TBS") was the federal body that was tasked with coordinating the Budget 2018's regulatory agenda in response to the conclusions of the Economic Strategy Table reports.[658] The TBS asked stakeholders "to

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[652] *Ibid* at 84.

[653] *Ibid* at 118.

[654] Advisory Council on Economic Growth, *Investing in a Resilient Canadian Economy* (1 December 2017), online: <www.budget.gc.ca/aceg-ccce/pdf/investing-in-a-resilient-canadian-economy-eng.pdf>.

[655] *Ibid* at 11.

[656] *Ibid*.

[657] Canada's Economic Strategy Tables, *Health and Biosciences* (undated) at 8 online: <www.ic.gc.ca/eic/site/098.nsf/vwapj/ISEDC_HealthBioscience.pdf/$file/ISEDC_HealthBioscience.pdf> [emphasis added].

[658] Canada, Treasury Board of Canada Secretariat, "What We Heard Report on Regulatory Reviews and Modernization Stakeholder Consultations" (Date modified: 2 April 2019) online:

provide feedback on ways to enable regulations to be more agile, transparent, and responsive resulting in benefits for all Canadians."[659] The TBS stated that it received "over 30 written responses to the Health and Biosciences Regulatory Review…[in addition to] 13 cross-sectoral submissions."[660] TBS summarized these consultations as it applied to medical device regulation in a report titled *What We Heard: Health and Biosciences*:[661]

> 3. Medical devices
> Stakeholders suggested that there should be fast-track approval processes for novel products.[662]

6.2.2.2.2. Health and Biosciences Sector Regulatory Roadmap ("HBSR")

The consultations carried out under TBS's targeted regulatory review process resulted in the *HBSR*, which was published by Health Canada and serves as the formal policy rationale of the *ATPAs*. Health Canada described the *HBSR* as "lay[ing] out a regulatory modernization plan to support innovation and economic growth in the health and biosciences sector."[663] Health Canada and industry stated that the mainstream market entry pathway was an impediment to innovation and was "ill-suited" to new medical device products that challenge the typical "development, delivery and fabrication"[664] of

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<www.canada.ca/en/treasury-board-secretariat/services/federal-regulatory-management/targeted-reg-review/wwh-reg-rvw-mod-cnsltation.html#h-6-sub3> [Treasury, "What We Heard"].

[659] Canada, "Targeted Regulatory Reviews" (date modified: 25 January 2021) online: <www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/targeted-regulatory-reviews.html> [Canada, "Targeted Regulatory Reviews"].

[660] Treasury, "What We Heard", *supra* note 658 at 'webpage'.

[661] *Ibid*.

[662] *Ibid*.

[663] Canada, "Targeted Regulatory Reviews" *supra* note 659.

[664] Canada, Health Canada, "Policy and Program Initiatives and Novel Regulatory Approaches" (Ottawa: Health Canada, date modified 7 June 2019) [Health Canada, "Novel Reg"].

medical devices. A new regulatory framework was said to facilitate access to "cutting edge technologies, which have the potential to protect, extend, or improve their quality of life."[665] The new approach to regulation would "reduc[e] the amount of information required to be submitted."[666]

Health Canada noted that a new market entry route would allow the Minister of Health to authorize a product through "regulatory sandboxes" which are "designed to support patient safety while allowing for significant flexibility."[667] These sandboxes will allow the Minister to authorize a product based on "customized requirements."[668] Health Canada stated that regulatory sandboxes would be for the purposes of enabling innovation while "maintain[ing] Health Canada's high standards for evidence to protect patient safety and decision-making."[669] According to Health Canada, the rationale of the *HBSR* was to promote health treatment, rather than facilitate economic growth and promote jobs.

6.2.2.2.3. Health Canada, "What We Heard Summary of Scanning and Consultations on What's Next for Health Product Regulation" (March 2019)

A relevant point in the legislative history of the *ATPAs* is a comment that Health Canada should issue certifications for products subject to a new regulatory framework that would eventually be the *ATPAs*. Health Canada noted that industry:

> suggested a designation be issued earlier on in the process to support product innovation and investment, and indicated that they would value some form of certification from Health Canada (e.g., licence). Such a

[665] Health Canada, *Roadmap*, *supra* note 635.

[666] *Ibid*.

[667] Health Canada, "Novel Reg", *supra* note 664.

[668] *Ibid*.

[669] *Ibid*.

> certification was also suggested to facilitate engagement among manufacturers, health care practitioners, and patients.[670]

The practical effect of being issued a licence or order by Health Canada under the *ATPAs* acts as a vouch for product quality, which helps establish trust between a seller and payor to promote confidence in commercial contracts for these products.[671]

6.2.2.3. Budget 2019: Investing in the Middle Class

Budget 2019: Investing in the Middle Class introduced Health Canada's *HBSR* and it reiterated the government's five year-plan to promote job creation and build a stronger middle class.[672] The *HBSR* was introduced in Chapter 2—Building a Better Canada, in Part 5: Building a Nation of Innovations: Bringing Innovation to Regulations.[673] In Part 5, the federal government introduced "[a]s a next step…the first three 'Regulatory Roadmaps' to specifically address stakeholder issues and irritants in these sectors,…"[674] The Government of Canada was said to have spent up to $219.1 million over a five-year period beginning in 2019-2020 to carry out legislative and regulatory revisions "so that regulatory departments and agencies (Canada Food Inspection Agency, Health Canada and Transport Canada) can move forward on the Roadmaps."[675] The regulatory roadmaps are not described in terms of conveying health

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[670] Canada, Health Canada, "What We Heard Summary of Scanning and Consultations on What's Next for Health Product Regulation" (March 2019) at 7 online: <www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/consultation-summary-health-product-regulation/consultation-summary-health-product-regulation-eng.pdf>.

[671] See Amanda Warren-Jones, "Regulatory theory: commercially sustainable markets rely upon satisfying the public interest in obtaining credible goods" (2017) 12 Health Economics, Policy & L 471.

[672] *Budget 2019*, *supra* note 630 at 9.

[673] *Ibid* at 116.

[674] *Ibid*.

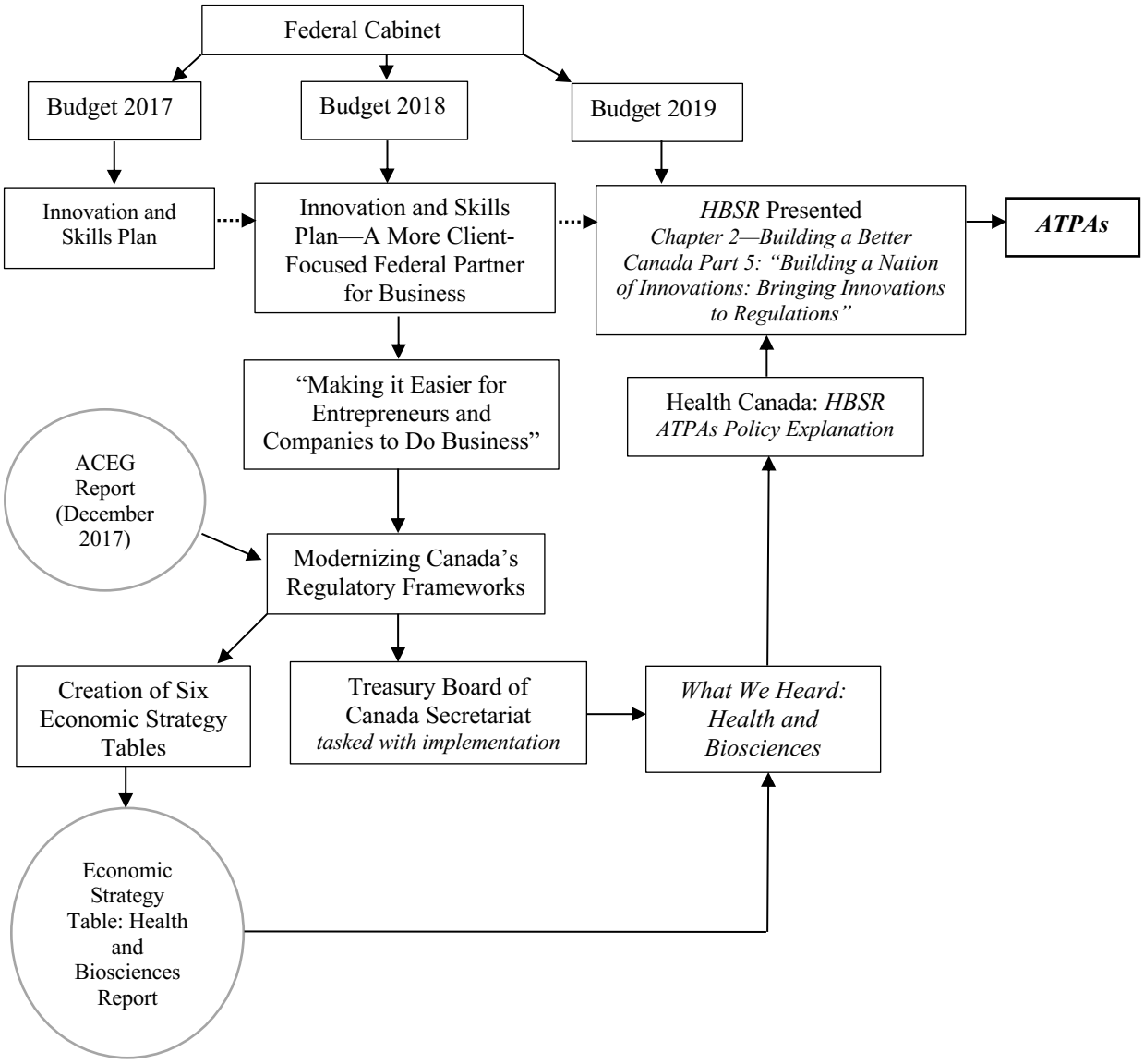
[675] *Ibid* at 117.

benefits to Canadians, but focus on promoting innovation defined as enabling economic and job growth.

6.2.2.4. Legislative History: Conclusion

The *ATPAs*' policy basis is seeded in the executive branch of government's federal Cabinet under Budget 2017's Innovation and Skills Plan that was subsequently expanded in Budget 2018's Innovation and Skills Plan—A More Client-Focused Federal Partner for Business, specifically the Making it Easier for Entrepreneurs and Companies to Do Business component. Overall, the *ATPAs* were motivated by economic interests and job growth. Health Canada's policy rationale of the *ATPAs* under the *HBSR* respecting health promotion is an ex post rationalization that describes the pathway in relation to health as opposed to economic growth and job creation. The legislative history did not refer to concerns over patient safety, or misleading evidence. Figure 1 summarizes the legislative history of the *ATPAs* as a policy matter that stems from the federal Cabinet:

Figure 1: Legislative History of the *ATPAs*



6.2.3. Conclusion: Dominant Purpose

The legal effect of the *ATPAs* provides for an exemption for all market entry requirements under the mainstream market entry scheme under Part 1 of the *MDRs* without a principled basis to justify this sweeping exemption from all regulations enabled by the *F&D Act*. The legislative history of the *ATPAs* does not support the claim that the mainstream market entry route under Part 1 of the *MDRs* is incompatible with "advanced

therapeutic products." Even for medical devices that incorporate artificial intelligence-based functions, there appears to be a significant need for more rigorous clinical studies including randomized controlled trials based on findings that certain types of medical AI disease-prediction tools have not been able to perform as claimed.[676]

Under Part 1 of the *MDRs,* even for high-risk medical devices (Class III), there is an absence of a requirement for clinical evidence. From a logical standpoint, the current market entry scheme, combined with the "Special Access" route under Part 2 of the *MDRs*, is more than likely sufficient to accommodate the market entry of medical devices that are deemed to be medical, scientific, or technical developments.

The *ATPAs* were passed as part of an omnibus law in Bill C-97 to implement Budget 2019. There may be two ways that the dominant purpose of the *ATPAs* could be characterized. First, it could be defined in terms of fostering economic activity in the sale of ATPs by exempting a person from importing or selling an ATP from the regulatory requirements under Part 1 of the *MDRs*.

Second, and in the alternative, the dominant purpose could be defined in terms of a market entry scheme that facilitates a medical device's rapid market entry to promote health and access to potentially 'novel' medical devices. For example, under the *ATPAs*

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[676] Konstantin Genin & Thomas Grote, "Randomized Controlled Trials in Medical AI: A Methodological Critique" (2021) 2 Philosophy of Medicine 1 at 3: ("[v]arious publications claim that medical AI systems perform as well, or better, than clinical experts. However, there have been very few controlled trials and the quality of existing studies has been called into question. There is growing concern that existing studies overestimate the clinical benefits of AI systems."; the authors also summarize the literature to evaluate AI-based medical devices with randomized controlled trials (RCT) and describe how to address methodological issues for AI); see also Qian Zhou, *et al*, "Clinical impact and quality of randomized controlled trials involving interventions evaluating artificial intelligence prediction tools: a systematic review" (2021) 4:154 npj Digital Medicine 1 at 1 (noting that AI prediction tools, including its subsets (machine learning and deep learning) need to be supported by rigourous scientific studies before clinical application: "rigorous studies are required before the clinical application of these tools"); see also Eric J Topol "Welcoming New Guidelines for AI Clinical Research" (2020) 26:9 Nature Medicine 1318.

licences or orders may be issued only if a person is able to demonstrate that the product is a medical, technical or scientific "development." In legal effect, this finding alleviates a person that wishes to sell an ATP from the requirements under Part 1 of the *MDRs* by default, which may facilitate their faster market access. However, this health promotion characterization of the *ATPAs*' dominant purpose emphasizes the intrinsic evidence at the expense of extrinsic evidence of the policy intent that drove the development of the *ATPAs*. The overriding rationale of the *ATPAs* based on its legislative history was the promotion of innovation defined as economic growth and job creation.

6.3. Classification

The dominant purpose characterizations of the *ATPAs* are unlikely to be classified under the criminal law power because of the absence of a valid criminal law purpose. Although selling an 'advanced therapeutic product' ("ATP") medical device without a licence or order is a prohibited action that is backed with serious penal sanctions, "the prohibition of a real or apprehended evil, and the concomitant protection of legitimate societal interests — must also be present."[677] The *ATPAs*' extrinsic evidence based on the legislative history does not support the claim that its dominant purpose, or even its secondary purpose (although irrelevant under the pith and substance doctrine as discussed in Chapter 4) was to apprehend evil or protect societal interests (for e.g., public safety or misleading statements of effectiveness).

Apart from the absence of a criminal law purpose sufficient to demonstrate its invalidity under the criminal law power, the requirement for a valid prohibition further

[677] *Reference re AHRA*, *supra* note 326 at 234.

appears unmet. The extensive discretion afforded to the executive branch of government that permits this branch to determine conditions (the breach of which is a prohibition) for the market entry of ATP medical devices does not conform to the test in *Reference re Firearms* (SCC) for regulatory versus criminal 'prohibitions' (untailored discretion is not valid).[678] The *ATPAs* represent a form of near "untrammeled 'discretion.'"[679]

At least under the *MDRs*, the scientific evidence requirements are incorporated by reference to the ISO definition of "objective evidence," and additional although nominal scientific evidence 'requirements' are enumerated according to risk class under s. 32 as discussed in Chapters 2 and 5 (see Table 1). Although these scientific evidence requirements may not themselves be sufficient to meet the criminal law prohibition requirement because they have been exclusively determined by the executive branch of government without clear constraints in primary legislation (under the *F&D Act*), they are at minimum broadly defined under binding secondary legislation (regulation). Under the *ATPAs*, scientific evidence requirements for licensing appear absent from the law. For example, in respect to licensing, "sufficient evidence" does not have a clear meaning. Decisions respecting the making of orders also provides the Minister with unrestricted discretion based on the absence of any condition under the law to make an order under the *F&D Act*.

It is unlikely that the *ATPAs* could be saved under the ancillary powers doctrine. The *ATPAs* are not rationally connected or necessarily incidental to an otherwise valid part of the *F&D Act* as it respects medical device licensing. The federal government

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[678] See *Reference re Firearms* (SCC), *supra* note 50.

[679] See *Canada (Minister of Citizenship and Immigration) v Vavilov*, 2019 SCC 65 at para 108, citing *Roncarelli v Duplessis*, [1959] SCR 121.

would likely need to provide a 'factual matrix' if it sought to assert a need for the *ATPAs* (i.e., as a logistical necessity to accommodate the market entry of 'newer' technologies). Health Canada and industry's assertions in the *HBSR* that describe a need for a new regulatory pathway may be insufficient to constitute a factual matrix of evidentiary support.[680] If it is correctly assumed there was an absence of evidentiary support that explains how technologies are incongruent with existing market entry schemes under the *MDRs*, the federal government may not be able to provide this explanation after enactment of the *ATPAs.* As discussed in Chapter 4, the dominant purpose of the law is a 'historical fact'. A 'factual matrix' likely needs to exist prior to the law's enactment so that the dominant purpose is not perceived as "shifting," This rule prevents ex post rationalizations of a law's dominant purpose.[681]

Considering the flexibility under the mainstream market entry scheme under Part 1 of the *MDRs*, evidence of the rationale or necessity for this pathway may not be convincing. For example, the "Custom Use" pathway under Part 2 of the *MDRs* is sufficient to accommodate newer technologies such as 3D implants. As it respects artificial-intelligence ("AI")-based medical devices, there are calls for the technology's safety and effectiveness to be based on rigorous scientific evidence because of concerns over misleading claims:[682] "[m]any claims about AI effectiveness in the relevant studies are not backed by their own statistical analyses."[683] Therefore, the assessment of safety

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[680] See *References re GGPPA*, *supra* note 61 at para 133; *Reference re Securities Act*, 2011 SCC 66 at para 115-16.

[681] As discussed in Chapter 4, see *Big M Drug Mart*, *supra* note 415 at para 91: ("Purpose is a function of the intent of those who drafted and enacted the legislation at the time, and not of any shifting variable.").

[682] See Genin & Grote, *supra* note 676; Zhou, *et al*, *supra* note 676.

[683] Genin & Grote, *ibid* at 3.

and effectiveness of AI-based technologies is not in a functional conflict with the basic scientific evidence requirements under the mainstream market entry pathway under Part 1 of the *MDRs*. If the safety and effectiveness of certain types of medical devices could not be assessed under the current market entry schemes, then the *ATPAs* may be justified under the ancillary powers doctrine insofar as it relates to that technology, but again, this appears unlikely given the flexibility of other schemes. Assuming that the *ATPAs* are dependent on the criminal law power for their constitutional validity, the scheme has the potential to be held *ultra vires* if challenged.

6.4. Conclusion

The scientific evidence requirement of "sufficient evidence" is a scientific evidence standard that is left unnecessarily undefined in the era of evidence-based medicine. The extensive delegation of power to the executive branch of government, a key legal effect of the *ATPAs*, is likely an invalid grant of delegation under the criminal law power jurisprudence discussed in Chapter 3. Terms and conditions for licences and orders likely need to be specified in greater detail in primary legislation. Conditions for licensing likely must include rigorous scientific evidence requirements to enable the finding that the law is based on a valid criminal law purpose and prohibition. Challenging the validity of the *ATPAs* on federalism grounds may invalidate the *ATPAs*. This has the potential to better ensure licensing of medical devices in relation to safety and effectiveness remains more precisely focused on validating safety and effectiveness under a unified and valid market entry pathway.

CHAPTER 7 CONCLUSION

This thesis sought to assess how medical devices legally enter the market under the mainstream market entry scheme under Part 1 of the *MDRs* and the *Advanced Therapeutic Products Amendments* with a focus on the scientific evidence requirements for proof of safety and effectiveness (RQ1). As discussed in Chapter 2, scientific evidence requirements are vague, and there is an absence of explicit expectations or requirements for methodologically rigorous forms of scientific evidence to substantiate safety and effectiveness under both market entry schemes.

This absence of methodologically rigourous scientific evidentiary requirements contrasts with specific market entry schemes under model US law, specifically under (or influenced by[684]) the *Kefauver-Harris Amendments* (1962) recognized as the modern basis of evidence-based medicine.[685] This US law requires manufacturers to submit "adequate and well-controlled investigations" in proof of safety and effectiveness, defined according to objective criteria (for e.g., blinding, randomization, and a valid control, i.e., possibly a placebo control, if feasible and ethical, to prove causative effectiveness). In short, these laws establish expectations (or requirements) for at least one blinded, randomized (validly)-controlled trial, and waivers from the default requirement may be justified if the requirements are deemed "not reasonably applicable" and if other valid scientific evidence can demonstrate "clinically significant results."[686] Chapter 2 concluded that scientific evidence requirements for safety and effectiveness

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[684] See *MDAs 1976*, *supra* note 196, see "Premarket Approval": 21 USC §360c(a)(3)(A) & 21 CFR §860.7(f).

[685] Djulbegovic & Guyatt, *supra* note 41.

[686] See 21 CFR §860.7(e)(1); see Tables 3 and 4.

should reflect methodologically rigorous requirements with appropriate exemptions similar to the US model law, and these requirements should be embedded under primary legislation to ensure their stability.

This thesis then sought to analyze whether the existing scientific evidence requirements and the scope of discretion under the *F&D Act* that enables the executive branch of government to control medical device licensing falls within federal authority under s. 91 of the *Constitution Act, 1867* (RQ2). Chapter 3 broadly sought to define how federal authority over licensing of medical devices in relation to safety and effectiveness may operate. Specifically, it sought to assess if this policy matter could be held dependent on the criminal law power under s. 91(27) of the *Constitution Act, 1867* to determine if the federal government may be confined to regulating this matter according to standards of valid criminal law.

The scope of the trade and commerce power (s. 91(2)) and the p.o.g.g. power (s. 91) and their branches were explored. Apart from the interprovincial and international trade branch under the trade and commerce power that may provide a tangential basis for licensing of medical devices in relation to safety and effectiveness based on *Saputo* (2011, FCA), all other branches appear improbable as a basis to support this matter. *Saputo,* however, is described as a unique case where Parliament was successful in regulating an industry under this branch.[687] Based on *Saputo*, the federal government would likely need to establish objective scientific evidentiary requirements to evaluate safety and effectiveness.

[687] Régimbald & Newman, *supra* note 239 at 314.

The most probable basis for federal licensing of medical devices in relation to safety and effectiveness, however, is the criminal law power given the hesitancy in secondary commentary noting that the interprovincial and international trade branch is not a general regulatory power, in contrast to the US Commerce Clause. Chapter 3 therefore found that the federal government may be dependent on the criminal law power to support licensing of medical devices in relation to safety and effectiveness.

Chapter 3 then turned to define standards of valid criminal law to understand criteria that a licensing scheme would need to reflect to be valid under this power. As an overarching standard, the federal government would need to devise a licensing scheme that was premised on suppressing harm from threatened interests (a valid criminal law purpose) and establish the licensing scheme in terms of technical requirements of a prohibition and penal sanction. Absence of methodologically rigorous scientific evidence requirements for safety and effectiveness may comprise the law's ability to meet a valid criminal law purpose. Major components of licensing may also need to be defined in primary legislation according to the test in *Reference re Firearms* (SCC), such as methodologically rigorous scientific evidence requirements in proof of safety and effectiveness deemed pivotal to patient safety.[688]

Chapters 4-6 sought to analyze the constitutional validity of: 1) the scientific evidence requirements under the mainstream market entry pathway under Part 1 of the *MDRs* (Chapter 5 (5.2)); 2) the law-making authority that enables this licensing scheme under s. 30(1) of the *F&D Act* (Chapter 5 (5.3)); and 3) the *ATPAs* as a whole (Chapter 6) to determine if these laws reflect standards of valid criminal law, and thus fall within the

[688] Van Calster, *et al*, *supra* note 45.

federal government's likely scope of authority over licensing of medical devices in relation to safety and effectiveness (RQ3).

Chapter 4 first described the legal process to examine a law's constitutional validity on federalism grounds by explaining that the first step is to characterize a law's dominant purpose according to the pith and substance doctrine. As described, a dominant purpose of a law will be defined in terms of the enacting government's purpose and its legal and practical effects, both of which are informed by intrinsic and extrinsic evidence sources. The second step of this process requires that the law be classified under a head of power. If a law is unclassifiable under the enacting government's powers, then a third step may apply to save the otherwise invalid law from an *ultra vires* declaration if it can be deemed "ancillary" to an otherwise valid scheme.

This process was then applied to the impugned laws in Chapters 5 and 6. In respect to the scientific evidence requirements under ss. 9(2) and 32, this thesis found these provisions potentially *ultra vires* federal authority in part because they do not clearly meet a valid criminal law purpose. Their practical effects do not provide reasonable assurance of safety and effectiveness and are non-objectively enforceable standards for safety and effectiveness. This contrasts with the *prima facie* objective to ensure medical device safety and effectiveness and the public welfare nature connoted by the penal sanctions under the *F&D Act*.

Chapter 5 then examined the constitutional validity of the procedure (law-making authority) that enables the executive branch of government to discretionarily govern the licensing of medical devices under s. 30(1) of the *F&D Act*, specifically through its promulgation of Part 1 of the *MDRs*. The scope of discretion afforded under s. 30(1) may

not meet requirements for a valid criminal law purpose or prohibition. Core aspects of medical device licensing may need to be vested in primary legislation to be consistent with the requirements in *Reference re Firearms* (SCC) (2000).

Chapter 6 proceeded to analyze the constitutional validity of the new, and non-mainstream market entry pathway under the *ATPAs*, which amended the *F&D Act*. The *ATPAs* are characterizable by the extensive scope of discretion provided to the executive branch of government, which enables this branch to define virtually all licensing and order conditions for medical devices deemed "advanced therapeutic products." The legislative history of the *ATPAs* does not provide evidence that the rationale of this scheme was premised on a valid criminal law purpose.

Assuming that licensing of medical devices in relation to safety and effectiveness is dependent on the criminal law power, scientific evidence requirements in proof of safety and effectiveness may need to be more methodologically rigorous to indicate that the dominant purpose of these requirements reflect a valid criminal law purpose. Further, core conditions of medical device licensing in relation to safety and effectiveness likely need to be based in primary legislation.

Although medical device safety and effectiveness has not been described as a public health crisis, the US National Academy of Medicine has found there is a lack of data to attest to the full scope of harms.[689] This thesis proposes that the *Constitution Act, 1867* and particularly the criminal law power, s. 91(27), may potentially be a legal policy

[689] IOM, *Report*, *supra* note 195 at 192.

tool[690] to embed stable and explicit methodologically rigorous scientific evidence requirements in federal law.

[690] See Hogg & Wright, *supra* note 51, § 59:2 (declarations of invalidity have become a "popular remedy to challenge official action of various kinds,"); see generally Abbe R Gluck & Nicole Huberfeld, "What Is Federalism in Healthcare For?" (2018) 70:6 Stan L Rev 1689 at 1787: ("One way to think about federalism as a tool for policy is that it generates a particular *kind* of policy solution. As discussed above, local variation and experimentation are the kinds of policy values typically associated with federalism. But a different way to think about federalism as a tool for policy is that federalism may generate the best specific policy outcomes on a particular substantive question.") [emphasis in original]; *ibid* at 1787: ("The political and judicial arenas tend to give more attention to federalism for federalism's own sake—for the political and constitutional values it advances—than for policy goals."); see also Heather K Gerken, "Federalism and Nationalism: Time for a Détente" (2015) 59:4 St Louis U LJ 997 at 1039.

Bibliography

LEGISLATION & RELATED DOCUMENTS

Canada:

An act respecting firearms and other weapons, SC 1995, c 39

An Act Respecting Food, Drugs, Cosmetics and Therapeutic Devices, SC 1952-53, c 38.

An Act to implement certain provisions of the budget tabled in Parliament on March 19, 2019 and other measures, SC c 29.

Assisted Human Reproduction Act, SC 2004, c 2.

Bill C-97, *An Act to implement certain provisions of the budget tabled in Parliament on March 19, 2019 and other measures*, SC c 29.

Canadian Charter of Rights and Freedoms, Part I of the *Constitution Act, 1982,* being Schedule B to the *Canada Act 1982* (UK), 1982, c 11.

Canadian Environmental Protection Act, RSC, 1985 c 16.

Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, reprinted in RSC 1985, Appendix II, No 5.

Constitution Act 1982, being Schedule B to the *Canada Act 1982* (UK), 1982 c 11.

Criminal Code, RSC 1985, c C-46.

Department of Justice Act, RSC 1985, c J-2.

Energy Efficiency Act, SC 1992, c 36.

Food and Drugs Act, RSC, 1927, ch 76.

Food and Drugs Act, RSC 1970, c F-27.

Food and Drugs Act, RSC, 1985, c F-27.

Food and Drug Regulations, CRC 1978, c 870.

Food and Drug Regulations, CRC 2020, c 870.

Food and Drug Regulations and the Dairy Products Regulations, Regulations Amending the, SOR/2007-302.

Medical Devices Regulations, SOR/98-282.

Medical Devices Regulations, SOR/98-282, (1998) C Gazette II.

Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), SC 2014, c 24.

Revised Statutes of Canada, 1985 Act, RSC 1985 c 40 (3rd Supp).

United States:

21 Code of Federal Regulations.

Federal Food, Drug, and Cosmetic Act, 21 USC ch 9.

Drug Amendments of 1962 (*Harris-Kefauver Act*), 76 Stat 780, amending 21 USC s 301.

The 1976 Medical Device Amendments, Pub L No 94-295, 90 Stat 539 (1976).

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes, (1938) Pub L No 75-717, 52 Stat 1040 (titles amended 21 USC: Food and Drugs).

US Constitution, art 1, §8, cl 3.

England:

Statute of the Pillory and Tumbrel, and of the Assize of Bread and Ale, etc, 51 Hen III (1266) ch 6.

CASE LAW

Canada:

Adam v Ledesma-Cadhit, 2014 ONSC 5726 (Ont SCJ).

British Columbia v Imperial Tobacco Canada Ltd, 2005 SCC 49.

Boggs v The Queen, [1981] 1 SCR 49.

Caloil v Canada (AG), [1971] SCR 543.

Canada (AG) v Can Nat Transportation, Ltd, [1983] 2 SCR 206.

Canada (AG) v PHS Community Services Society, 2011 SCC 44.

Canada (Minister of Citizenship and Immigration) v Vavilov, 2019 SCC 65.

Canada (Procureure générale) c Hydro-Québec, [1997] 3 SCR 213.

Canadian Western Bank v Alberta, 2007 SCC 22.

Carter v Canada (AG), 2015 SCC 5.

Citizens' Insurance Co of Canada v Parsons (1881), 7 App Cas 96 (PC).

Chatterjee v Ontario (AG), 2009 SCC 19.

Desgagnés Transport Inc v Wärtsilä Canada Inc, 2019 SCC 58.

Dominion Stores Ltd v R, [1980] 1 SCR 844.

Drady v Canada (Minister of Health), 2008 ONCA 659.

Friends of the Oldman River Society v Canada (Minister of Transport), [1992] 1 SCR 3.

General Motors of Canada Ltd v City National Leasing, [1989] 1 SCR 64.

Global Securities Corp v British Columbia (Securities Commission), 2000 SCC 21.

Goodyear Tire and Rubber Co of Canada v The Queen, [1956] SCR 303.

Hospira Healthcare Corp v Canada (AG), 2010 FC 213.

Hospira Healthcare Corp v Canada (AG), 2010 FCA 345.

ITO-International Terminal Operators Ltd v Miida Electronics Inc, [1986] 1 SCR 752.

John Deere Plow Co v Wharton, [1915] AC 330 at 338-39 (PC).

Kirkbi AG v Ritvik Holdings Inc, 2005 SCC 65.

Kitkatla Band v British Columbia (Minister of Small Business, Tourism and Culture), 2002 SCC 31.

Klein v American Medical Systems Inc, [2005] OJ No 4910 (Ont SCJ).

Klein v American Medical Systems Inc, [2006] OJ No 2188 (Ont SCJ).

Klein v American Medical Systems Inc, [2006] OJ No 5181 (Ont Div Ct).

Labatt Breweries of Canada Ltd v (AG) Canada, [1980] 1 SCR 914.

Lord's Day Alliance of Canada v Attorney General of British Columbia, [1959] SCR 497.

Murphy v CPR, [1958] SCR 626.

Ontario (AG) v Reciprocal Insurers, [1924] AC 328 (PC).

Ontario Hydro v Ontario (Labour Relations Board), [1993] 3 SCR 327.

Quebec (AG) v Canada (AG), 2015 SCC 14.

Quebec (AG) v Lacombe, 2010 SCC 38.

R v Boggs, [1981] 1 SCR 49.

R v Big M Drug Mart Ltd, [1985] 1 SCR 295.

R v Crown Zellerbach Canada Ltd, [1988] 1 SCR 401.

R v Morgentaler, [1988] 1 SCR 30.

R v Morgentaler, [1993] 1 SCR 462.

R v Rube, [1991] 54 BCLR (2d) 419 (BCCA), aff'd [1992] 3 SCR 159.

R v Sault Ste Marie, [1978] 2 SCR 1299.

R v Swain, [1991] 1 SCR 933.

R v Trophic Canada Ltd (1980), [1981] 3 WWR 158 (BCCA).

R v Wetmore, [1983] 2 SCR 284.

Rebuck v Ford Motor Company, 2022 ONSC 2396.

Reference Re Alberta Legislation, [1938] SCR 100.

Reference Re Anti-Inflation Act, 1975 (Canada), [1976] 2 SCR 373.

Reference Re Assisted Human Reproduction Act, 2010 SCC 61.

Reference re Employment Insurance Act (Can), *ss 22 and 23,* 2005 SCC 56.

Reference re Farm Products Marketing Act (Ontario), [1957] SCR 198.

Reference Re Firearms Act (Canada), 1998 ABCA 305.

Reference Re Firearms Act (Canada), 2000 SCC 31.

Reference Re Genetic Non-Discrimination Act, 2020 SCC 17.

Reference Re Pan-Canadian Securities Regulation, 2018 SCC 48.

Reference Re Secession of Quebec, [1998] 2 SCR 217.

Reference re Securities Act, 2011 SCC 66.

Reference Re Validity of s 5(a) of Dairy Industry Act (Canada), (Margarine Case), [1949] SCR 1.

References re Greenhouse Gas Pollution Pricing Act, 2021 SCC 11.

RJR—MacDonald Inc v Canada (AG), [1994] 1 SCR 311.

Robinson v Medtronic Inc, 2010 ONSC 1739 (Ont SCJ).

Roncarelli v Duplessis, [1959] SCR 121.

Saputo Inc v Canada (AG), 2011 FCA 69.

Saumur v Quebec (City of), [1953] 2 SCR 299.

Schneider v The Queen, [1982] 2 SCR 112.

Scowby v Glendinning, [1986] 2 SCR 226.

Standard Sausage Co v Lee, [1933] 4 DLR 501.

The Queen v Zelensky, [1978] 2 SCR 940.

Ward v Canada (AG), 2002 SCC 17.

Wellesley Therapeutics Inc v Canada (Minister of Health), 2010 FC 573.

United States:

In re CR Bard, Inc, MDL No 2187, Pelvic Repair System Products Liability Litigation, 810 F3d 913 (USCA 4th Cir, 2016).

Cipollone v Leggett Group, Inc, 505 US 504 (USSC 1992).

Medtronic Inc, v Lohr, 518 US 470 (USSC 1996).

POM Wonderful, LLC v FTC, 777 F 3d 478 (DC Cir 2015).

Riegel v Medtronic, Inc, 552 US 312 (USSC 2008).

The People of the State of California v Johnson & Johnson, Corp; Ethicon Inc; Dose 1, 37-2016-00017229-CU-MC-CTL (Sup Ct Cal 2020).

Weinberger v Hynson, Westcott & Dunning, Inc, 412 US 609 (USSC 1973).

Abel, Albert S. “The Neglected Logic of 91 and 92” (1969) 19:4 UTLJ 487.

Avorn, Jerry *et al*. “Forbidden and Permitted Statements about Medications — Loosening the Rules” (2015) 373 New England J Medicine 967.

Baker, Nathaniel. “Short-Sellers Grego, Cohodes Takes Aim At Penumbra”, *Forbes* (18 November 2020), online: <www.forbes.com/sites/nathanielbaker/2020/11/18/short-sellers-grego-cohodes-take-aim-at-penumbra/?sh=1d24f21b80a2>.

Bauman, Jordan. “The ‘Déjà vu Effect,’ Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration’s Contentious 510(k) Program” (2012) 67 Food & Drug LJ 337.

Beaulac, Stéphane & Pierre-André Côté. “Dreiedger’s ‘Modern Principle’ at the Supreme Court of Canada: Interpretation, Justification, Legitimization” (2006) 40 RJT 131.

Bothwell, Laura E, *et al*. “Assessing the Gold Standard — Lessons from the History of RCTs” (2016) 374:22 New England J Medicine 2175

Bouchard, Ron A & Monika Sawicka. “The Mud and the Blood and the Beer: Canada’s Progressive Licensing Framework for Drug Approval” (2009) 3:1 McGill JL & Health 49.

CBC News (n/a). “Metal-on-metal hip implants since 2006 may be more likely to fail: study”, *CBC News* (28 April 2016), online: <https://www.cbc.ca/news/health/hip-implants-1.3558050>.

CMAJ, “MPs Call for Removal of Health Canada’s Breast Implant Panel Members” (2005) 173:10 CMAJ 114.

CTV News.ca Staff (unauthored). “BC man launches class-action lawsuit over hip implant”, *CTV News* (31 August 2019), online: https://www.ctvnews.ca/health/b-c-man-launches-class-action-lawsuit-over-hip-implant-1.4573679>.

Darrow, Jonathan J. “FDA Regulation and Approval of Medical Devices: 1976-2020” (2021) 326:5 JAMA 420.

Davidoff, Frank. “Heterogeneity: We Can’t Live With It, And We Can’t Live Without It” (2011) 20 BMJ: Quality & Safety i11.

Djulbegovic, Benjamin & Gordon H Guyatt. “Progress in Evidence-Based Medicine: A Quarter Century On” (2017) 390:10092 Lancet 415.

Genin, Konstantin & Thomas Grote. “Randomized Controlled Trials in Medical AI: A Methodological Critique” (2021) 2 Philosophy of Medicine 1.

Gerken, Heather K. “Federalism and Nationalism: Time for a Détente” (2015) 59:4 St Louis U LJ 997.

Gluck, Abbe R & Nicole Huberfeld. “What Is Federalism in Healthcare For?” (2018) 70:6 Stan L Rev 1689.

Godina, Jenya. “Left to Their Own Devices: How the Dangers of Power Morcellators Went Undetected by FDA for Two Decades” (2019) 74:1 Food & Drug LJ 128.

Gottlieb, Scott. “The FDA Wants You for Sham Surgery”, *Wall Street Journal* (18 February 2014), online: <www.wsj.com/articles/the-fda-wants-you-for-sham-surgery-1392769018>.

Grady, Denise & Katie Thomas. “F.B.I. Investigates Whether Harm From Surgical Power Tool was Ignored”, *New York Times* (27 May 2015), online: <www.nytimes.com /2015/05/28/business/fbi-investigates-whether-harm-from-surgical-power-tool-was-ignored.html>.

HeartLife Foundation. “Cardiac device implants in Canada: Are they worth the risk?”, *HeartLife.ca* (14 February 2019) online: <https://heartlife.ca/2019-2-14-cardiac-device-impacts-in-canada-are-they-worth-the-risk/>.

Heath, Edward. “How Federal Judges Use Legislative History” 25:1 J Legis 95.

Horvath, George. “Trading Safety for Innovation and Access: An Empirical Evaluation of the FDA’s Premarket Approval Process” (2017) 5 BYU L Rev 991.

Husten, Larry. “WSJ Attack on Sham Surgery is About Healthy Profits, Not Patients”, *Forbes* (20 February 2014), online: <https://www.forbes.com/sites/larryhusten/2014/02/20/wall-street-journal-op-ed-on-sham-surgery-gets-it-wrong/?sh=47bcc6a74eb2>.

Hutt, Peter Barton & Robert Temple. “Commemorating the 50th Anniversary of the Drug Amendments of 1962” (2013) 68:4 Food & Drug LJ 449.

Inman, Robert P. “Federalism’s Values and the Value of Federalism” Working Paper 13735 (Cambridge, MA: National Bureau of Economic Research, 2008).

International Consortium of Investigative Journalists. “Medical Devices Harm Patients Worldwide As Governments Fail On Safety”, *ICIJ* (25 November 2018), online: <www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/>:

International Consortium of Investigative Journalists. *The Implant Files* (2018 – 2021 last updated), online: <https://www.icij.org/investigations/implant-files/>.

Interventional News (unauthored). “Symplicity Renal Denervation System receives Health Canada licence”, *Interventional News* (18 April 2012), online: <https://interventionalnews.com/symplicity-renal-denervation-system-receives-health-canada-licence/>.

Kadakia, Kushal T *et al*. Kushal T “Renewing the Call for Reforms to Medical Device Safety—The Case of Penumbra” (2022) 182:1 JAMA Internal Medicine 59.

Kelly, Susan. “FDA says 18 deaths linked to intragastric weight loss balloons”, *MedTechDive* (28 April 2019), online: <www.medtechdive.com/news/fda-18-deaths-linked-to-apollo-endosurgery-intragastric-balloon-weight-loss-treatment/576874/>.

Kim Spencer McPhee Barristers. “Settlement Approved in ASR Hip Implant Class Action” *Cision* (2 October 2021), online: <www.newswire.ca/news-releases/settlement-approved-in-asr-hip-implant-class-action-816983973.html>.

Kong, Hoi L. “Republicanism and the Division of Powers in Canada” (2014) 64:3 UTLJ 359.

Kramer, Daniel B *et al*. “Premarket Clinical Evaluation of Novel Cardiovascular Devices: Quality Analysis of Premarket Clinical Studies Submitted to the Food and Drug Administration 2000-2007” (2010) 17 American J Therapeutics 2.

Lederman, W R. “The Concurrent Operation of Federal and Provincial Laws in Canada” (1963) 9:3 McGill LJ at 186.

Lexchin, Joel. *Private Profits Versus Public Policy: The Pharmaceutical Industry and the Canadian State* (Toronto: University of Toronto Press, 2016).

Limacorporate, s.p.a.. “LimaCorporate Announces The First Surgery of SMR Stemless Reverse Shoulder System In The IDE Study”, *Cision, PR Newswire*, (20 April 2021), online: <https://www.prnewswire.com/news-releases/limacorporate-announces-the-first-surgery-of-smr-stemless-reverse-shoulder-system-in-the-ide-study-301271806.html>.

Lipschultz, Bailey & Josh Fineman. “Short Seller QCM Questions Safety of Penumbra Stroke Device”, *Bloomberg* (10 November 2020), online: <www.bloomberg.com/news/articles/2020-11-10/short-seller-qcm-questions-safety-of-penumbra-stroke-device#xj4y7vzkg>.

Mathieu, Ghislaine & Bryn Wiilliams-Jones. “Examining the National Regulatory Environment of Medical Devices: Major Issues in the Risk-Assessment of High-Risk Devices” (2016) 9:1 McGill JL & Health 17.

McCarthy, Ryan. “Did the FTC Actually Lose POM Wonderful? Health Claims, Prior Substantiation, and the First Amendment” (2016) 35:2 Rev Litig 353.

Meier, Barry. “Study of Medical Device Rules Is Attacked, Unseen”, *New York Times* (27 July 2011), online: <www.nytimes.com/2011/07/28/health/28institute.html>.

Minow, Martha. “Archetypal Legal Scholarship – A Field Guide” (2013) 63(1) J Leg Ed 65.

Mitchell, Graeme G. “Not a General Regulatory Power: A Comment on Reference re Assisted Human Reproduction Act” (2011) 54:22 SCLR 633.

Morse, Susan C. “Safe Harbors, Sure Shipwrecks” (2016) 49 UC Davis L Rev 1385.

Motluk, Alison. “Caution Issued Against Use of Morcellators” (2015) 187:2 CMAJ 99.

Ouellet, Valérie & Sylvène Gilchrist. “Thousands of suspected injuries tied to breast implants revealed in manufacturer data dump, CBC analysis finds” *CBC News* (13 January 2022), online: <https://www.cbc.ca/news/investigates/breast-implants-health-canada-allergan-mentor-1.6312587>.

Oxford Centre for Evidence-Based Medicine. “The Oxford 2011 Levels of Evidence” online: <www.cebm.net/index.aspx?o=5653>.

Patrick Malone & Associates PC. “US Watchdogs Tally $1.5 billion cost for one type of defective medical device” *JD Supra* (17 October 2017), online: <www.jdsupra.com/legalnews /u-s-watchdogs-tally-1-5-billion-cost-53798/>.

Penumbra, Inc. “Urgent Voluntary Medical Device Recall Notification Immediate Action Required”, (15 December 2020), online: <www.penumbrainc.com/wp-content/uploads/2020/12/JET-7XF-15Dec20.pdf>.

Polisena, Julie. *Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and an Investigation of the Continuous Quality Improvement Data Automatically Reported by Wireless Smart Infusion Pumps*, (PhD Thesis, University of Ottawa: Faculty of Medicine; School of Epidemiology, Public Health, and Preventative Medicine, 2015), online: <https://ruor.uottawa.ca/bitstream/10393/33414/1/Polisena_Julie_2015_thesis.pdf>.

Quintessential Capital Management. “Penumbra and its ‘killer catheter’: A tale of corporate greed and seemingly blatant disregard for patients’ lives” (10 November 2020) [QCM] online: <www.qcmfunds.com/wp-content/uploads/2020/11/QCM-on-Penumbra-presentation-Final-.pdf>.

Ray, Seth. “A Guide to FDA’s Evolving Interpretation of How Sponsors Can Demonstrate Substantial Evidence of Effectiveness for Human Drug and Biological Products”, *JDSupra* (25 March 2020), online: <www.jdsupra.com/legalnews/a-guide-to-fda-s-evolving-74753/>.

Rochon | Genova LLP. “Notice of Discontinuance of Johnson & Johnson Class Action – Transvaginal Mesh for Stress Urinary Incontinence and Pelvic Organ Prolapse” (3 June 2020) online: <www.rochongenova.com/wp-content/uploads/sites/1100729/2021/01/Notice-of-Discontinuance-English.pdf>.

Rutkow, Lainie & Jon S Vernick. “The US Constitution’s Commerce Clause, the Supreme Court, and Public Health” (2011) 126:5 Public Health Reports 750.

Shapiro, Sidney A. “The Complexity of Regulatory Capture: Diagnosis, Causality, and Remediation” (2012) 17:1 Roger Williams U L Rev 221.

Shun-Shin, Matthew J, James P Howard & Darrel P Francis. “Removing the Hype from Hypertension: Symplicity HTN-3 illustrates the importance of randomisation and blinding for exciting new treatments” (2014) 348 BMJ 1937.

Stankiewicz, Kevin. “Shares of medical device maker Penumbra tank after short seller releases critical report”, *CNBC* (08 December 2020), online: <www.cnbc.com/2020/12/08/shares-of-penumbra-tank-after-short-seller-releases-critical-report.html>.

Temple, Robert & Susan Ellenburg. “Placebo-Controlled Trials and Active-Control Trials in the Evaluation of New Treatments” (2000) 133:6 Annals Internal Medicine 455.

The Editorial Board. “80,000 Deaths. 2 Million Injuries. It’s Time for a Reckoning on Medical Devices”, *New York Times* (4 May 2019), online: <www.nytimes.com/2019/05/04/opinion/sun day/medical-devices.html>.

Topol, Eric J. “Welcoming New Guidelines for AI Clinical Research” (2020) 26:9 Nature Medicine 1318.

Tower, Stephen. “Hip Metallosis and Corrosion—A Million Harmed Due to FDA Inaction” (2019) 15:3 J Patient Safety 257.

Van Calster, Ben, et al. “Methodology over Metrics: Current Scientific Standards are a Disservice to Patients and Society” (2021) 138 J Clinical Epidemiology 219.

Wagner, Wendy E. “Administrative Law, Filter Failure and Information Capture” (2010) Duke LJ 1322.

Walker, Joseph. “Medtronic Makes Surprise Turn on Blood-Pressure Device”, *Wall Street Journal* (29 March 2014), online: <http://www.wsj.com/articles/SBloool424o527o23o46881o457 9468500895597252>.

Ward, James R & P John Clarkson. “An Analysis of Medical Device-Related Errors: Prevalence and Possible Solutions” (2009) 28 J Medical Engineering & Technology 1 at 5.

Warren-Jones, Amanda. “Regulatory theory: commercially sustainable markets rely upon satisfying the public interest in obtaining credible goods” (2017) 12 Health Economics, Policy & L 471.

Wright, Megan S. “A Case for Randomized, Double-Blinded, Sham-Controlled Class III Medical Device Trials” (2015) 34:1 Yale L & Pol’y Rev 199.

Wright, Wade. “Against Privileging the Charter: The Case of Federal Pre-Enactment Constitutional Review” (2020) 25:1 Rev Const Stud 49.

Zettler, Patricia J, Eli Y Adashi & I Glenn Cohen. “A Divisive Ruling on Devices — Genus *Medical Technologies v FDA*” (23 December 2021) 385:26 New England J Medicine 2409.

Zhou, Qian *et al*. “Clinical impact and quality of randomized controlled trials involving interventions evaluating artificial intelligence prediction tools: a systematic review” (2021) 4:154 npj Digital Medicine 1.

SECONDARY MATERIAL: BOOK CHAPTERS & MONOGRAPHS

Côté, Pierre-André, Stéphane Beaulac & Mathieu Devinat. *The Interpretation of Legislation in Canada*, translated by Steven Sacks (Toronto: Carswell, 2011).

Driedger, Elmer A. *The Construction of Statutes*, 2nd ed (Toronto: Butterworths, 1983).

Hogg, Peter W & Wade K Wright. *Constitutional Law in Canada* (5th ed) (2021 online) (Toronto: Carswell, 2007).

Hutchinson, Terry. "Doctrinal Research: Researching the Jury" in Dawn Watkins & Mandy Burton, eds, *Research Methods in Law* (New York: Routledge, 2018) 8.

Keyes, John Mark. *Executive Legislation*, 2nd ed (Markham: LexisNexis Canada, 2010).

Keyes, John Mark. *Executive Legislation*, 3rd ed (Toronto, ON: LexisNexis, 2021).

Mathen, Carissma & Patrick Macklem *et al*, eds. Canadian *Constitutional Law*, 6th ed (Toronto: Emond Montgomery Publications, 2022).

Régimbald, Guy & Dwight Newman. *The Law of the Canadian Constitution*, 2nd ed, (Toronto: LexisNexis Canada, 2017).

Régimbald, Guy & John J. Wilson. Halsbury's Laws of Canada, *Constitutional Law (Division of Powers)* (2019 Reissue).

Rivard, Glen. "Federal and Provincial Jurisdiction with Respect to Health: Struggles Amid Symbiosis" in Trudo Lemmens, et al, eds, *Regulating Creation: The Law, Ethics, and Policy of Assisted Human Reproduction* (Toronto: University of Toronto Press, Scholarly Publishing Division, 2017) 63.

Rodriguez, Gary P. "Legislative Histories, Food and Drugs Act" in *Crankshaw's Criminal Code of Canada* [WestlawNext Canada].

Salembier, Paul. *Regulatory Law and Practice*, 3rd ed (Toronto: LexisNexis Canada, 2021).

Sullivan, Ruth. *Statutory Interpretation*, 3ed (Toronto: Irwin Law, 2016).

Sullivan, Ruth. *Sullivan on the Construction of Statutes*, 6th ed (Markham, ON: LexisNexis Canada, 2014).

Tribe, Laurence. *American Constitutional Law*, 3rd ed, vol 1 (New York: Foundation Press, 2000).

GOVERNMENT & RELATED DOCUMENTS

Canada:

Advisory Council on Economic Growth, *Investing in a Resilient Canadian Economy* (1 December 2017), online: <www.budget.gc.ca/aceg-ccce/pdf/investing-in-a-resilient-canadian-economy-eng.pdf>.

Canada, *Budget 2017: Building a Strong Middle Class: #Budget2017*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 22 March 2017, online: <www.budget.gc.ca/2017/docs/plan/budget-2017-en.pdf>.

Canada, *Budget 2018: Equality + Growth: A Strong Middle Class*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 27 February 2018, online: <https://budget.gc.ca/2018/docs/plan/budget-2018-en.pdf>.

Canada. *Budget 2019*, *Investing in the Middle Class*, Tabled in the House of Commons by the Honourable William Francis Morneau, PC, MP, Minister of Finance, 19 March 2019, online: <www.budget.gc.ca/2019/docs/plan/toc-tdm-en.html>.

Canada. "Guide to the Federal Regulatory Development Process: Steps in the Regulatory Development Process" (date modified 17 April 2014), online: https://www.canada.ca/en/ government/ system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/guide-federal-regulatory-development-process.html#t7>.

Canada. Canada's Economic Strategy Tables, *Health and Biosciences* (undated) online: <www.ic.gc.ca/eic/site/098.nsf/vwapj/ISEDC_HealthBioscience.pdf/$file/ISEDC_Health Bioscience.pdf>.

Canada. House of Commons, *Minutes of Proceedings and Evidence of the Special Committee on Regulatory Reform* (6 November 1980) online: <https://parl.canadiana.ca/view/oop.com _HOC _3201_41_3/466?r=0&s=1> [*Special Committee on Regulatory Reform*].

Canada. House of Commons, *Minutes of Proceedings and Evidence, Sub-Committee on Regulations and Competitiveness of the Standing Committee on Finance*, 34th Leg, 3rd Sess, Vol 1 (7 May 1992) [*Sub-Committee on Regulations and Competitiveness*], online: <https://parl.canadiana.ca/view/oop.com_HOC_3403_94_1/11?r=0&s=1>.

Canada. "Targeted Regulatory Reviews" (date modified: 25 January 2021) online: <www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/targeted-regulatory-reviews.html>.

Canada, Treasury Board of Canada Secretariat. "What We Heard Report on Regulatory Reviews and Modernization Stakeholder Consultations" (Date modified: 2 April 2019) online: <www.canada.ca/en/treasury-board-secretariat/services/federal-regulatory-management/targeted-reg-review/wwh-reg-rvw-mod-cnsltation.html#h-6-sub3>.

Canada, Health Canada. Dear Healthcare Professional Letter, “Intragastric Balloons and Potential Risk of Gastric and Esophageal Perforation, Pancreatitis, and Overinflation” (17 April 2019), online: <https://recalls-rappels.canada.ca/en/alert-recall/intragastric-balloons-and-potential-risk-gastric-and-esophageal-perforation>.

Canada, Health Canada. Guidance on Supporting Evidence to be provided for New and Amended Licence Applications for Class III and Class IV Medical Devices, not including In-Vitro Diagnostic Devices (IVDDs) (date adopted: 2012/06/08, effective date: 2012/07/04).

Canada, Health Canada. *Health and Biosciences Sector Regulatory Review Roadmap* (Ottawa: Health Canada 2019) (date modified: 7 June 2019; date accessed: 15 December 2019).

Canada, Health Canada. “Health Canada’s Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness and Quality” Discussion Paper (Ottawa: Health Canada, December 2018).

Canada, Health Canada. Information Update. “Health Canada suspends Allergan’s licences for its Biocell breast implants after safety review concludes an increased risk of cancer,” (28 May 2019), online: <https://recalls-rappels.canada.ca/en/alert-recall/health-canada-suspends-allergan-s-licences-its-biocell-breast-implants-after-safety>.

Canada, Health Canada. “Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing (2020-12-15)” (date posting: 30 December 2020), online: <https://recalls-rappels.canada.ca/en/alert-recall/penumbra-jet-7-reperfusion-catheter-and-penumbra-hi-flow-aspiration-tubing-2020-12-15>.

Canada, Health Canada. “Policy and Program Initiatives and Novel Regulatory Approaches” (Ottawa: Health Canada, date modified 7 June 2019).

Canada, Health Canada. “Regulatory Decision Summary – A.L.P.S. Clavicle Plating System” [Class III, date of decision: 2019-09-19], online: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10494>.

Canada, Health Canada. “Regulatory Decision Summary – HIRES ULTRA 3D COCHLEAR IMPLANT” [Class III, date of decision: 2018-03-29] online: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10347>.

Canada, Health Canada. “Regulatory Decision Summary – PENUMBRA SYSTEM” [Class IV, date of decision: 2020-03-12], <online: https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS10743>.

Canada, Health Canada. “Regulatory Decision Summary – SMR STEMLESS” New device licence application” [Class III (high risk medical device), date of decision: 2019-09-19], online: < https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-medical-device-detail.php?lang=en&linkID=RDS11272>.

Canada, Health Canada. “What We Heard Summary of Scanning and Consultations on What’s Next for Health Product Regulation” (March 2019) online: <www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/consultation-summary-health-product-regulation/consultation-summary-health-product-regulation-eng.pdf>.

Canada, Office of the Auditor General of Canada. *2011 June Status Report of the Auditor General of Canada: Chapter 6—Regulating Medical Devices—Health Canada* (Ottawa: Minister of Public Works and Government Services Canada, 2011), online: <www.oag-bvg.gc.ca/internet/English/parl_oag_201106_06_e_35374.html>.

Canada, Office of the Auditor General of Canada. *Report of the Auditor General of Canada to the House of Commons: Chapter 2: Health Canada—Regulation of Medical Devices* (Ottawa: Minister of Public Works and Government Services Canada, 2004) online: <www.oag-bvg.gc.ca/internet/docs/20040302ce.pdf>.

Canada, Office of the Auditor General of Canada. *Report of the Auditor General of Canada to the House of Commons: Chapter 8: Allocating Funds to Regulatory Programs—Health Canada* (Ottawa: Minister of Public Works and Government Services Canada, 2006) at 1, online: <www.oagbvg.gc.ca/internet/English/parl_oag_ 200611 _08_e_14976.html>.

Reference re Genetic Non-Discrimination Act, 2020 SCC 17 (Factum of the Appellant) online: <www.scc-csc.ca/WebDocuments-DocumentsWeb/38478/FM010_Appellant_ Canadian-Coalition-for-Genetic-Fairness.pdf>.

Canada, Regulatory Impact Analysis Statement, SOR/98-282, (1998) C Gaz II 1680.

Canada, Medical Devices Review Committee, “Direction for Change: Report of the Medical Devices Review Committee” (Ottawa: The Committee, 1992).

Marc Bosc & André Gagnon, ed, *House of Commons Procedure and Practice*, 3rd ed (Ottawa: 2017).

Senate, *Votes and Proceedings: Senate Committee on Public Health and Welfare*, 21st Parl, 7th Sess, vol 1, online: <https://parl.canadiana.ca/view/oop.com_SOC_2107 _2_1/18?r=0&s=1>.

United States:

Declaration of Robert Temple, MD. *Allergan, Inc v United States*, 1:09-cv-01879 (DDC, 2009).

Institute of Medicine of the National Academies. “Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years”, Committee on the Public Health Effectiveness of the FDA 510(k) Process: Board on Population Health and Public Health Practice (Washington, DC: National Academies Press, 2011).

Legislative Attorney (name redacted), “*Riegel v Medtronic, Inc*.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval” (Washington, DC: Congressional Research Service, 2012).

National Academies of Sciences. Engineering and Medicine. *Reproducibility and Replicability in Science* (Washington: DC: National Academies Press, 2019).

United States, Food and Drug Administration. *Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products* (Silver Spring, MD, Food and Drug Administration, January 2017).

United States, Food and Drug Administration. "Penumbra's Recall of the JET 7 Reperfusion Catheter Due to Distal Tip Damage" online: <www.fda.gov/medical-devices/medical-device-recalls/penumbras-recall-jet-7-reperfusion-catheter-due-distal-tip-damage> (describing 14 unique patient deaths among other serious patient injuries).

United States, Food and Drug Administration. "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff" (Silver Spring, MD: Food and Drug Administration, issued 28 July 2014), online: <www.fda.gov/media/82395/download>.

United States, National Institutes of Health: US National Library of Medicine, *ClinicalTrials.gov*, "SMR Stemless Reverse vs SMR Reverse Shoulder System", (First posted: 6 January 2021), online: <https://clinicaltrials.gov/ct2/show/NCT04697004>.

United States Senate, *A Delicate Balance: FDA and the Reform of the Medical Device Approval Process*: Hearing Before the Special Committee on Aging, 112th Congress (Frederic S Resnic citing a GAO study), online: <https://www.govinfo.gov/content/pkg/CHRG-112shrg67694/html/CHRG-112shrg67694.htm>.

MISSELANEOUS

Canada, Library of Parliament. Canadian Parliamentary Historical Resources, online: <https://parl.canadiana.ca>.

International Organization for Standardization. “ISO 13485:2016(en) Medical devices — Quality management systems — Requirements for regulatory purposes”, online: <www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en>.

International Organization for Standardization. “Life Cycle” ISO:8402:1994 (withdrawn) → ISO:9000:2000 (withdrawn) → ISO:9000 2005 (withdrawn) → ISO:9000:2015 (Published), see online: <https://www.iso.org/standard/29280.html>; and <https://www.iso.org/standard/42180.html>.

National Academy of Medicine. “About the National Academy of Medicine”, online: <https://nam.edu/about-the-nam/>.

National Cancer Institute, Dictionary of Cancer Terms, online: <www.cancer.gov/publications/dictionaries/cancer-terms/>.

The United States Court of Appeals for the Fourth Circuit. “About the Court”, online: <www.ca4.uscourts.gov/about-the-court>.

Appendix A

MDRs Section	Case Law Treatment
Section 10	1. *Drady v Canada (Minister of Health)*, 2008 ONCA 659 (action against Health Canada arguing for a private law duty of care in relation to Health Canada's failure in the 1980s to obtain a Notice of Compliance from a medical device manufacturer; unrelated to current *MDRs*) 2. *Robinson v Medtronic Inc,* 2010 ONSC 1739 (Ont SCJ) (class proceeding related to Medtronic Inc.'s (Defendant) motion to strike a Plaintiff's conspiracy claim that alleged Medtronic Inc, "was negligent in the design, testing, development, manufacture and distribution of their Sprint Fidelis defibrillation leads (the 'Leads') and that Medtronic failed to warn the public about alleged defects in those Leads. The Plaintiffs also alleged a conspiracy to conceal the alleged defects." para 2 (case irrelevant) 3. *Klein v American Medical Systems Inc*, [2006] OJ No 2188 (Ont SCJ) 4. *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ)
Section 11	1. *Robinson v Medtronic Inc,* 2010 ONSC 1739 (Ont SCJ) 2. *Drady v Canada (Minister of Health)*, 2008 ONCA 659 *3. Adam v Ledesma-Cadhit*, 2014 ONSC 5726 (Ont SCJ) (related to a death alleged to be caused by an H1N1 vaccine). 3. *Klein v American Medical Systems Inc*, [2006] OJ No 5181 (Ont Div Ct) 4. *Klein v American Medical Systems Inc*, [2006] OJ No 2188 (Ont SCJ) 5. *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ)
Section 12	1. *Robinson v Medtronic Inc,* 2010 ONSC 1739 (Ont SCJ) 2. *Adam v Ledesma-Cadhit*, 2014 ONSC 5726 (Ont SCJ) 3. *Klein v American Medical Systems Inc*, [2006] OJ No 5181 (Ont Div Ct) 4. *Klein v American Medical Systems Inc*, [2006] OJ No 2188 (Ont SCJ) 5. *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ)
Section 13	Same cases as section 12.
Section 14	1. *Adam v Ledesma-Cadhit*, 2014 ONSC 5726 (Ont SCJ) 2. *Klein v American Medical Systems Inc*, [2006] OJ No 5181 (Ont Div Ct) 3. *Klein v American Medical Systems Inc*, [2006] OJ No 2188 (Ont SCJ) 4. *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ)
Section 15	1. *Drady v Canada (Minister of Health)*, 2008 ONCA 659 2. *Adam v Ledesma-Cadhit*, 2014 ONSC 5726 (Ont SCJ) 3. *Klein v American Medical Systems Inc*, [2006] OJ No 5181 (Ont Div Ct) 4. *Klein v American Medical Systems Inc*, [2006] OJ No 2188 (Ont SCJ) 5. *Klein v American Medical Systems Inc*, [2005] OJ No 4910 (Ont SCJ)
Section 16-20	Same cases as section 14.