McGill Journal of Law and Health ~ Revue de droit et santé de McGill

MJLH
RDSM

Montreal 2017 Montréal

ISSN: 1920 – 4825 (Print Edition), 1920 – 4833 (Online Edition)

McGill Journal of Law and Health ~ Revue de droit et santé de McGill

MJLH
RDSM

Vol. 11, No. 2
2017

ARTICLES

A Proposal for Access to Treatment Contrary to Clinical Judgment

*Hilary Young**

Remarkably, it is unclear in much of Canada whether physicians must provide treatment contrary to their clinical judgment when it is requested by patients. The Supreme Court of Canada held in *Cuthbertson v Rasouli* that an Ontario statute allows patients to demand certain life-sustaining treatment contrary to clinical judgment. However, much confusion remains in Ontario when non-life-sustaining treatments are at issue, and the common law across Canada remains unsettled. To assess the benefits and detriments of different approaches to the issue, the laws of Ontario and England are compared. Whereas in Ontario physicians must provide (at least) certain life-sustaining treatment contrary to clinical judgment, in England, courts have consistently held that physicians may refuse to provide treatment contrary to their clinical judgment. English physicians may withdraw even life-sustaining treatment from patients, despite opposition from patients or their families, if the physicians believe continued treatment is medically inappropriate. Each approach has benefits and detriments. Ontario's law, for example, has the benefit of promoting patient autonomy,

Remarquablement, il n'est clair dans une grande partie du Canada si les médecins doivent fournir des traitements allant à l'encontre de leurs jugements cliniques lorsqu'ils sont demandés par des patients. La Cour suprême du Canada a décidé dans *Cuthbertson c Rasouli* qu'une loi ontarienne permet aux patients de demander certains traitements de maintien de la vie contraires au jugement clinique. Cependant, une grande confusion demeure en Ontario lorsque des traitements autres que ceux du maintien de la vie sont impliqués, et la *common law* à travers le Canada demeure incertaine. Pour évaluer les avantages et désavantages des différentes approches vis-à-vis ce problème, le droit en Ontario et en Angleterre sont comparés. Alors qu'en Ontario les médecins doivent fournir (au moins) certains traitements contraires à leurs jugements cliniques, en Angleterre, les tribunaux ont uniformément décidé que les médecins peuvent refuser de fournir des traitements contraires à leurs jugements cliniques. Les médecins anglais peuvent même retirer les traitements de maintien de la vie à leurs patients, malgré l'opposition des pa-

* Associate Professor, University of New Brunswick. Professor Young wishes to thank Brianna Carmichael and Colleen Thrasher for their consistently excellent research assistance. She also wishes to thank Jocelyn Downie and Mike Hadskis for a valuable brainstorming session on unilateral withholding and withdrawal of treatment. Finally, she wishes to thank the peer reviewers for their helpful comments.

Citation: Hilary Young, "A Proposal for Access to Treatment Contrary to Clinical Judgment" (2017) 11:2 McGill JL & Health 1.

Référence : Hilary Young, « A Proposal for Access to Treatment Contrary to Clinical Judgment » (2017) 11 : 2 RD & santé McGill 1.

while England's approach recognizes that physicians' role is in part moral and helps protect patients. Opting neither for the English approach nor the Ontarian approach, I ultimately suggest that physicians should be required to provide patients with the treatment they request, even if contrary to clinical judgment, unless a court or tribunal determines the requested treatment to be unreasonable in the circumstances. Unreasonableness should be assessed based on medical criteria, the patient's values, availability of resources, and any other relevant consideration. This approach has the advantage of giving patients a large degree of autonomy and limiting the cost of access to justice, while acknowledging that the physicians should continue to have some role in limiting access to medical interventions.

tients ou de leurs familles, si les médecins croient que la poursuite du traitement serait médicalement inappropriée. Chaque approche a ses avantages et désavantages. Le droit en Ontario, par exemple, a l'avantage de promouvoir l'autonomie du patient, alors que l'approche de l'Angleterre reconnaît que le rôle des médecins est en partie moral et aide à protéger les patients. Optant ni pour l'approche anglaise ni pour l'approche ontarienne, je suggère ultimement que les médecins devraient être obligés de fournir aux patients les traitements qu'ils demandent, même s'ils sont contraires à leurs jugements cliniques, à moins qu'un tribunal administratif ou judiciaire détermine que le traitement soit déraisonnable dans les circonstances. Le caractère déraisonnable du traitement devrait être évalué sur la base de critères médicaux, des valeurs du patient, de la disponibilité des ressources, et de toute autre considération pertinente. Cette approche a l'avantage d'accorder aux patients un grand degré d'autonomie et de limiter les coûts d'accès à la justice, tout en reconnaissant que les médecins devraient continuer à avoir un certain rôle en limitant l'accès aux interventions médicales.

> *Without discretionary latitude, the physician cannot … fulfill her obligation to use her knowledge for the patient's best interests. Without constraints on discretionary latitude, the physician's decisions can violate the patient's values or produce physical harm. The balance between too narrow and too wide a definition of discretionary space is a delicate, but increasingly important, one to strike.*[1]

Introduction

When the Supreme Court of Canada struck down the criminal prohibition on medical assistance in dying (MAID) in *Carter v Canada (AG)*[2] and Parliament began drafting MAID legislation, questions were raised about physicians' ability to refuse to participate in the procedure on grounds of conscience. It quickly became clear that physicians would not be required to perform MAID and that, at most, they would have to refer their patients to a willing physician.[3] This is therefore a situation in which physicians' right to

---

1 Edmund D Pellegrino, "Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship" (1994) 10 J Contemp Health L & Pol'y 47 at 61 [Pellegrino, "Patient and Physician Autonomy"].

2 2015 SCC 5, [2015] 1 SCR 331 [*Carter*].

3 See *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)*, SC 2016, c 3, s 3 [*MAID Act*], amending *Criminal Code*, RSC 1985, c C-46, s 241.2(9) ("nothing in this section compels an individual to provide or assist in providing medical assistance in dying"). Minister of Health Jane Philpott, debating the bill that would become the *MAID Act*, stated that "this proposed legislation does not compel any health care practitioner to provide medical assistance in dying. Practitioners will have the right to choose as their conscience dictates": *House of Commons Debates*, 42nd Parl, 1st Sess, No 45 (22 April 2016) at 2602. The College of Physicians and Surgeons of Ontario has imposed an obligation on physicians to provide an effective referral, and this is currently the subject of a judicial review based on physicians' freedom of conscience: see Amanda Pfeffer, "Ontario Doctors Challenge Policy Forcing Referrals for Medically Assisted Dying", *CBC News* (15 June 2017), online: <www.cbc.ca/news/canada/ottawa/medically-assisted-dying-ontario-college-1.4159660>. The Québec medical assistance in dying (MAID) law enshrines a right to refuse to administer MAID based on personal convictions, without providing a direct referral, although physicians must report the request to the institution's director or the local health authority: *An Act respecting end-of-life care*, CQLR 2014, c S-32.0001, ss 31, 50.

refuse to provide treatment, based on their personal or professional ethics, is recognized in law.

In *Cuthbertson v Rasouli*,[4] fifteen months before *Carter* was decided, the Supreme Court adjudicated a dispute over whether a patient's life-sustaining treatment should be continued. Two doctors argued that it would place them in an "untenable ethical situation" to have to continue providing treatment to their patient if it provided "no medical benefit to, or even [harmed], the patient."[5] In six brief paragraphs, the Court rejected the physicians' ethical argument out of hand, essentially on the basis that ethical tensions are "inherent to medical practice."[6]

The law governing the refusal to provide MAID is not inconsistent with the decision in *Rasouli* – the legal bases are different, as are some of the issues raised. Nevertheless, the courts' different approaches to whether doctors must treat patients in a manner they object to on ethical grounds inspired this article.

This article focuses on whether physicians may deny treatment requested by patients or their substitute decision makers (SDMs) because the treatment is contrary to their clinical judgment. In essence, it asks whether patients should be able to receive whatever treatment they want, regardless of medical norms and subject only to minimal exceptions, such as lack of resources. Put another way, the article asks whether there is still a role for physicians as gatekeepers of "good medicine."

Although *Rasouli* clarified to some extent Ontario law on this question, as grounded in the *Health Care Consent Act* (*HCCA*),[7] considerable uncertainty remains in Ontario and elsewhere. This is in part because the issue is relatively new. It arises because of the increasing weight given to patient autonomy in the medical sphere. Whereas traditionally, physicians would paternalistically make decisions for their patients, patients now have a much greater role in medical decision making. This can only be a good thing. Yet the pendulum continues to swing in favour of patient autonomy such that it is sometimes "elevated to the status of a trumping principle, morally as

---

4 2013 SCC 53, [2013] 3 SCR 341 [*Rasouli*].

5 *Ibid* at para 71.

6 *Ibid* at paras 71–76.

7 *1996*, SO 1996, c 2, Schedule A [*HCCA*].

well as legally."[8] Some speak of "patient paternalism."[9] The principle of patient autonomy is being argued to ground not only negative rights against being treated against one's will or without first receiving relevant information, but also to ground de facto entitlements to treatment. And once this door has been opened, difficult questions arise about *which* treatments must be provided. Objectively ineffective treatments, like antibiotics to treat a viral condition, may pose few problems. But treatment can be ineffective in subjective ways – for example, when is it clear that a patient will not make a meaningful recovery such that one might argue that life-sustaining treatment should be withdrawn. In addition, it can be argued that effectiveness (or medical benefit) is not the only relevant criterion. Some, for example, believe that life should always be preserved because of its sanctity or inherent value, regardless of considerations of medical benefit. Given this, determining who should have the final say about treatment contrary to clinical judgment requires considering a wide range of issues and balancing competing interests. This question often arises in the context of end-of-life treatment decisions. The present article therefore draws on these examples in outlining current approaches, but ultimately recommends a policy solution that is broadly applicable to requests for treatment contrary to clinical judgment.

The issue of who should ultimately be able to decide whether requested treatment is provided has received relatively little scholarly attention in Canada, although that may be changing in light of the Supreme Court's decision in *Rasouli*.[10] Downie, Willmott, and White's article is a notable

---

8 Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 58. Pellegrino continues: "In the United States, these threats to the physician's autonomy and conscience derive from the evolution of autonomy from a negative to a positive right" (*ibid* at 58–59).

9 Judith F Daar, "A Clash at the Bedside: Patient Autonomy v. a Physician's Professional Conscience" (1993) 44:6 Hastings LJ 1241 at 1244–45 [Daar, "Clash"].

10 See e.g. Hilary Young, "Why Withdrawing Life-Sustaining Treatment Should Not Require '*Rasouli* Consent'" (2012) 6:2 McGill JL & Health 54 [Young, "Withdrawing Life-Sustaining Treatment"]; Hilary Young, "*Cuthbertson v. Rasouli*: Continued Confusion over Consent-Based Entitlements to Life Support" (2015) 52:3 Alta L Rev 745 [Young, "Continued Confusion over Consent-Based Entitlements"]; Brandon Trask, "The Economics of Life and Death: Morals and Ethics in an Environment of Medical-Resource Scarcity" (2013) 37:1 Man LJ 233.

exception.[11] There is, however, a great deal of relevant scholarship from other jurisdictions.[12] There is also considerable scholarship on related issues such as physician conscientious objection[13] and on the concept of medical futility.[14]

---

[11] Jocelyn Downie, Lindy Willmott & Ben P White, "Next Up: A Proposal for Values-Based Law Reform on Unilateral Withholding and Withdrawal of Potentially Life-Sustaining Treatment" (2017) 54:3 Alta L Rev 803. See also Glen Rutland, "Futile or Fruitful: The *Charter* and the Decision to Withhold or Withdraw Life-Sustaining Treatment" (2009) 17 Health LJ 81, which predates *Rasouli* but addresses the issue of patients' *Charter* rights to treatment contrary to clinical judgment.

[12] See Downie, Willmott & White, *supra* note 11 at 806 (states that PubMed literature searches for unilateral withholding and withdrawal of treatment turned up over 2000 articles). For examples from the United States, see Daar, "Clash", *supra* note 9; Judith F Daar, "Medical Futility and Implications for Physician Autonomy" (1995) 21:2&3 Am JL & Med 221 at 225–27; Patrick Moore, "An End-of-Life Quandary in Need of a Statutory Response: When Patients Demand Life-Sustaining Treatment that Physicians are Unwilling to Provide" (2007) 48:2 Boston College L Rev 433; Amir Halevy, "Medical Futility, Patient Autonomy, and Professional Integrity: Finding the Appropriate Balance" (2008) 18:2 Health Matrix 261. For examples from the United Kingdom, see Jonathan Montgomery, "Conscientious Objection: Personal and Professional Ethics in the Public Square" (2015) 23:2 Med L Rev 200; Søren Holm & Andrew Edgar, "Best Interest: A Philosophical Critique" (2008) 16:3 Health Care Anal 197; John Coggon, "Best Interests, Public Interest, and the Power of the Medical Profession" (2008) 16:3 Health Care Anal 219; Simon Woods, "Best Interests: Puzzles and Plausible Solutions at the End of Life" (2008) 16:3 Health Care Anal 279; Edwina A Brown, "Ethnic and Cultural Challenges at the End of Life: Setting the Scene" (2014) 40:1 J Ren Care 2; Jonathan CW Youngs, "Can the Courts Force the Doctor's Hand? *St George's Healthcare NHS Trust v P* [2015] EWCOP 42", Case Comment, (2015) 24:1 Med L Rev 99; Maria K Sheppard, "Fallacy or Functionality: Law and Policy of Patient Treatment Choice in the NHS" (2016) 24:4 Health Care Anal 279.

[13] See e.g. Daphne Gilbert, "Let Thy Conscience Be Thy Guide (but not My Guide): Physicians and the Duty to Refer" (2017) 10:2 McGill JL & Health 47; Jocelyn Downie, Carolyn McLeod & Jacquelyn Shaw, "Moving Forward with a Clear Conscience: A Model Conscientious Objection Policy for Canadian Colleges of Physicians and Surgeons" (2003) 21:3 Health L Rev 28.

[14] See e.g. Stuart J Youngner, "Who Defines Futility?" (1988) 260:14 JAMA 2094; James L Bernat, "Medical Futility: Definition, Determination, and Disputes in Critical Care" (2005) 2:2 Neurocrit Care 198; Lawrence J Schneiderman, "Defining Medical Futility and Improving Medical Care" (2011) 8:2 J

To ground a discussion of the issues, the article compares Ontario law to that in England and Wales (henceforth simply "England"). Whereas Ontario law rejects physicians' claims not to have to practice contrary to their clinical judgment (at least for certain life-sustaining treatment), English courts have upheld such claims. That is, English courts have generally rejected patients' claims to treatment that physicians refuse to provide because it is contrary to their clinical judgment. Despite similar legal systems generally, the laws of Ontario and England have diverged considerably and provide useful examples for assessing the benefits and detriments of unilateral decision making by physicians versus allowing patients to demand treatment contrary to clinical judgment.[15]

What the law in Canadian jurisdictions should be – particularly outside Ontario – is a matter for legislation informed by public debate. To contribute to that debate, I offer my own suggestion which differs from the approaches in England and Ontario. I propose a presumption in favour of patient choice that can be rebutted if a physician establishes that the requested treatment is unreasonable in the circumstances.

Note that although this article focuses on law regarding *physicians*' duties, they are by no means the only ones who have concerns about treating patients in ways they consider contrary to the dictates of their profession. According to one physician, nurses are often the ones who first experience moral distress at what they view at prolonging patients' suffering.[16] Other medical professionals may also have concerns about their role in treatment. Nevertheless, the scope of this article is limited to physicians' claims to be able to refuse to administer treatment that is contrary to their clinical judgment.

Finally, note that the article deals with treatment contrary to clinical judgment, which has been described as the "flexible, interpretive capacity that enables moral reasoners … to determine the best action to take when

---

Bioeth Inq 123; Lawrence J Schneiderman, Nancy S Jecker & Albert R Jonsen, "Medical Futility: Its Meaning and Ethical Implications" (1990) 112:12 Ann Intern Med 949; Thaddeus Mason Pope, "Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment" (2007) 75:1 Tenn L Rev 1.

15 For a discussion of approaches to the issue of unilaterally withholding or withdrawing treatment in other common law jurisdictions, see Downie, Willmott & White, *supra* note 11.

16 See personal communication with Dr. Brian Cuthbertson (6 July 2016).

knowledge depends on circumstance."[17] It implicates ethics but is a process of arriving at proposals for treatment based on available knowledge and skill. For our purposes, clinical judgment may be understood as a reasoned decision about what treatments should or should not be offered in specific circumstances.

This judgment may be based on any number of facts and opinions including purely medical or more ethical ones. In the context of withholding or withdrawing life-sustaining treatment, professional ethics will often be implicated. For example, we will see the example of physicians who considered it unethical to continue to "torture" a dying patient by keeping him alive. However, clinical judgment not to offer a particular treatment may be grounded in other considerations, such as resource allocation or the physician's lack of skill. By focusing on clinical judgment rather than professional ethics we can consider ethical considerations as well as those other reasons for withholding or withdrawing treatment.

The standard of care, which is sometimes referred to below, is also different than clinical judgment. It refers to the fault standard of reasonableness in negligence law. In medicine, it is generally defined in terms of customary medical practice.[18] For our purposes, relevant differences between the standard of care and clinical judgment include that the standard of care is objectively determined whereas clinical judgment is subjective. Further, a range of treatments may be reasonable while a physician, in her clinical judgment, may approve of only a subset of these. Finally, it is possible for clinical judgment to be contrary to the standard of care.

I. Requests for Treatment Contrary to Clinical Judgment: Four Examples

Generally, when patients request a particular treatment it will either be provided, because it is indicated and the physician is willing to provide it, or else it will not be provided, because it is not indicated, and another treat-

---

17 Kathryn Montgomery, *How Doctors Think: Clinical Judgment and the Practice of Medicine* (New York: Oxford University Press, 2006) at 4–5, citing Aristotle, *Nicomachean Ethics*, translated by Terence Irwin (Indianapolis: Hackett, 1985) at 5–6.

18 See Allen M Linden & Bruce Feldthusen, *Canadian Tort Law*, 10th ed (Toronto: LexisNexis, 2015) at 184–85.

ment will be provided that satisfies the patient. Increasingly, however, as patient autonomy assumes greater importance in medical decision making, patients or their SDMs may insist on treatment that physicians do not consider medically appropriate.

In some situations in which treatment contrary to physicians' clinical judgment is requested, it is clear how such requests should be addressed. If patients request opioids despite not being in pain or request antibiotics despite having a viral infection, few would argue that doctors should have to provide these. The patients' moral claim to such treatment, grounded primarily in autonomy, is outweighed by other considerations such as not wanting to harm the patient. The Supreme Court referred to this as "common sense."[19]

More difficult situations arise, however, in the context of end-of-life treatment. There may be legitimate disagreements between patients (or their SDMs) and physicians as to whether life-prolonging or life-sustaining treatments should be provided or continued. What is medically indicated and what patients or family members value may conflict. What is medically indicated may not even be clear. For example, precisely when does life-support that starts out as indicated become contraindicated, as the patient fails to improve over time? There can be no single, objectively correct answer to this question. Further, even if there were a clear answer, it would not follow that providing any contraindicated treatment would be at odds with the proper practice of medicine. For example, if it became clear that continued life-support was no longer beneficial and therefore not indicated, good medical care might require spending time with family members to try to arrive at a consensus before ending treatment.

The following are four examples of litigated conflicts – or potential conflicts, in the *Burke* case – between the wishes of patients or SDMs and physicians' wishes not to be compelled to practice contrary to their clinical judgment.

A. Cuthbertson v Rasouli

Hassan Rasouli suffered complications from brain surgery and has been in a minimally conscious or persistent vegetative state since October 2010.

---

[19] *Rasouli*, *supra* note 4 at para 58.

Despite some disagreement between his doctors and his family as to his diagnosis, it is undisputed that Mr. Rasouli needs a mechanical ventilator and artificial hydration and nutrition in order to survive.[20] When this article was being finalized, he had spent seven years in this state at Sunnybrook Hospital in Toronto.

Mr. Rasouli's physicians sought to withdraw his mechanical ventilation, with the virtually inevitable result that he would die. They believed there was nothing more that could be done for Mr. Rasouli medically, that continued treatment was contrary to the standard of care, and that being required to continue treating Mr. Rasouli would conflict with their views about the proper practice of medicine.[21] For both medical and religious reasons,[22] Mr. Rasouli's family refused consent to have treatment discontinued and sought a court order to prevent the doctors from doing so.

B. Golubchuk v Salvation Army Grace General Hospital

Samuel Golubchuk was a very ill 84-year-old. He needed a ventilator to breathe and a feeding tube to eat. He was minimally responsive to pain and other stimuli and medical staff said Mr. Golubchuk had little if any conscious existence, although as in *Rasouli*, his family disputed this. He had a serious heart condition. His kidneys had begun to fail, although their deterioration had ceased. He had brain damage.[23] And yet he lived. For more than a year, Mr. Golubchuk lived in the Salvation Army Grace Hospital's intensive care unit.

After a few months, the hospital wanted to remove Mr. Golubchuk's mechanical ventilator and let him die, but the family refused based on their religious beliefs.[24] The case ended up in the courts where the family obtained an injunction preventing the ventilator from being withdrawn until the matter could be resolved on its merits.

---

20 See *ibid* at para 5.

21 See *ibid* at paras 6, 71.

22 See *ibid* at paras 7, 89.

23 See *Golubchuk v Salvation Army Grace General Hospital*, 2008 MBQB 49 at paras 4–9, 290 DLR (4th) 46 [*Golubchuk*].

24 See *ibid* at para 10.

In the meantime, doctors did what they could for Mr. Golubchuk. This included "hack[ing] away" at infected flesh "to keep infection at bay."[25] Pressure sores continued to develop because Mr. Golubchuk's circulatory system was not functioning well enough to prevent them. Doctors had to keep cutting away the sores until there was "little flesh left between his knees and the small of his back."[26]

This was so upsetting to medical staff that one physician quit so he would not be forced to continue treatment that he viewed as "tantamount to torture,"[27] "grotesque,"[28] and "an abomination."[29] Two other physicians refused to participate in Mr. Golubchuk's treatment on moral grounds. This put such pressure on the intensive care unit that there was some concern about the hospital's ability to keep it open.[30]

Before the matter could be decided on its merits, Mr. Golubchuk died.

C. Burke v General Medical Council

Oliver Leslie Burke suffered from spinocerebellar ataxia, a degenerative brain disease that would erode his physical functions but not his mental

---

[25] "Doctor Quits over Dispute on Whether to Treat Winnipeg Man", *Canadian Press* (4 June 2008), online: CBC <www.cbc.ca/news/canada/manitoba/doctor-quits-over-dispute-on-whether-to-treat-winnipeg-man-1.698422>.

[26] Michael Smith, "Special Report: Court-Ordered End-of-Life Care for Comatose Patient Deemed Torture", *MedPage Today* (14 August 2008), online: <www.medpagetoday.com/PublicHealthPolicy/PublicHealth/10552>.

[27] *Ibid*; "2 More Winnipeg Doctors Resign in Dispute over Elderly Man's Treatment", *CBC News Manitoba* (16 June 2008), online: <www.cbc.ca/news/canada/manitoba/2-more-winnipeg-doctors-resign-in-dispute-over-elderly-man-s-treatment-1.722204>) [CBC News, "2 More Winnipeg Doctors"].

[28] Smith, *supra* note 26.

[29] *Ibid*.

[30] See Jamie Komarnicki, "Two More Doctors Resign over Life-Support Case", *The Globe and Mail* (17 June 2008), online: <www.theglobeandmail.com/news/national/two-more-doctors-resign-over-life-support-case/article674697> ("critical-care doctors from the city's other hospitals are being asked to take on shifts to support Grace Hospital's three remaining doctors on the unit" and "chief medical officer Elizabeth Cowden expressed concern that the ICU could be forced to close if other physicians followed Dr. Kumar's lead and resigned").

capacity.[31] The prognosis was that Mr. Burke would end up dependent on artificial hydration and nutrition to survive because he would eventually be unable to swallow on his own.[32]

At the time of trial, Mr. Burke was not yet in need of artificial nutrition and hydration but he anticipated such a need and wanted the courts to declare that it would be provided to him – that physicians could not decide that "his life is no longer worth living" and cease providing life-sustaining treatment.[33] It was expected he would retain his capacity until near the very end of his life, such that he would be the one making his own medical decisions.

Mr. Burke was concerned that certain provisions of the United Kingdom's General Medical Council (GMC) guidance on end-of-life treatment might permit physicians unilaterally to withdraw his artificial hydration and nutrition.[34] He therefore sought a declaration that those provisions were contrary to the *European Convention on Human Rights* (*ECHR*)[35] and that, under certain circumstances, withdrawing artificial hydration and nutrition would be contrary to the *ECHR*.[36]

D. AVS v A NHS Foundation Trust

Finally, consider the situation of Mr. AVS. He had Creutzfeldt-Jakob disease (CJD), a fatal condition that attacks the brain.[37] While still competent, Mr. AVS appointed his brother to be his attorney for personal care, but

---

31 See *Burke, R (on the application of) v General Medical Council*, [2005] EWCA Civ 1003 at para 2, [2005] 3 WLR 1132 [*Burke*].

32 See *ibid*.

33 *Ibid* at paras 5–6.

34 See *ibid* at para 14, referring to UK, General Medical Council, "Withholding and Withdrawing Life-Prolonging Treatment: Guidance for Doctors" (2002, withdrawn July 2010) at paras 32, 38, 81, online: <www.gmc-uk.org/Withholding_and_withdrawing_guidance_for_doctors.pdf_33377901.pdf>.

35 Convention for the Protection of Human Rights and Fundamental Freedoms, 4 November 1950, 213 UNTS 221 (entered into force 3 September 1953).

36 See *Burke*, *supra* note 31 at para 14.

37 See *AVS v A NHS Foundation Trust*, [2011] EWCA Civ 7 at para 3, [2011] 2 FLR 1 [*AVS*].

the litigation concerned events that occurred after Mr. AVS lost capacity. In fact, during the litigation he was in a persistent vegetative state or "very close to it" although, as in *Rasouli* and *Golubchuk*, the family disputed this diagnosis.[38]

Mr. AVS apparently told his brother to pursue all treatment options and to never "give up."[39] The brother discovered an experimental treatment for CJD and a doctor who was willing to administer it. There was some indication of the treatment's success in slowing down the disease's progression but, when the pump used in the treatment failed, the hospital refused to provide the surgery needed to resume treatment. The medical evidence suggested that Mr. AVS' condition had deteriorated to the point that the experimental treatment could have no further benefit. The treating physician determined that it would be medically inappropriate to continue the experimental treatment under the circumstances.[40] There was some evidence that another physician was willing to resume the treatments but it seems that no facility was found where this could take place.[41]

The brother sought a declaration that continued treatment, via the experimental method, was in Mr. AVS' best interests with the intention that this declaration would force the resumption of the experimental treatment.[42]

Each of the above cases involves a patient's claim to be entitled to treatment that physicians considered contrary to clinical judgment. In each, failure to provide the requested treatment would either lead to the patient's imminent death (*Rasouli*, *Golubchuk*, *Burke*) or deny the patient a perceived opportunity to slow the progression of a fatal disease (*AVS*).

Three involve incompetent patients whose decisions were being made by SDMs (*Rasouli*, *Golubchuk*, *AVS*, although *AVS* apparently involves a prior competent wish), while one involves a competent patient (*Burke*).

---

38 *Ibid* at para 5.

39 *Ibid* at para 9.

40 See *ibid* at para 7.

41 See *ibid* at para 10.

42 See *ibid* at paras 35, 38.

At least three involve the withdrawal of treatment that was previously being provided (mechanical ventilation in *Rasouli* and *Golubchuk*, artificial nutrition and hydration in *Burke*). One involves withholding rather than withdrawing treatment (*AVS*). Although the experimental treatment had previously been provided, it was discontinued due to a mechanical failure. At the time the decision was made as to whether the treatment should be offered, it was a case of potentially providing a treatment that was not presently being provided.[43]

These examples paint a picture of a particular problem that will presumably become more common as technology for keeping patients alive improves and the role of patient autonomy in medical decision making assumes greater importance. The problem is that of conflicts between patients' (or their SDMs') interest in determining their medical treatment and physicians' and society's interest in physicians not having to practice medicine contrary to their clinical judgment. The next section examines how courts in England and Ontario have resolved those conflicts.

II. The Law in England and Canada

In Canada, the common law is somewhat uncertain with regard to physicians' obligation to treat contrary to clinical judgment.[44] Some provinces have health care consent statutes that do not explicitly address the issue,[45] but as we shall see, the Ontario statute has been interpreted as requiring physicians sometimes to treat contrary to their clinical judgment. This is in contrast to the law in England, where courts have rejected patients' claims to treatment contrary to clinical judgment, even where physicians' decision not to treat would lead to death. I begin with English law, since it represents a starting point. Canadian law on this issue seems once to have been the same

---

43 For another case that involves withholding rather than withdrawing treatment, see *Rotaru v Vancouver General Hospital Intensive Care Unit*, 2008 BCSC 318, [2008] BCJ No 456 (QL) [*Rotaru*], discussed below.

44 See *Rasouli*, *supra* note 4 at para 53.

45 See e.g. *Health Care (Consent) and Care Facility (Admission) Act*, RSBC 1996, c 181 [British Columbia *Act*]; *The Health Care Directives Act*, SM 1992, c 33, CCSM c H27 [Manitoba *Act*]; *Advance Health Care Directives Act*, SNL 1995, c A-4.1 [Newfoundland *Act*]; *Infirm Persons Act*, RSNB 1973, c I-8.

as current English law, although there was little case law on point, but it has since diverged in Ontario.

A. England and Wales

England's courts have consistently held that doctors do not have to treat contrary to their clinical judgment. Recall that in *Burke*, a man was seeking to have the courts declare certain provisions of the General Medical Council guidance on end-of-life treatment to be contrary to the *ECHR*. Although Mr. Burke was successful at trial, the decision was overturned on appeal. The England and Wales Court of Appeal (EWCA) stated that "a patient cannot demand that a doctor administer a treatment which the doctor considers is adverse to the patient's clinical needs."[46] The decision rejected the notion that

> provided that there are no resource implications, doctors who have assumed the care of a patient must administer such treatment as is in the patient's best interests and that, where a patient has expressed an informed wish for a particular treatment, receipt of such treatment will be in the patient's best interests.[47]

The court went on to endorse the following views of the General Medical Council, which are set out here in their entirety since they are clear and, as we shall see, quite contrary to Ontario law:

> i) The doctor, exercising his professional clinical judgment, decides what treatment options are clinically indicated (i.e. will provide overall clinical benefit) for his patient.
>
> ii) He then offers those treatment options to the patient in the course of which he explains to him/her the risks, benefits, side effects, etc involved in each of the treatment options.
>
> iii) The patient then decides whether he wishes to accept any of those treatment options and, if so, which one. In the vast majority of cases he will, of course, decide which treatment option he considers to be in his best interests and, in doing so,

---

46 *Burke*, *supra* note 31 at para 55.

47 *Ibid* at paras 27, 29.

> he will or may take into account other, non clinical, factors. However, he can, if he wishes, decide to accept (or refuse) the treatment option on the basis of reasons which are irrational or for no reasons at all.
>
> iv) If he chooses one of the treatment options offered to him, the doctor will then proceed to provide it.
>
> v) If, however, he refuses all of the treatment options offered to him and instead informs the doctor that he wants a form of treatment which the doctor has not offered him, the doctor will, no doubt, discuss that form of treatment with him (assuming that it is a form of treatment known to him) but if the doctor concludes that this treatment is not clinically indicated he is not required (i.e. he is under no legal obligation) to provide it to the patient although he should offer to arrange a second opinion.[48]

The clarity of the EWCA's position in *Burke* was somewhat undermined by the court's conclusion that to deny Mr. Burke artificial nutrition and hydration (ANH), given his express wish to receive it, would effectively be murder.[49] This followed from the fact that hospitals and doctors owe a duty of care to patients: "Where ANH is necessary to keep the patient alive, the duty of care will normally require the doctors to supply ANH."[50] Because of the patient's anticipated competence at the end of his life, the EWCA could not conceive of it being consistent with clinical judgment to withdraw ANH contrary to the patient's competent wishes. The point was moot as "[t]here are no grounds for thinking that those caring for a patient would … take a decision to withdraw ANH in such circumstances."[51]

In *Burke*, the EWCA stated:

> Autonomy and the right of self-determination do not entitle the patient to insist on receiving a particular medical treatment regardless of the nature of the treatment. *Insofar as a doctor has a legal obligation to provide treatment this cannot be*

---

48 *Ibid* at para 50.

49 *Ibid* at para 34.

50 *Ibid* at para 32.

51 *Ibid* at para 13.

> *founded simply upon the fact that the patient demands it. The source of the duty lies elsewhere*.[52]

In *AVS* six years later, the EWCA reiterated the law as espoused in *Burke*:

> It is trite that the court will not order medical treatment to be carried out if the treating physician/surgeon is unwilling to offer that treatment for clinical reasons conscientiously held by that medical practitioner.[53]

Recall that *AVS* involved a request by a SDM to have an experimental treatment which had had some benefit declared to be in a patient's best interests. The EWCA held that it was unnecessary to decide that question because even if resuming the treatment were in Mr. AVS' best interests, physicians would not be required to continue the treatment if they considered it no longer to be indicated. In other words, a

> declaration [that resuming treatment is in the patient's best interests] will not force the respondent hospital to provide treatment against their clinicians' clinical judgment. To use a declaration of the court to twist the arm of some other clinician … is an abuse of the process of the court and should not be tolerated.[54]

Finally, consider *Aintree University Hospitals NHS Foundation Trust v James*.[55] Like *Rasouli*, it involved a disagreement between physicians and family members over whether life-sustaining treatment would be provided. *James* was an appeal of a decision of the Court of Protection, which is similar to Ontario's Consent and Capacity Board (CCB) in that it makes determinations of capacity, appoints SDMs, and makes determinations of best interests.[56] The hospital had sought a declaration that it would be legal to withhold three treatments (invasive support for circulatory problems,

---

52 *Ibid* at para 31 [emphasis added].

53 *AVS*, *supra* note 37 at para 35.

54 *Ibid* at para 38.

55 [2013] UKSC 67, [2014] AC 591 [*James*].

56 See "Court of Protection", online: Government of the United Kingdom <www.gov.uk/courts-tribunals/court-of-protection>.

renal replacement therapy, and CPR) from a patient, Mr. James. Although Mr. James died before the UK Supreme Court could hear the matter, the widow's appeal was allowed to proceed in order to clarify the relevant law under the *Mental Capacity Act 2005*.[57]

The Supreme Court noted that as a "starting point," there is "a strong presumption that it is in a person's best interests to stay alive."[58] However, the Court agreed with the EWCA that the relevant issue was whether *treatment proposed to be provided* was in the patient's best interests.[59] This did not mean that treatment could be ordered to be provided contrary to clinical judgment because it was in the patient's best interests. The best interests inquiry only related to treatment proposed by physicians to be provided at all. The Court was clear that under the relevant legislation, "the court has no greater powers than the patient would have if he were of full capacity."[60]

The Supreme Court cited the 1990 EWCA decision in *Re J (A Minor) (Wardship: Medical Treatment)* for the proposition that "the court could not require the [health] authority to follow a particular course of treatment," but could "withhold consent to treatment of which it disapproves and … express its approval of other treatment proposed by the authority and its doctors."[61] It also cited with approval the EWCA decision in *Burke* to the effect that "a patient cannot demand that a doctor administer a treatment which the doctor considers is adverse to the patient's clinical needs."[62]

From *James* it appears that the primary limit on physicians' authority to refuse to provide treatment that is contrary to their clinical judgment is the negligence standard of care. The Supreme Court acknowledged that "[o]f course, there are circumstances in which a doctor's common law duty of care towards his patient requires him to administer a particular treatment."[63]

---

57 *James*, *supra* note 55 at paras 1, 15, referring to (UK), c 9.

58 *Ibid* at para 35.

59 *Ibid* at para 40.

60 *Ibid* at para 18.

61 *Ibid*, citing [1990] 3 All ER 930, [1991] Fam 33 at 48 (CA).

62 *James*, *supra* note 55 at para 18, citing *Burke*, *supra* note 31 at para 55.

63 *James*, *supra* note 55 at para 18. The Court went on to say: "It also follows that (provided of course that they have acted reasonably and without negligence)

Note that in Canada, fiduciary duties owed by physicians to patients could also constitute a limitation on physician discretion, but in England, where physician-patient relationships have not tended to be considered fiduciary,[64] such a limitation would not exist.

---

the clinical team will not be in breach of any duty towards the patient if they withhold or withdraw" treatment (*ibid* at para 22).

[64] In Canada, it is clear that the physician-patient relationship is fiduciary in nature. See e.g. Timothy Caulfield & Maeghan Toews, "Rare Diseases and Resource Allocation Policy: The Role of Canadian Legal and Ethical Norms" (2016) 49:1 UBC L Rev 789 at 809. Yet, "the question of how far this fiduciary duty extends" is a more recent and developing subject of "ethical and legal concern" (*ibid*). The existence of a fiduciary duty has certainly never been interpreted to mean that patients are entitled to whatever they ask of their physicians. Rather it has, for example, grounded a right to a copy of one's medical file. See *McInerney v MacDonald*, [1992] 2 SCR 138 at 150, 126 NBR (2d) 271 [*McInerney*]. In *McInerney* at 149, Justice La Forest stated:

> In characterizing the physician-patient relationship as "fiduciary", I would not wish it to be thought that a fixed set of rules and principles apply in all circumstances or to all obligations arising out of the doctor-patient relationship. As I noted in *Canson*, not all fiduciary relationships and not all fiduciary obligations are the same; these are shaped by the demands of the situation (citing *Canson Enterprises Ltd v Boughton & Co*, [1991] 3 SCR 534, 85 DLR (4th) 129).

In England, the doctor-patient relationship tends not to be considered fiduciary at all. See e.g. Peter Bartlett, "Doctors as Fiduciaries: Equitable Regulation of the Doctor-Patient Relationship" (1997) 5 Med L Rev 193 ("English courts have been loathe in recent years to characterize the doctor-patient relationship as being of a fiduciary character" at 193). In a more recent article, Ost explains why UK courts have tended not to recognize the physician-patient relationship as fiduciary:

> This judicial reluctance to connect fiduciary law with the doctor-patient relationship can be explained in part because English law has tended to view the concept of fiduciary relationship as a function of property law and equitable limitations on ownership. It comes into play, therefore, as the mechanism for controlling the abuse of property improperly obtained from relationships of trust and, as such, the concept primarily denotes a relationship with the property and/or economic interest rather than with the person (Suzanne Ost, "Breaching the Sexual Boundaries in the Doctor-Patient Relationship: Should English Law Recognise Fiduciary Duties?" (2016) 24:2 Med L Rev 206 at 223).

The best interests test is an important one in English law, but it cannot itself ground a duty to provide treatment: the test is simply that treatment proposed for an incompetent patient must be in her best interests. Another point worth noting about best interests is that in England, physicians determine a patient's best interests (subject to review by the Court of Protection), even though best interests include non-medical factors such as the patient's values.[65] This is in contrast to the approach in Canadian jurisdictions, where SDMs determine best interests and it is physicians who must challenge those decisions if they disagree with them.[66]

B. Canada: Common law

In the first cases dealing with patients' requests for treatment contrary to clinical judgment, Canadian courts seemed to take the same approach as English ones, although there were few cases and none dealt with *Canadian Charter of Rights and Freedoms* (*Charter*)[67] arguments on their merits.

In *Child and Family Services of Central Manitoba v RL* (*Lavallee*), decided in 1997, the Manitoba Court of Appeal held that consent was not required for a physician to refrain from treating a patient. The physician could place a "do not resuscitate" (DNR) order on a patient's chart regardless of an SDM's objection: "There is no need for a consent from anyone for a doctor to refrain from intervening."[68] The issue was decided on the basis that, considering the *Child and Family Services Act*[69] and the common law tort of battery, physicians are not legally required to provide treatment that is not medically indicated.[70]

---

65 See *James*, *supra* note 55 at para 29, interpreting UK, Office of the Public Guardian, Department of Constitutional Affairs, *Mental Capacity Act 2005: Code of Practice* (London: The Stationery Office, 2007), s 5.33, online: Government of the UK <www.gov.uk/government/publications/mental-capacity-act-code-of-practice>.

66 For the approach in Ontario, see *HCCA*, *supra* note 7, s 37(1).

67 Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11.

68 *Child and Family Services of Central Manitoba v RL* (1997), 123 Man R (2d) 135 at para 13, 154 DLR (4th) 409 (CA) [*Lavallee*].

69 SM 1985–86, c 8, CCSM c C80.

70 *Lavallee*, *supra* note 68 at paras 12–14.

Sawatzky v Riverview Health Centre Inc also addressed whether a physician could place a DNR order on a patient's chart contrary to the wishes of the SDM.[71] Unlike *Lavallee*, the matter was interlocutory. Mr. Sawatzky's spouse requested that the court remove the existing DNR order pending the outcome of a decision on the merits of the case.[72]

Although interlocutory, *Sawatzky* is notable for three reasons. First, it takes seriously the claims of physicians not to have to practice contrary to their clinical judgment. The court states that the issues raised include "fundamental questions relating to a patient's right to medical treatment and a doctor's obligation to provide that treatment. Those questions raise serious legal, moral, ethical, medical and practical issues."[73] Justice Beard referred to the 1992 EWCA decision in *Re J (A Minor) (Wardship: Medical Treatment)* in which one judge said that it would be an abuse of power to force a doctor to practice contrary to her "bona fide clinical judgment"[74] and another stated that a court order forcing a doctor to treat contrary to clinical judgment would "place a conscientious doctor in an impossible position."[75]

A second reason why *Sawatzky* is notable is that it suggests that one's claim not to have to treat may be diminished if one had previously been willing to treat. With regard to the physician who imposed the DNR, Justice Beard stated: "If he viewed that decision as an ethical dilemma, it was clearly one that he was able to live with for some time."[76]

A third reason is that *Sawatzky* distinguishes between objection grounded in professional ethics, and objection grounded in personal ethics: "The treatment does not, in and of itself, raise the same type of ethical problems for the doctor that could be associated with controversial procedures like

---

71 (1998), 132 Man R (2d) 222 at para 1, 167 DLR (4th) 359 (QB) [*Sawatzky*].

72 *Ibid*.

73 *Ibid* at para 5.

74 *Ibid* at para 19, citing [1992] 4 All ER 614 at 622, [1993] Fam 15 (CA), Lord Donaldson, MR [*Re J*, 1992]. Note that this England and Wales Court of Appeal case is unrelated to the one cited at note 60, though they bear the same style of cause.

75 *Sawatzky*, *supra* note 71 at para 20, citing *Re J*, 1992, *supra* note 74 at 625, Balcombe LJ.

76 *Sawatzky*, *supra* note 71 at para 31.

abortions."[77] Given that this was one of the reasons cited for removing the DNR order pending a decision on the merits of the case, the implication is that requiring physicians to perform "controversial procedures" (presumably a violation of *personal* ethics) is a greater intrusion than requiring them to treat contrary to their professional ethics, although why this would be was not explained.

Ultimately, Justice Beard required the DNR order to be removed pending a decision on the merits. She recognized that Canadian law did not seem to require physicians to provide treatment contrary to their clinical judgment, but noted that there was little case law on point.[78] Further, the patient's spouse was raising *Charter* arguments that had never been considered by courts.[79]

Mr. Sawatzky died before the matter could be decided on its merits. *Sawatzky* therefore is not precedent on the question of any obligation to provide requested treatment, but provides valuable context in the development of Canadian law.

In the *Golubchuk* case, as in *Sawatzky*, the court granted an interim injunction requiring that treatment continue, on the basis that the law was unresolved as to who had the final say about withdrawing treatment.[80] Thus, although treatment was required to continue, neither *Sawatzky* nor *Golubchuk* stands for the proposition that physicians must provide non-indicated treatment to patients. Mr. Golubchuk also died before the matter could be resolved on its merits.

In 2008, the Supreme Court of British Columbia upheld a physician's decision not to provide certain treatment. In this case, *Rotaru v Vancouver General Hospital Intensive Care Unit*, a daughter sought a court order requiring her mother's treatment, including dialysis, to resume.[81] Physicians had discontinued treatment because, according to one of them, "[t]o continue life-support, in my opinion, is unethical, as it has no chance of

---

77 *Ibid*.

78 *Ibid* at para 26.

79 *Ibid* at para 28.

80 *Golubchuk*, *supra* note 23 at paras 25, 32.

81 *Supra* note 43 at paras 1, 5.

changing the prognosis, and it does do harm in that it is prolonging Mrs. Priboi's suffering."[82] The court denied the order in part because it considered intervention to be inappropriate on the facts. The court was convinced that the patient's daughter was mistaken about her mother's medical situation and that continued treatment would not have been in the patient's best interests.[83]

In *obiter*, however, the court discussed whether it would ever be appropriate for a court to require a physician to treat contrary to her clinical judgment. It noted that the issue was unresolved in Canada and referred to a range of foreign and secondary authorities. Justice Burnyeat quoted *Legal Liability of Doctors and Hospitals in Canada* for the proposition that

> once a doctor-patient relationship is formed, the doctor's obligation is to treat the patient. However, this does not mean that the doctor has a duty to provide (and the patient a correlative right to receive) whatever treatment the patient may request. If a patient requests treatment which the doctor considers to be inappropriate and potentially harmful, the doctor's overriding duty to act in the patient's best interests dictates that the treatment be withheld. A doctor who accedes to a patient's request (or demand) and performs treatment which he or she knows, or ought to know, is contraindicated and not in the patient's best interests, may be held liable for any injury which the patient suffers as a result of the treatment.[84]

Justice Burnyeat then quoted an excerpt from an EWCA decision:

> It is trite law that in general a doctor is not entitled to treat a patient without the consent of someone who is authorised to give that consent. … However consent by itself creates no obligation to treat. It is merely a key which unlocks a door. ... The decision whether to treat is dependent upon an exercise of his own professional judgment, subject only to the threshold requirement that, save in exceptional cases usually of emer-

---

82 *Ibid* at para 6.

83 *Ibid* at para 18.

84 *Ibid* at para 11, citing Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Thomson Carswell, 2007) at 345–46.

> gency, he has the consent of someone who has authority to give that consent.[85]

Then, like Justice Beard in *Sawatzky*, Justice Burnyeat referred to the 1992 English case *Re J* in concluding that the court could not order treatment to resume contrary to the physician's duty to her patient:

> [T]he Lord Justices in *Re J*, were of the view that they could not conceive of any circumstances in which it would be other than an abuse of power to require a medical practitioner to act contrary to the fundamental duty which that practitioner owed to his or her patient. … I agree with that view.[86]

Note, however, that the *Rotaru* court distinguished its decision from that in *Golubchuk* on the basis that *Rotaru* involved a request for treatment to be resumed, while *Golubchuk* involved a family's objection to discontinuing treatment.[87] Thus, Justice Burnyeat seems to have been drawing a distinction between withholding treatment – as in *Rotaru* – and withdrawing it – as in *Golubchuk*.

The first Canadian decision to seriously question the legal authority of physicians not to have to treat contrary to their clinical judgment was *Sweiss v Alberta Health Services* in 2009.[88] A physician had placed a DNR order on Mr. Sweiss' chart and sought to discontinue mechanical ventilation because, in his "firm belief," "forcing anything but palliative care and comfort measures upon Mr. Sweiss would be medically futile and ethically inappropriate."[89] In Dr. Williams' view, "[a]llowing the mechanical ventilation support to continue and requiring that CPR be performed was contrary to [the guiding principle that physicians should do no harm] and bordering on inhumane."[90] Thus, as with cases discussed above, the physician's rationale was partly grounded in the ethical practice of medicine.

---

85 *Rotaru*, *supra* note 43 at para 12, citing *Re R (A Minor) (Wardship: Medical Treatment)*, [1992] Fam 11, [1991] 4 All ER 177 at 184, 187 (CA).

86 *Rotaru*, *supra* note 43 at para 16, citing *Re J*, 1992, *supra* note 74 at 622.

87 *Rotaru*, *supra* note 43 at para 15.

88 2009 ABQB 691, 483 AR 340 [*Sweiss*].

89 *Ibid* at paras 8, 12.

90 *Ibid* at para 13.

There was evidence, however, of Mr. Sweiss' beliefs as a Muslim and what such beliefs meant in the context of medical treatment. Specifically, there was evidence that according to the Muslim faith, it was impermissible to remove life-support in Mr. Sweiss' circumstances.[91]

The Alberta Court of Queen's Bench addressed head on the issue of what to do where a patient's wishes or values are contrary to a physician's judgment that certain treatment should not be provided. That said, the court was primarily concerned with the test for granting an injunction, rather than the test for resolving the matter on its merits. The court noted that, unlike other motions for injunctions, cases like Mr. Sweiss' are not likely ever to be litigated on their merits, and that applying the traditional test for granting an injunction would therefore be inappropriate.[92] It held that the test should instead be whether the injunction is in the patient's best interests, as defined similarly to the best interests test in substitute decision making, including consideration of the patients' values, medical situation, and what is "just and equitable."[93] As such, neither the physician's clinical judgment nor the patient's values automatically prevail. On the facts, Justice Ouellette granted an injunction to prevent mechanical ventilation from being discontinued, but denied an injunction to remove the DNR order from Mr. Sweiss' chart. This could be viewed as drawing a distinction between withholding treatment – in this case, CPR – and withdrawing it – in this case, mechanical ventilation – but the court did not explicitly draw this distinction in making its order.

Given that the *Sweiss* court was discussing the basis for granting an injunction as opposed to interpreting the law governing medical decision making generally, caution is warranted. Nevertheless, three points are worth noting. First, Justice Ouellette explicitly disagrees with the proposition, as reflected in the law of England, that physicians should never have to treat contrary to their clinical judgment.[94] Rather, their clinical judgment is but one factor. Neither it nor patient values trump the other.

Second, Justice Ouellette interprets the *Personal Directives Act* as meaning that where there is a valid personal directive requesting indefinite

---

91 See *ibid* at paras 10–11.

92 *Ibid* at paras 51–52.

93 *Ibid* at para 73.

94 *Ibid* at para 62.

life-support, it must be provided, even if contrary to clinical judgment: "[T]he direction must be followed despite the fact that life-support may be required for an indefinite period of time."[95] Presumably, then, the best interests analysis set out in *Sweiss* is inapplicable where there is a valid personal directive. In that case, the patient's wishes prevail and physicians may be made to treat contrary to their clinical judgment.

This is in contrast to the reasons in *Lavallee* and *Sawatzky*, which suggest a strong legal distinction between patients' right to refuse treatment and their right to demand it. And it is certainly contrary to the law in England, which maintains a clear distinction between refusing and demanding treatment.

In my opinion, Justice Ouellette errs in *Sweiss* in interpreting the *Personal Directives Act* to require treatment contrary to clinical judgment. He relies on the language of the statute, which states that where there is a valid personal directive, medical professionals "must … follow any clear instructions in the personal directive that are relevant."[96] Yet surely this must be understood to mean that instructions *that the patient could have given if competent* must be followed. If a competent patient cannot insist on treatment contrary to clinical judgment, putting the instruction in a personal directive cannot render it legally effective any more than a directive for the physician to stand on his head would be legally effective. Justice Ouellette is either implying that competent patients may insist on contraindicated treatment (and therefore a personal directive to the same effect is valid), or that the *Personal Directives Act* gives patients the right to dictate treatment in a personal directive that they could not dictate while presently capable. Both of these propositions lack a clear legal foundation.[97]

Third, given the court's recognition that these injunction cases concerning life-sustaining treatment rarely go to trial, Justice Ouellette's best

---

95 *Ibid* at para 48.

96 *Personal Directives Act*, RSA 2000, c P-6, s 19(1).

97 As an editor of this article noted, this point was made in *James* regarding the *Mental Capacity Act 2005*, *supra* note 57:

> This Act is concerned with enabling the court to do for the patient what he could do for himself if of full capacity, but it goes no further. On an application under this Act, therefore, the court has no greater powers than the patient would have if he were of full capacity (*supra* note 55 at para 18).

interests test is the de facto law in Alberta governing whether incompetent patients are entitled to life-sustaining treatment contrary to clinical judgment. Whereas the common law, as recognized in *Lavallee* and *Sawatzky*, allows patients to refuse but never to demand treatment physicians do not offer to provide, the *Sweiss* best interests test allows treatment found to be in a patient's best interests to be demanded on behalf of incompetent patients, even if the treatment is contrary to physicians' clinical judgment.

Thus in *Sweiss*, perhaps for the first time in Canada, a court stated that the law will sometimes require physicians to provide treatment that is contrary to their clinical judgment. Justice Ouellette explicitly rejects English law on this issue.

C. Ontario: The Health Care Consent Act

Finally, we come to *Cuthbertson v Rasouli*, in which the Supreme Court of Canada addressed on the merits a conflict between patient values and physicians' clinical judgment. Recall that Mr. Rasouli was unconscious and needed mechanical ventilation and artificial hydration and nutrition to live. His doctors wanted to stop providing life-support and his SDM disagreed.

The Court took a novel approach, requiring physicians sometimes to provide life-sustaining treatment contrary to their clinical judgment and their professional ethics. The legal basis for the Court's decision was the law of informed consent. The Ontario *HCCA* requires consent to "treatment,"[98] and the Court interpreted the statutory definition of "treatment"[99] broadly enough to encompass withholding and withdrawing treatment.[100] Thus, the Court held that consent – either that of the patient, expressed before capacity was lost, or that of the SDM – was required to withdraw Mr. Rasouli's mechanical ventilation.[101]

---

98 *HCCA*, *supra* note 7, s 10.

99 *Ibid*, s 2(1).

100 *Rasouli*, *supra* note 4 at para 50.

101 *Ibid* at para 118.

I have written elsewhere about problems with the Court's reasoning[102] and do not repeat those arguments here. What is important to understand is that patients or their SDMs can effectively demand certain treatment – even harmful treatment – by refusing to consent to the treatment being withheld or withdrawn. That is, by requiring consent to withhold or withdraw treatment, the Court created a de facto entitlement to treatment. Further, the Court found this to be the case even where the treatment in question is harmful,[103] is contrary to physicians' professional ethics,[104] or offers no medical benefit.[105] This is essentially because the statutory definition of "treatment," for which consent is required, is unrelated to the standard of care[106] and to professional ethics.[107]

It has been suggested that *Rasouli* only applies to withdrawing treatment and not to withholding it.[108] However, the *HCCA* draws no distinction between withholding and withdrawing treatment. Further, the Ontario Health Professions Appeal and Review Board has since interpreted *Rasouli* as applying to both withholding and withdrawing.[109]

The de facto entitlement to treatment created in *Rasouli* is not unlimited, however: "[T]he withdrawal of treatment may sometimes, although not always, constitute 'treatment' [for which consent is required]."[110] In addition to potential resource constraints, which the parties in *Rasouli* did not address at all,[111] the Court recognized problems inherent in allowing

---

102 Young, "Withdrawing Life-Sustaining Treatment", *supra* note 10; Young, "Continued Confusion over Consent-Based Entitlements", *supra* note 10.

103 *Rasouli*, *supra* note 4 at paras 6, 71–72.

104 *Ibid* at paras 71–76.

105 *Ibid* at paras 34–44.

106 See *ibid*.

107 See *ibid* at paras 73–76.

108 See Chris Kaposy et al, "The Distinction between Withholding and Withdrawing Treatment in *Rasouli*: Providing a Solution to an Ethical Problem" (2014) 21 Health LJ 29 at 30.

109 *EGJW v MGC*, 2014 CanLII 49888 at para 51 (Ont HPARB).

110 *Rasouli*, *supra* note 4 at para 59.

111 *Ibid* at para 4.

patients to demand whatever they want. The Court suggested that common sense must guide the interpretation of the legislation.[112] For example, patients cannot insist on the renewal of a prescription for a harmful drug.[113] The Court therefore attempted to distinguish situations in which patients' or SDMs' consent is required from those in which it is not, but considerable confusion remains.

As for the actual *ratio* of *Rasouli*, it is that the *HCCA*'s definition of "treatment" extends to withdrawing – and, as suggested above, likely to withholding – life-support in Mr. Rasouli's particular situation.[114] The Court notes that the "[t]his case does not stand for the proposition that consent is required under the *HCCA* for withdrawals of other medical services or in other medical contexts."[115] At a minimum, this means that consent is required to withdraw treatment where (1) mechanical ventilation is being administered; (2) turning off the ventilator will lead to imminent death; and (3) between the time the ventilator is turned off and the patient dies, palliative care drugs will have to be administered. I have suggested that, given the Court's "treatment package" reasoning, consent could be required to withhold or withdraw other life-sustaining treatments, especially if palliative care or other interventions involving touching are necessary.[116]

A further point to note is that where a patient lacks capacity and an SDM requests treatment, it must be in the patient's best interests. If patients with capacity or advance directives request that life-sustaining treatments be administered as long as possible,[117] doctors must presumably comply,

---

112 *Ibid* at para 58.

113 See *ibid*.

114 *Ibid* at para 70 ("'treatment' in the *HCCA* should be understood as extending to withdrawal of life-support in the situation at issue here and as that process is described in these proceedings").

115 *Ibid*.

116 Young, "Continued Confusion over Consent-Based Entitlements", *supra* note 10 at 753.

117 It is very unlikely that physicians would ever want to stop providing life-sustaining treatment to a patient with present capacity who wants the treatment. See e.g. *Burke*, *supra* note 31 at para 13. It is much more likely, however, that a physician would eventually recommend stopping life-sustaining treatment in the context of an advance directive requesting that all possible measures be taken to prolong life.

or else they violate the *HCCA* as interpreted by the Court in *Rasouli*.[118] But if the patient lacks capacity and a substitute decision is required, that decision must be in the patient's best interests according to subsection 21(2) of the *HCCA*.[119]

Though one might think that the best interests requirement would solve the problem of physicians having to treat contrary to their clinical judgment in cases like those of Mr. Sawatzky, Mr. Golubchuk, Mr. Rasouli, or Mr. AVS, this is not necessarily so. First, any wish, expressed while the patient was capable, to have treatment continue as long as possible would be determinative: a best interests analysis would not be undertaken. Advance directives continue to gain in popularity and, where there is a valid advance directive, a best interests analysis is not undertaken. Thus, Mr. AVS' prior expressed wish to pursue all treatment avenues would arguably be determinative if these facts were to arise in a Canadian case.

Second, the statutory test for determining a patient's best interests takes into account (1) wishes the patient expressed while incompetent, (2) the medical implications of treatment (or non-treatment), and (3) the patient's values.[120] With no priority given to any of these, a wide range of decisions could be found to be in a patient's best interests. Given the Jewish and Muslim religious beliefs of Mr. Golubchuk and Mr. Rasouli respectively, it may be that continued treatment contrary to a physician's clinical judgment would be found to be in their best interests. Even in Mr. Sawatzky's case, evidence that he was a fighter or would not want to quit could be enough to satisfy a court that continued life-sustaining treatment was in his best interests. If physicians believe that treatment is not in a patient's best interests, the onus is on the physicians to prove it.[121] Given this onus and the nature of the best interests test, it will often be difficult for physicians to establish that treatment contrary to clinical judgment is *not* in a patient's best interests. There is some evidence that the Ontario CCB was inclined to side with

---

118 This is presumably subject to resource considerations, but *Rasouli* does not address this issue.

119 *Supra* note 7. See also *Rasouli*, *supra* note 4 at paras 87–88.

120 See *HCCA*, *supra* note 7, s 21(2).

121 This follows from the fact that it is the SDM who determines the patient's best interests. That determination would apply unless someone (such as a physician, another family member, or the patient herself) challenged that decision before the Consent and Capacity Board. See *ibid*, s 21.

physicians on best interests assessments, but there is also evidence that, even before *Rasouli* was decided, this was changing.[122]

To be clear, the Court did not require the *Rasouli* physicians to continue treatment, but rather offered "practical solutions" such as transferring the patient to another hospital.[123] This is an acknowledgement that if doctors' concerns can be addressed without undue inconvenience to the patient, that would be permissible. However, such transfers will often be hard to obtain. Where the objection to treatment is grounded in clinical judgment, other physicians may also not want to take on the patient's care for the same reason. In Mr. Rasouli's own situation, doctors were unable to find another hospital to which to transfer Mr. Rasouli,[124] despite this occurring in Toronto – a large city where transfer options are presumably as numerous as anywhere in Canada. Recall that in Mr. Goluchuk's situation, three physicians refused to treat Mr. Golubchuk, causing disruptions in the intensive care unit. That said, according to Jeff Blackmer, then executive director of the Office of Ethics at the Canadian Medical Association, "someone will always step forward."[125]

In response to the physicians' argument in *Rasouli* that being required to treat contrary to their professional ethics placed them in an "untenable ethical position,"[126] the Supreme Court simply noted that ethical tensions are "inherent to medical practice."[127] It compared the physicians' ethical concerns to those of physicians wanting to impose treatment in accordance with the standard of care on patients who wish to refuse it. Notably, the

---

122 According to a study of Ontario Consent and Capacity Board (CCB) decisions, before 2009 the CCB always agreed with physicians' assessments of best interests. However, between 2009 and 2012, the CCB sided with the SDM in five cases (38% of cases). After *Rasouli*, which places such weight on patient values at the end of life, it will be interesting to see whether SDMs begin to succeed even more often when it comes to best interests determinations. See Paula Chidwick, Robert Sibbald & Laura Hawryluck, "Best Interests at End of Life: An Updated Review of Decisions Made by the Consent and Capacity Board of Ontario" (2013) 28 J Crit Care 22 at 23–24.

123 *Rasouli*, *supra* note 4 at para 75.

124 See *Rasouli*, *supra* note 4 (Factum of the Appellant at para 19).

125 Smith, *supra* note 26.

126 *Rasouli*, *supra* note 4 at para 71.

127 *Ibid* at para 73.

Court analogized to *Malette v Shulman*, in which a doctor performed a blood transfusion on a patient who was a Jehovah's Witness and who possessed a card indicating her refusal to have a blood transfusion under any circumstances.[128] On this point, the Court affirmed, the law is clear: a physician cannot force a blood transfusion on a patient just because it is medically indicated, or because it would implicate the physician's professional ethics *not* to provide it.[129] Therefore, the Court reasoned, the physicians' ethical argument cannot prevail over the autonomy interests of patients.

In essence, then, the Supreme Court rejected the distinction between acts and omissions in this context: it equated *requiring* physicians to treat contrary to their professional ethics with *not allowing* them to treat according to their professional ethics. By the same token, the Court dismissed the claim that inflicting harmful treatment would necessarily conflict with the fundamental duty of physicians not to harm their patients:[130] so long as the course of treatment is determined in accordance with the framework of the *HCCA*, a physician cannot be faulted.[131]

In addition to dismissing the doctors' ethical concerns as "inherent to medical practice," the Court noted that the physician's clinical judgment may conflict with the standard of care or fiduciary duties in which case, as under the *HCCA*, the law may require the physician to treat contrary to her professional ethics.[132] This is a red herring. While true that such a conflict could exist and could require treatment contrary to a doctor's clinical judgment and ethics,[133] that was not the situation in cases like *Rasouli*, *Golubchuk*, and *Sawatzky*. Rather, the refusal to provide treatment

---

128 *Ibid*, citing *Malette v Shulman* (1990), 72 OR (2d) 417, 67 DLR (4th) 321 (CA).

129 *Rasouli*, *supra* note 4 at para 73.

130 Also known as the principle of nonmaleficence, the obligation to do no harm is described in Tom L Beauchamp & James F Childress, *Principles of Biomedical Ethics*, 6th ed (New York: Oxford University Press, 2009) at 149.

131 *Rasouli*, *supra* note 4 at paras 71–72.

132 *Ibid* at para 73.

133 Imagine, for example, that a physician decided not to offer her patients a new cancer drug, despite its potential effectiveness, because she holds a minority view that it has not been sufficiently tested. Assuming the standard of care required prescribing the drug, the physician could be negligent in failing to do so despite an objection grounded in professional ethics.

in the cases canvassed above seemed to be consistent with the standard of care[134] and fiduciary duties.[135] *James*, discussed above, suggests that in England, a physician's clinical judgment will not prevail if it is unreasonable (i.e., contrary to the standard of care), but *Rasouli* is not a case that raises such conflicts.

Thus, notwithstanding the possibility of "practical solutions," the Court was dismissive of the physicians' claims not to have to provide treatment contrary to their professional ethics. It did not engage with English law and dismissed Canadian common law as "not at all settled."[136]

Nothing in the legislative history suggests that the Ontario legislature intended for the *HCCA*, which was based in large part on the common law, to create entitlements to treatment contrary to clinical judgment.[137] Yet its language, combined with the Court's reasoning in *Rasouli*, makes this inevitable. Ontario law now requires doctors to provide certain treatment requested by patients or SDMs, even if contrary to clinical judgment and professional ethics and even if harmful to patients.[138] The fact that a substitute decision to insist on treatment must be in a patient's best interests does not negate the possibility of treatment contrary to clinical judgment being legally required. Such situations will presumably not arise often, but the law of Ontario allows for them to arise.

This is a new situation for physicians. Before *Rasouli*, Canadian doctors arguably owed no legal duties to treat contrary to their clinical judgment – at least so long as that judgment was consistent with the standard of care and

---

134 In *Rasouli*, *supra* note 4 at para 38, the Court effectively acknowledged that the withdrawal of treatment was consistent with the standard of care: "The issue here is not the correctness of the physicians' professional opinion that sustaining life in Mr. Rasouli's situation confers no medical benefit. In fact, their opinion appears to reflect a widely accepted view in the medical community."

135 In fact, the majority in *Rasouli* says that since the law of fiduciary duties has not been used to condemn physicians' "good-faith treatment decisions," it is unlikely to protect patients in Mr. Rasouli's situation (*ibid* at para 111).

136 *Ibid* at para 53.

137 The Court stated that the *HCCA* was not simply a codification of the common law (*ibid* at para 52). But see Young, "Withdrawing Life-Sustaining Treatment", *supra* note 10 at 68.

138 See e.g. *Rasouli*, *supra* note 4 at paras 71–72.

fiduciary duties.[139] Patient autonomy meant that patients always had a say in their treatment, but there was a clear dividing line between their right to refuse treatment, which was almost absolute, and their right to have it, which was limited in a number of ways. Treatment could not be withheld discriminatorily or unreasonably, as this would constitute negligence, violate rules of professional conduct, or violate human rights law, but doctors apparently enjoyed considerable discretion in which treatments they proposed to provide.

This may still describe the common law, but in Ontario per the *HCCA*, doctors' clinical judgment carries little weight – at least when it comes to whether to continue certain life-sustaining treatment. Physicians will sometimes be required to practice contrary to clinical judgment unless they can arrange for the patient to be treated by another doctor.

The trend toward greater patient autonomy means that the boundary between refusing and demanding treatment has been blurred. And as a result, there may increasingly be demands for treatment that physicians consider contrary to their clinical judgment. Some will continue to refuse to provide such treatment on the basis that they have no obligation to provide it, but particularly where end-of-life care is at issue, their right to do so is uncertain.

One final thing to note is that the scope of the *Rasouli* decision is unclear. It is grounded in Ontario legislation. I have written elsewhere about the extent to which *Rasouli* is likely to be considered binding or persuasive in other Canadian jurisdictions.[140] Essentially, given that legislation similar to the *HCCA* exists in British Columbia, Prince Edward Island, and Yukon, *Rasouli* should be highly persuasive in those jurisdictions.[141] In Manitoba, Newfoundland and Labrador, and the Northwest Territories, *Rasouli* may be persuasive because of their health care directives statutes,[142] but I have

---

139 *Sweiss* could be viewed as authority to the contrary, but it dealt with the test for injunctions only.

140 Young, "Continued Confusion over Consent-Based Entitlements", *supra* note 10.

141 British Columbia *Act*, *supra* note 45; *Consent to Treatment and Health Care Directives Act*, RSPEI 1988, c C-17.2; *Care Consent Act*, s 3, being Schedule B to the *Decision Making Support and Protection to Adults Act*, SY 2003.

142 Manitoba *Act*, *supra* note 45; Newfoundland *Act*, *supra* note 45; *Personal Directives Act*, SNWT 2005, c 16.

argued that the statutes are sufficiently different than the *HCCA* that *Rasouli* should not govern their interpretation.[143] The remaining common law jurisdictions (Alberta, New Brunswick, Nova Scotia, Saskatchewan, and Nunavut) have legislation even less similar to the *HCCA*, so *Rasouli* should not guide the interpretation of those jurisdictions' statutes at all. Finally, since Québec has no statute like the *HCCA* and is not governed by the common law, it is least likely to be affected by *Rasouli*, as is reflected in *Centre hospitalier de l'Université de Montréal c WL*, discussed below. That said, it may be that courts will interpret other provinces' statutes or develop their common law to reflect the Supreme Court's reasons in *Rasouli*.

D. Canada: Civil law (Québec)

Since *Rasouli*, the only relevant reported decision from a jurisdiction other than Ontario is from Québec. A court there held that a Montréal doctor was entitled to remove mechanical ventilation from a patient in a persistent vegetative state ("état neurovégétatif") despite the objections of the patient's SDMs and despite arguments based on *Rasouli*.[144] The court implicitly considered continued life-support not to be in the patient's best interests. It noted that substitute decisions in Québec must be in a patient's best interests and that being kept alive is not always in a person's best interests.[145] Since in Ontario substitute decisions must also be in a patient's best interests, it is not clear whether and to what extent relevant Québec law differs from that in Ontario.

To summarize, Canada has a patchwork of statutory and common law approaches, with the common law being largely unsettled. Although confusion remains as to the interpretation of statutes, including the *HCCA*, the law in Ontario is settled on the point that physicians must sometimes provide treatment if a refusal to do so would lead to imminent death preceded by a need for palliative care. This is so even if the treatment is contrary to the standard of care or contrary to a physician's professional ethics, although subject to the requirement that substitute decisions be in a patient's

---

143 Young, "Continued Confusion over Consent-Based Entitlements", *supra* note 10 at 751.

144 *Centre hospitalier de l'Université de Montréal c WL*, 2014 QCCS 1864 at paras 1, 2, 7, 12, 16, [2014] JQ no 2991 (QL).

145 *Ibid* at paras 4, 10.

best interests. In addition, all such treatment requested by competent patients (in an advance directive, for example) must be respected. This is in contrast to the law of England under which physicians' clinical judgment prevails. In general, this means that if a physician decides that treatment is not indicated, it need not be provided even if requested by a patient or SDM and even where life-sustaining treatment is at issue.

III. Reasons for and against Allowing Physicians to Limit Access to Treatment Based on Their Clinical Judgment

The law in Ontario is relatively settled, although unclear in some of its details. That does not preclude legislative amendment, although that seems unlikely in the near future. But in many parts of Canada, legislators or courts will have to confront the issue of whether physicians must provide treatment contrary to clinical judgment – especially at the end of life. In arriving at a principled approach, it will be useful to assess the benefits and detriments of the different options. To help structure the analysis, I set out the benefits of allowing clinical judgment to prevail (essentially, the law of England) and of allowing patient/family wishes to prevail (the law of Ontario regarding life-sustaining treatment, but not necessarily other treatments).

A. Reasons for allowing clinical judgment to prevail

1. Physicians have a moral claim to practice according to their clinical judgment

Practicing according to one's clinical judgment has profound moral implications for physicians. It is not simply a matter of wanting to avoid professional disciplinary proceedings. Unlike performing MAID or abortions, these implications are not grounded in personal values, but rather in the values and ethics of the medical profession.[146]

The moral claim to practicing according to clinical judgment flows from the nature of the profession and its role in society. Doctors share a "common

---

[146] See e.g. Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 51–52; TA Cavanaugh, "Professional Conscientious Objection in Medicine with Attention to Referral" (2010) 9:1 Ave Maria L Rev 189 at 191; Montgomery, *supra* note 12 at 201; Daar, "Clash", *supra* note 9 at 1244–45.

purpose and a common set of ethical ideals" that are "morally grounded."[147] According to Pellegrino, autonomy as a physician is grounded in the inequality of the doctor-patient relationship, the nature of medical knowledge and decision making, and the moral complicity of physicians in what happens to their patients.[148] These factors suggest that

> the physician [must] be free to use [her knowledge] according to her best judgment. If the physician is to fulfill the moral requirement to make her knowledge available to those who need it, she must be allowed sufficient discretionary latitude to apply that knowledge as rationally, efficiently, and safely as possible.[149]

Pellegrino continues:

> For patients to claim a right to any procedures they wish is to challenge a conscientious physician's integrity as a physician. It depreciates his expertise, reduces his discretionary latitude in decision-making, and makes him a technical instrument of another person's wishes. … Such demands violate the internal morality of medicine as a practice.[150]

Montgomery notes that the medical profession is "ethically as well as scientifically orientated," and claims that protecting professional discretion is not simply a matter of deference to professional skill, but of "ensur[ing] that professional morality can prevail."[151]

Few could doubt that physicians have a moral claim to practicing their profession in a certain way, but of course that does not mean that such a claim should prevail in law. Like all moral claims, claims to practice according to clinical judgment must be assessed in light of the interests of others.

---

147 Edmund D Pellegrino, "The Medical Profession as a Moral Community" (1990) 66:3 Bull NY Acad Med 221 at 226.

148 *Ibid*.

149 Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 52–53.

150 *Ibid* at 59.

151 Montgomery, *supra* note 12 at 204.

2. Physicians' clinical judgment protects patients

One might think that the claim of physicians to practice according to their professional standards is relatively weak in light of the fact that the patient is the one with the most at stake – their interests must generally prevail as physicians must put patients' interests first. However, physicians have argued that allowing them to practice according to their clinical judgment is justifiable precisely because that approach is the best for patients. Montgomery argues:

> [T]he consistent and persistent protection of clinical judgement in medical and healthcare law … is related not to the personal expertise and morality of doctors … but to the way in which they are thought to embody a tradition of both technical expertise and moral values. The normative legitimacy of this extensive respect for professional discretion lies principally in the belief that protecting this embodied tradition provides a reliable protection for patient interests. These are understood as being more than merely the expression of individual patient wishes.[152]

Pellegrino adds that simply allowing patients to have whatever treatment they want, without regard to professional ethics, can be bad for patients:

> [Patient demands] can redound to the patient's harm by undermining the physician's moral obligation to provide sound advice and sound practice and to avoid medically useless or futile treatments.[153]

This is, of course, paternalism. Physicians are saying that they know better than patients what is good for them. This approach to medicine has largely been discredited in the refusal context. That is, patients may refuse any treatment regardless of whether physicians believe it is in the patient's medical interests. The law has recognized that patients are the best judges of their own best interests.

Yet the issue being examined in this article is not the refusal context, it is the demand context. We must therefore consider whether there is some role for paternalism in a demand context, notwithstanding the fact that in

---

[152] *Ibid* at 209.

[153] Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 59.

law there is virtually none in the refusal context. A system that rejects paternalism completely in favour of patient autonomy must give capable patients whatever they want, including antibiotics for a viral infection and opiates when they are not in pain. And capacity is a low threshold that can be met despite serious mental illness, for example.[154] I think that most would agree that physicians should be allowed to deny prescriptions for antibiotics and opiates for the good of the patient. If so, we have not abandoned paternalism completely.

Arguably, there is still a role for clinical judgment to prevail so as to prevent patients from being able to demand whatever they want. It is well established that patients can and should be able to refuse treatment regardless of clinical judgment. But there should perhaps be a sharp line between the demand and refusal contexts – between acts and omissions.

The Supreme Court in *Rasouli* was not persuaded by the moral relevance of this distinction, since it equated the impact of forcing physicians to treat contrary to their clinical judgment with denying them the opportunity to treat according to their clinical judgment. Although the distinction between acts and omissions is not always of great moral significance, there are important differences between requiring a doctor to act contrary to her clinical judgment and not permitting her to act in a manner supported by her clinical judgment.

There is an important difference in both the nature of the interference with the physician's freedom and the nature of the impact on the patient. Requiring physicians not to intervene in circumstances where they would like to help raises ethical issues, but presumably not to the same degree (all other things being equal) as forcing them to intervene in a manner they feel violates their professional obligations.[155]

---

[154] See *Starson v Swayze*, 2003 SCC 32 at paras 55, 77, [2003] 1 SCR 722.

[155] This conclusion is based on the general proposition that prohibiting acts is less of an infringement on liberty than requiring acts. That said, this statement should not be understood to mean that physicians can have no ethical objection to being denied the ability to practice in a certain way. See Jacqueline Shaw & Jocelyn Downie, "Welcome to the Wild, Wild North: Conscientious Objection Policies Governing Canada's Medical, Nursing, Pharmacy and Dental Professions" (2014) 28:1 Bioethics 33 at 34 ("[t]ypically, healthcare conscientious actions are negative, involving 'conscientious refusals' of requested procedures. However, objection may also involve positive activity").

But the rule that patients may refuse but not demand treatment is not primarily grounded in the moral distinction *for physicians* between acts and omissions (i.e., being *forced* to treat contrary to clinical judgment versus not being *allowed* to treat). Rather, the rule has more to do with the serious nature of imposing unwanted medical treatment *on the patient*. Patients' negative right against interference with their bodily integrity is of profound importance. The issue is quite different where a positive claim of entitlement to treatment is raised: there is no prospect of forcing unwanted treatment on someone and at least arguably no issue of interference with bodily integrity.[156] It is therefore problematic, in my view, for the Supreme Court simply to dismiss physicians' claims not to have to practice contrary to their professional ethics by analogizing this tension to their inability to impose unwanted medical treatment on unwilling patients.

The other important difference between the demand and refusal contexts is that only in the former is there any realistic possibility of treatment being offered contrary to the standard of care. Assuming that doctors only offer treatments that are indicated, the patient may refuse to her physical detriment and it is her underlying condition that will cause her physical harm. She will not, however, receive treatment that is not indicated and that may harm her, unlike in the demand context. This is another reason why requiring doctors to act contrary to their clinical judgment is not morally equivalent to not permitting them to treat at all.

The different nature and consequences of allowing physicians to select the range of options from which a patient may choose versus allowing physicians to impose unwanted treatment on patients justify a different legal approach to each. The former may be justifiable even if the latter is not.

Some have made a different kind of argument to the effect that allowing physicians to practice according to clinical judgment is good for patients. It is that to require physicians to simply do whatever patients ask of them would have such a detrimental effect on the medical profession as a whole that all patients would be worse off. Bleich states that requiring doctors to do what their patients want them to do, regardless of clinical judgment, is "likely to have a corrosive effect upon the dedication and zeal with which

---

156 I say "arguably" because part of the Court's reasoning in *Rasouli* relied on the fact that removing the ventilator would require touching and that giving palliative care drugs definitely requires touching (*supra* note 4 at paras 62–64). In other words, the Court's reasoning relied in part on the claim that bodily integrity *is* implicated when certain life-sustaining treatment is withdrawn.

[a physician] ministers to patients."[157] He argues that the more a physician becomes simply the instrument of her patient's wishes, the less able she will be to carry out the full range of roles that make the medical profession what it is.

Yet one should not take this argument too far. A similar point might once have been made against allowing patients unlimited discretion to refuse treatment. That too might have been argued to interfere with the physician's complex role and affect their "zeal."

3. A publicly-funded medical system should not provide "bad medicine"

Another argument in favour of allowing physicians to practice according to clinical judgment is that a medical system funded by taxpayers should not provide medically inappropriate interventions simply because patients want them.

There are two aspects to this argument. One relates to resources. Rationing is necessary in our publicly funded system. We cannot give every patient every medically useful intervention in a timely manner, so why would we expend public resources on medically useless or harmful ones? One answer to this is that what is medically useful is not the sole consideration when it comes to medical decision making, and this is incontrovertible. Patients may refuse treatment for non-medical reasons. But there is a difference between, on the one hand, taking patient values into account in deciding whether to have one or another (or neither) of the proposed, medically endorsed treatments, and, on the other, allowing patient values to justify providing treatment that is not medically endorsed. The fact that health

---

[157] J David Bleich, "The Physician as a Conscientious Objector" (2002) 30:1 Fordham Urb L J 245 at 245. See also Daar, "Clash", *supra* note 9 at 1245:

> At the very least, ignoring the moral, ethical, and professional make-up of the physician can only serve to chill communications between doctors and patients. That is, stripped of their ability to advocate based on their own belief system, doctors may begin to perceive themselves as "medical vending machines" whose only role is to dispense medical treatments. This image of a physician as a mere purveyor of medical "goods" belies the notion that an essential element of the doctor-patient relationship is open communication about treatment options.

care resources are finite is an additional reason for allowing only medically endorsed treatments to be provided.

The other aspect of the argument is that, beyond the issue of resources, the state should not participate in a system that administers potentially harmful interventions solely because they have been requested. If a system of unconstrained autonomy – or autonomy constrained only minimally (by lack of resources, for example) – can be harmful to patients, as suggested above, then the state should not condone this through its regulation and funding of the health care system.

One may accept these points in principle but disagree about whether a particular treatment is medically appropriate. What constitutes "bad medicine" is subjective and contentious. The literature on futility demonstrates how difficult it is to objectively determine whether treatment is beneficial. This point is discussed further in Part III(B)(3) below.

4. A life-sustaining treatment exception is difficult to justify

One might agree that patients should not *generally* be able to demand whatever medical interventions they want, regardless of how harmful or expensive, but still conclude that there should be a narrow entitlement only to *life-sustaining* treatment. Although this is currently the law in Ontario, I do not view such a distinction as principled.

The Supreme Court in *Rasouli* justified an entitlement to life-sustaining treatment, but not to other kinds of treatment (e.g., a prescription for harmful drugs) in part on the basis that life-and-death decisions implicate autonomy in a fundamental way, such that a different approach to them could be justified.[158] But there are two problems with this assumption. The first is the effect of incapacity on autonomy. The *Rasouli* Court stated that autonomy interests are diminished in incapable patients:

> If a patient is incapable … [t]he focus shifts from the patient's autonomy interest, *which is compromised or extinguished*, to whether receiving treatment is in the best interests of the patient.[159]

---

158 *Supra* note 4 at paras 51, 57, 68.

159 *Ibid* at para 21 [emphasis added].

Many, if not most, decisions about whether life-sustaining treatment should be withheld or withdrawn will involve patients who lack capacity. SDMs, not patients, will make these decisions, at least in the absence of an advance directive.

The second problem in the Court's reasoning is that it cannot account for why certain interventions like a prescription for a harmful drug would *not* be considered treatment, given that autonomy is clearly implicated. Although the Court implies it, it is not self-evident that life-and-death decisions are inherently more autonomy-implicating than other kinds of medical decisions. Decisions about whether to withhold or withdraw life-sustaining treatment tend to involve people who are extremely ill. It is misleading to frame these simply as decisions about whether a patient lives or dies. They are often better thought of as decisions about *when* a patient dies and about *how* she will spend her final days. These are, of course, important decisions. It is not obvious to me, however, that they are necessarily more autonomy-implicating, or otherwise worthy of respect, than other kinds of treatment decisions.

Consider, for example, the situation of a competent patient who, due to mental illness, wants a healthy limb amputated or an addicted patient who wants a prescription for a large quantity of opiates. These scenarios certainly implicate patient autonomy, arguably to a greater extent than the situation in *Rasouli*, since in these examples the patient is competent, aware, presently suffering, and will continue to suffer – perhaps for years – if the requested intervention is not provided. It is therefore difficult to create a principled, autonomy-based rationale that grounds patients' entitlement to life-sustaining treatment contrary to clinical judgment but not to other kinds of treatment.[160]

To summarize, arguments in favour of allowing physicians to deny access to treatment contrary to their clinical judgment include:

(1) physicians have a moral claim to practice according to their clinical judgment;

(2) physicians' clinical judgment protects patients;

(3) a publicly-funded medical system should not provide "bad medicine"; and

---

[160] For more on this argument, see Young, "Continued Confusion over Consent-Based Entitlements", *supra* note 10 at 755–57.

(4) a life-sustaining treatment exception is difficult to justify.

B. Reasons for allowing patient/family wishes to prevail

1. Respecting a patient's wishes promotes autonomy

The strongest argument against letting physicians limit treatment based on their clinical judgment is that giving patients what they want advances a patient-centered approach to medical decision making. It extends what patients already have in the refusal context – that is, virtually absolute control over decision making – to the demand context. The law has long acknowledged that competent patients may refuse treatment for non-medical reasons[161] – for religious reasons, for example, or because they value being free of significant pain over simply being alive. Yet patients' values affect decisions not only to refuse offered treatment but also to receive certain treatments that may not be offered. *Rasouli* acknowledges this by extending patient autonomy in medical decision making beyond the refusal context and into to the demand context, albeit in limited circumstances.

This is consistent with the development of the law of consent in recent decades. Consent to medical treatment began strictly as a matter of protecting bodily integrity. Consent was a defence to battery just as in non-medical contexts.[162] Later, the law of *informed* consent developed into a matter of the standard of care in negligence: it is negligent not to include the patient in decision making. Specifically, failing to provide relevant information before obtaining permission to treat is a breach of the standard of care in negligence.[163] Requiring physicians to provide requested treatment contrary to their clinical judgment therefore simply reflects the trend, widely considered positive, toward greater recognition of patient autonomy in medical decision making.

---

161 According to Pellegrino, citing *Schloendorff v Society of NY Hosps*, 105 NE 92, 93 (NY 1914), patients' right to make medical decisions that reflect their values, in the form of a right to refuse treatment, dates to 1914 (though this date may only reflect the US context) ("Patient and Physician Autonomy", *supra* note 1 at 59).

162 See e.g. *Non-Marine Underwriters, Lloyd's of London v Scalera*, 2000 SCC 24 at para 6, [2000] 1 SCR 551.

163 See *Reibl v Hughes*, [1980] 2 SCR 880, 114 DLR (3d) 1.

Although I argued against this point above, there is support for the proposition that at least where decisions have life-and-death consequences, patient autonomy justifies limiting physicians' discretion to withhold or withdraw treatment. The Supreme Court stated in *Rasouli* that "[t]he values of autonomy – *critical where life is at stake* – ... support regarding withdrawal of life-support as 'treatment' requiring consent."[164] The Court continued: "By removing medical services that are keeping a patient alive, withdrawal of life-support impacts patient autonomy in the most fundamental way."[165] Although the Court provides no support for this proposition, treating it as self-evident, I think many would agree. Thus, patient values could arguably ground entitlements to certain life-sustaining treatment but not to other kinds of requested treatment, even if the treatment is contrary to a physician's clinical judgment.

Some have argued for such an approach, based largely on the importance of patient autonomy. In their article, Downie, Wilmott, and White argue that physicians should not be able to withhold or withdraw potentially life-sustaining treatment from patients unless the situation falls within a narrow range of exceptions. These include impossibility (e.g., the doctor is not trained to provide the requested procedure); ineffectiveness (e.g., the patient requests antibiotics to cure her viral infection); and government resource allocation policies.[166] This proposal is similar in its effect to the law of Ontario, although it is clearer and more principled. That said, in my view it goes too far in terms of allowing patients and families to receive treatment contrary to clinical judgment.

2. Allowing physicians to decide could veil improper decisions

A second reason to support physicians being compelled to provide requested treatment contrary to their clinical judgment is that to do otherwise increases the risk that discriminatory or other improper decisions will be protected under the guise that the physician is applying clinical judgment.

Physicians have significant power. If they can unilaterally choose to withhold certain treatments from patients, how is one to know whether those decisions are grounded in objective medical science (e.g., in cases where

---

164 *Rasouli*, *supra* note 4 at para 51 [emphasis added].

165 *Ibid* at para 68.

166 Downie, Willmott & White, *supra* note 11 at 824–28.

antibiotics will not help someone with a viral condition) or in *personal* values. It may be that the physician would not want to live in the patient's state herself or that such pain would be intolerable to her. The physician's assessment that continued treatment is inappropriate could even be influenced – subconsciously, one hopes – by her views of particular patients. Perhaps fewer efforts would be made for a poor person than for a wealthy one, for a well-educated one than for an uneducated one, or for one without a loving family than for one with such a family. Indeed, "a high degree of discretion enables the prejudices of professionals on 'deserving' and 'undeserving' supplicants for services to go unchecked."[167]

Whereas it may be justifiable for physicians to deny treatment based on objective medical facts, it is not justifiable for them to deny treatment based on their personal value judgments. The physician has no special moral authority and "has no standing as an expert in human values."[168]

And yet, "[p]ersonal and professional ethics are not fully separable from each other."[169] Particularly where the decision is whether to withhold or withdraw life-sustaining treatment, value judgments are hard to avoid. Permitting physicians not to treat because of their clinical judgment means that decisions not to treat for other reasons may be impossible to detect.

This is a serious concern. Yet it might be somewhat mitigated by the fact that decisions about what is medically appropriate – particularly where life-sustaining treatment is involved – are often made by teams of physicians and other health care professionals rather than by individuals. This helps to protect against decisions that reflect the personal biases of individual doctors. Further, second opinions and the patient's opportunity to change doctors could help prevent such abuses. Nevertheless, physicians and the medical profession in general may share certain values and biases not shared by their patients.

3. Clinical judgment is often subjective

A related point concerns the issue of medical futility. As a matter of principle, few think that doctors should be required to provide truly futile

---

167 Montgomery, *supra* note 12 at 205.

168 Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 53.

169 *Ibid* at 51.

medical treatment. But in practice, what constitutes futile treatment is controversial and subjective.[170] It may be incontrovertible that providing antibiotics to a patient with a viral infection is futile, in the sense that it cannot be of medical benefit. But other applications of clinical judgment are more subjective. *Rasouli* provides a good example. Mr. Rasouli's wife, a physician herself, believed that continuing mechanical ventilation was of medical benefit to her husband. Doctors Cuthbertson and Rubenfeld disagreed. It is an ancient principle of medical ethics "to desist from treatment when the limits of medicine's power had been reached,"[171] but since there are often no objective criteria for assessing these limits, the question of when to stop treating is open to debate.

The physicians in *Rasouli* were initially willing to provide mechanical ventilation and other life-sustaining treatment because it was indicated. However, the longer patients like Mr. Rasouli go without any improvement in their condition, the less likely it is that they will recover.[172] At what point does the treatment go from being indicated to being contraindicated? Reasonable physicians can disagree. Although grounded in professional standards, the claim to practice according to clinical judgment is individual. Given this uncertainty and variability, the patient's values and wishes should arguably take on greater importance. Again, this risk might be mitigated somewhat by the ability to obtain second opinions and to change doctors. That said, this option will often be more theoretical than real, given power disparities between physicians and SDMs and issues of limited access to physicians in many Canadian communities.

4. Physicians make mistakes

Another reason not to allow physicians to limit treatment options based on their clinical judgment is that doctors make mistakes. They make

---

170 See e.g. *ibid* at 59–60. See also sources discussing medical futility, *supra* note 14.

171 Pellegrino, "Patient and Physician Autonomy", *supra* note 1 at 60.

172 See Steven Laureys, "Eyes Open, Brain Shut", *Scientific American* (May 2007) 32 at 34, online: <www.scientificamerican.com/article/eyes-open-brain-shut> ("After a month [in a vegetative state], however, the patient is said to be in a persistent vegetative state (PVS) and the probability of recovery diminishes as more time passes").

mistakes about diagnosis and prognosis, and they may misjudge the standard of care. Given that the medical knowledge grounding clinical judgment is imperfect and given that what constitutes sound medical care is contextual and can change over time, it could be argued that patients should have access to treatment even if contrary to a physician's clinical judgment.

That said, this argument might suggest that clinical judgment should prevail where there is certainty (or near certainty) about diagnosis, prognosis, treatment, etc. but not where there is less certainty. A rule based on such a distinction would, I think, be unwieldy and undesirable.

To summarize, arguments in favour of allowing patients to determine their treatment, even when contrary to a physician's clinical judgment, include:

(1) respecting a patient's wishes promotes autonomy;

(2) allowing physicians to decide could veil improper decisions;

(3) clinical judgment is often subjective; and

(4) physicians make mistakes.

IV. What Approach for Canada Going Forward?

I have set out some of the arguments for and against allowing physicians unilaterally to withhold or withdraw treatment on the basis that it is contrary to clinical judgment. What policy, then, should Canada's legislatures adopt?

I offer a novel approach. My own view is that the law took a misstep with *Rasouli*. The law of informed consent, in statute or at common law, should never be interpreted as creating a duty to treat contrary to clinical judgment. Duties to treat might reasonably be found in the law of negligence (duty or standard of care), in equity (fiduciary duties), or in professional standards. That said, it may be going too far to give physicians discretion limited only by fiduciary duties and professional standards (the standard of care generally being a question of customary practice).

My suggested approach would provide a middle ground. It offers some of the benefits of English and Ontario law while avoiding some of the worst drawbacks of each. I take as my starting point that there must be

some paternalism in the system: patients should not be entitled to any treatment they like, limited only by resource or effectiveness considerations, and perhaps also public health reasons.[173] In addition, my proposal relies on the view, discussed above, that it is unprincipled to have a distinct set of rules for life-sustaining treatments and other treatments. I do not think such a bright line, implicit in the Court's reasoning in *Rasouli*, is justifiable on the basis of autonomy or otherwise on the basis of the finality or gravity of death. My proposal would therefore apply to all treatment decisions.

In essence, my view is that where patients, or their SDMs, and physicians disagree about whether a treatment should be withheld or withdrawn, the test should be one of reasonableness. Unlike in negligence law, however, the question should not be whether a physician's treatment decision is reasonable. Rather, the question should be whether it is unreasonable to provide the treatment requested by the patient or her SDM in the circumstances. This makes the inquiry different from that in negligence law in three ways. First, the onus would be on physicians to show that providing a requested treatment is unreasonable in the circumstances. This decreases the burden on patients and SDMs. The second difference from a negligence analysis is that many more treatment options would be available to patients, while still allowing for truly harmful or otherwise unreasonable treatments (e.g., opioids for a patient who is not in pain) to be denied to patients. More options are available because anything that is not unreasonable is permitted, whereas under negligence law the physician's treatment decision is lawful unless it is unreasonable. Third, reasonableness would not be measured solely (or even primarily) with regard to professional standards. Where patient values, resources, or other non-medical criteria are at issue, they should inform the reasonableness analysis. This follows from the fact that the question is whether what the patient or SDM wants is unreasonable, as opposed to whether the physician's acts were reasonable. The latter implicates professional standards of care, whereas the former does not.

The best interests test would apply only in the refusal context for substitute decisions. That is, the proposed approach would apply to both capable and incapable patients where treatment is demanded by patients or their SDMs. In the refusal context, existing law would apply.

---

[173] The idea for a public health exception emerged out of conversations with Jocelyn Downie and Michael Hadskis.

A. Reasonableness

Several aspects of this proposal require elaboration. The first is the reasonableness assessment. This would emphatically *not* be a typical negligence analysis. Although a negligence analysis should take into account anything relevant to reasonableness, in practice, where a profession such as medicine is involved, much deference is given to customary practices.[174] This makes sense where the issue is whether a procedure was competently performed: how much tissue to remove during a breast reduction surgery or how long a procedure should take, for example.[175] However, it makes less sense when the issue necessarily implicates non-medical considerations. As we have seen, decisions about whether patients should have access to treatments contrary to a physician's clinical judgment implicate a range of interests. If the issue were resolved according to customary medical practice, the outcome would almost inevitably be that the physician's clinical judgment prevailed. This would defeat the purpose of having a reasonableness standard as opposed to simply adopting the standard of clinical judgment, as in England.

Thus, courts would have to consider the reasonableness of the requested treatment in light of the patient's values (expressed or implied), the medical prognosis, the potential harm to the patient, the professional medical standards (including ethical considerations), and any other factor relevant to whether it is reasonable to provide the treatment requested by the patient or SDM. Courts should not assume that life-sustaining treatment is always reasonable, nor that offering treatment of minimal or arguable medical benefit is always unreasonable.

---

[174] The standard of care is that of reasonableness and reasonable medical practice is not limited to what is medically indicated or to what professional standards dictate. For example, it would be contrary to the standard of care to provide a blood transfusion to a competent patient who refused it, even though the transfusion is medically indicated. Another example is that Canadian courts have found it unreasonable not to disclose material risks of treatment, even though professional standards at the time did not necessarily require all material risks to be disclosed. See e.g. *Hopp v Lepp*, [1980] 2 SCR 192 at 208–09, 22 AR 361. Nevertheless, in most circumstances, the standard of care is assessed with regard to professional norms.

[175] See e.g. *White v Turner* (1981), 31 OR (2d) 773 at paras 30–32, 55, 120 DLR (3d) 269 (H Ct J), aff'd 1982, 47 OR (2d) 764, 12 DLR (4th) 319 (CA).

Whether the patient's family's wishes and values should be taken into account should be considered by legislatures in formulating this approach. There is some support in the *HCCA* and *Rasouli* for the proposition that the family's wishes are important.[176] My view is that they should either not be considered at all or should be given only very little weight. This is consistent with the individualistic approach to patient autonomy that prevails in Canadian health law.

Resources must be considered: a patient cannot be entitled to a transplant kidney if no suitable one is available, nor should a patient be able to insist on access to other medical resources like tests, drugs, or access to specialists, if it is not reasonable to provide them due to cost or availability. Whether this is to be determined as part of the reasonableness assessment (e.g., it is not reasonable to have a transplant kidney if no suitable one is available) or whether resource considerations are to be assessed separately would need to be determined. This may or may not be a separate inquiry so long as it is clear that a lack of resources can justify withholding or withdrawing treatment from a patient.[177]

Legislative presumptions could be applied. In England, for example, there is a presumption in favour of maintaining life.[178] It is, however, only a starting point. As we have seen, English courts have often found that being

---

176 *HCCA*, *supra* note 7, s 1(e); *Rasouli*, *supra* note 4 at paras 43, 51.

177 It is not controversial that physicians may deny treatment that is unavailable – transplant organs or diagnostic tests, for example. Much more controversial is whether it is negligent for physicians to limit access to available resources in order to preserve access to them for more needy patients. Some cases have held that since physicians' duties are to their patients and not to the medical system, they must not consider resource allocation issues in deciding how to treat. See *Law Estate v Simice*, 21 CCLT (2d) 228, 1994 CanLII 3068 (BC SC), aff'd (1995) 17 BCLR (3d) 1, 19 CCLT (2d) 127 (CA). Other cases, however, acknowledge that resource considerations can be factored into the standard of care analysis. See *Manary v Strban*, 2013 ONCA 319 at para 73, 362 DLR (4th) 550.

178 See *James*, *supra* note 55 at para 35:

> The authorities are all agreed that the starting point is a strong presumption that it is in a person's best interests to stay alive. As Sir Thomas Bingham MR said in the Court of Appeal in *Bland*, at p 808, "A profound respect for the sanctity of human life is embedded in our law and our moral philosophy". Nevertheless, they are also all agreed that this is not an absolute.

kept alive is not in a patient's bests interests and have sided with physicians who wish to stop providing life-sustaining treatment. The test would still be reasonableness.

Another potential presumption is one in favour of promoting the patient's best interests. This would be true both of competent and incompetent patients.[179] What competent patients, or incompetent patients with valid advance directives, say they want is very strong evidence of their best interests but may not be determinative. For example, where a person with a drug addiction wants a prescription for opioids, it may not be in their best interests to have it. This is different than the refusal context, where it is well established that competent patients determine their own best interests. The proposed approach is paternalistic, but I have set out above why I think some paternalism must be retained in such decision-making contexts. For incompetent patients, determining what is in their best interests would presumably resemble the approach that currently exists at Canadian common law and in certain statutes, such as Ontario's *HCCA*.[180] That is, it would involve balancing medical considerations, patients' values, and patients' wishes expressed while competent. Contrary to the refusal context, however, there would only be a presumption in favour of best interests.

The proposed test would therefore require courts to consider a range of factors in assessing reasonableness. These include the patient's best interests – values, medical considerations, and expressed wishes – but would consider other factors as well. These include resource allocation, any effects on members of the health care team, who are sometimes traumatized by what they perceive as their complicity in prolonging patients' suffering,[181] and effects on the practice of medicine or on the health care system more broadly. What patients want or what is in their best interests should be given considerable weight, but should not be determinative in the demand context.

> There are cases where it will not be in a patient's best interests to receive life-sustaining treatment.

179 Recall that this test would only apply where treatment contrary to clinical judgment was requested. Refusals of offered treatment would still be resolved in the usual way, with competent patients being able to refuse for any reason and decisions for incompetent patients being determined based on their best interests.

180 *Supra* note 7, s 21(2).

181 See e.g. Smith, *supra* note 26; CBC News, "2 More Winnipeg Doctors", *supra* note 27; *Rotaru*, *supra* note 43 at para 6.

B. Onus

The issue of who should bear the onus amounts to determining what the presumption or default position should be. Should the presumption be that clinical judgment prevails, with patients or SDMs having to prove otherwise? Or should the default position be that patients may have whatever treatment they like, with physicians having to prove the treatment is unreasonable in order to avoid having to provide it?

As a practical matter, physicians are gatekeepers. The issue is whether physicians can be required to treat in a manner they consider medically inappropriate. They may be unwilling to do so without a court order. This results in a de facto primacy of clinical judgment, with patients having to get court orders to require physicians to treat.

Nevertheless, I think the default could and should be that physicians should have to give patients the treatment they want. The onus would therefore be the opposite of that in England, where patients must challenge physicians' treatment decisions if they disagree with them.[182] My proposal is that physicians who object to having to provide particular treatment, for whatever reason, would have the onus of establishing that the requested treatment is unreasonable. This onus has at least two benefits. First, it helps patients who may have less information and fewer resources than physicians. Unless a physician is willing to challenge the default position, the patient will not have to expend any resources and will not suffer the additional stress and inconvenience of a conflict with her health care provider.

Of course, it will still be a burden for patients to have to defend against a physician's challenge. This seems unavoidable unless we are to simply give patients whatever they request, a situation that I have argued is undesirable. The impact of the patient's burden to defend could be reduced by having special tribunals like Ontario's CCB decide these matters. This seems unlikely, however, in that other jurisdictions have shown no inclination to create their own CCBs. In Ontario, a legislative amendment would be required for the CCB to apply rules such as those proposed here.

---

[182] That said, physicians in England do have to get a court order to withdraw artificial nutrition and hydration from a patient in a persistent vegetative state. This originated with the House of Lords decision in *Airedale NHS Trust v Bland*, [1993] AC 789, [1993] 1 All ER 821.

The second benefit is that this onus places a high value on patient autonomy while maintaining some limitations on patients' ability to receive the treatment they request.

C. Legislation versus common law

A third point for elaboration is whether the proposed approach should be legislated or be developed at common law. In Ontario, of course, any such change would have to be legislated given the *HCCA* and the Supreme Court's interpretation of it. In other provinces and territories, jurisprudential developments may be possible but legislation is preferable for two reasons. First, my proposal represents a significant change from the status quo and such non-incremental changes are generally best left to legislatures. Second, the question of who gets to decide whether requested medical treatments are provided is a complex social issue with implications for patients, families, the medical profession, and the publicly funded health care system. Canadian courts have noted that complex issues of social significance are better addressed by legislatures than by courts.[183] A legislative approach to this issue is also advocated by Downie, Willmott, and White.[184]

To summarize, the principal benefits of the proposed approach are that it gives considerable weight to patient autonomy and patient best interests. It provides clear rules that apply broadly and do not rely on what I have argued is an untenable distinction between life-sustaining treatment and other kinds of treatment. This makes the approach both more principled and clearer than that in Ontario law. The rule of law is promoted when laws are clear

---

183 See *Alberta v Hutterian Brethren of Wilson Colony*, 2009 SCC 37 at para 53, [2009] 2 SCR 567, McLachlin CJ ("[T]he courts accord the legislature a measure of deference, particularly on complex social issues where the legislature may be better positioned than the courts to choose among a range of alternatives"). See also *R v Malmo-Levine*, 2003 SCC 74 at para 133, [2003] 3 SCR 571 (the Court stated, albeit in the criminal law context, that when a social issue involves harm, "the precise weighing and calculation of the nature and extent of the harm is Parliament's job." This is because legislators "have access to a broader range of information, more points of view, and a more flexible investigative process than courts do"); *R v Schmidt*, 2011 ONCJ 482 at paras 93, 99, 248 CRR (2d) 91.

184 Downie, Willmott & White, *supra* note 11 at 825.

and knowable.[185] It also, however, provides a role for clinical judgment. It acknowledges that patient autonomy is not the only relevant consideration and that requested treatment should sometimes be denied – whether for the patient's own good, for resource allocation considerations, or, more rarely, for public health reasons. The proposed approach also allows for adjudication where a physician's clinical judgment may be affected by improper considerations or where the physician may be mistaken about the medical situation in terms of diagnosis, prognosis, etc.

None of this would detract from physicians' existing duties to provide information and to discuss treatment options with patients. Where doctors and patients disagree as to whether treatment should be provided, reasonable efforts should be made to arrive at a consensus. Nor would this affect patients' rights to a second opinion or to have their care transferred to another physician who is willing to provide the requested treatment.

One potential problem with the proposed approach is that it gives considerable discretion to judges to decide particular cases based on what they consider to be reasonable. Given the value judgments involved, this approach arguably substitutes the judge's judgment for that of the physician. And yet courts are accustomed to balancing different interests (in determining best interests, for example) and to determining what is reasonable (in determining the negligence standard of care, for example). That is, by their very role, courts are better equipped to answer such questions than medical professionals.

Another potential problem is that a reasonableness approach is less certain than an approach that simply allows physicians to deny treatment according to their clinical judgment (as in England) or that allows patients to have certain treatments regardless of clinical judgment (as in Ontario). As in negligence law, however, the value of a reasonableness analysis is that it allows for a fact-specific, contextual approach to a complex situation.

In Canada, it should be exceedingly rare for courts to order physicians to treat contrary to their clinical judgment, but it should be possible if providing the requested treatment is not unreasonable in the circumstances.

---

[185] The rule of law has been noted as an important Canadian value when it comes to making laws governing the withholding and withdrawal of potentially life-sustaining treatment (*ibid* at 813).

Conclusion

Nearly two decades ago, Justice Beard stated the following in *Sawatzky*:

> I think that many Canadians have been surprised to learn that a doctor can make a "do not resuscitate" order without the consent of a patient or his or her family, yet that appears to be the current state of the law in Canada, Britain and the United States. While the courts may be an appropriate place to start the discussion of these issues in that the courts can clarify the existing state of the law in light of the *Charter of Rights and Freedoms*, it may be for the government to resolve any moral or ethical questions that remain at the end of the day. The government can ensure a much wider debate including all interested sectors of society, while a court proceeding is, by necessity, relatively narrow and limited even if some interventions are allowed. Regardless of the outcome of this hearing, these issues require full public discussion.[186]

So far, this call for legislation and full public discussion has gone unheeded. There is little political upside to legislating on this matter: some individuals and groups are bound to be unhappy with any statute. And yet the complexity of the issue and the difficult ethical questions involved are such that the legislatures are better suited to setting standards than the courts.

In *Rasouli*, the Supreme Court interpreted an Ontario statute so as to create a de facto entitlement to life-sustaining treatment contrary to physicians' clinical judgment. This approach may be adopted by other Canadian jurisdictions with similar legislation. This is in stark contrast to the law in England, where courts have consistently affirmed that while patients may refuse treatment, they have no positive right to treatment contrary to clinical judgment – even where withholding the treatment would result in the patient's death.

I have argued that the law in Ontario took a misstep in *Rasouli*. The law is now unprincipled and is often unclear, in that the scope of the *Rasouli* decision is uncertain. Further, the law of informed consent should not dictate the outcome of disputes between physicians and patients or SDMs about whether certain treatment should be provided.

---

186 *Sawatzky*, *supra* note 71 at para 5.

That does not mean, however, that England's approach of deference to clinical judgment is unproblematic. In light of the discussion above, it is clear that treatment decisions are not purely medical matters for physicians alone to decide.

Claims to be entitled to treatment contrary to clinical judgment will continue to arise in Canada. There should be limits on what patients can demand and these limits should go beyond considerations of resource allocation or objective ineffectiveness. After all, giving a person with an addiction a prescription for large quantities of opioids is not ineffective, nor does it engage resource considerations. Nevertheless, physicians should be able to resist such demands. One approach – that favoured by the Supreme Court in *Rasouli* – is to have a separate rule for life-sustaining treatment. Such a distinction, however, is not principled. Finally, it will not always be appropriate to limit treatment to what is clinically indicated.

Perhaps we can do no better, given the wide range of interests involved and fact scenarios that will arise, than for courts or tribunals, guided by the legislature, to assess what is reasonable when families and physicians cannot agree as to how to proceed.

Organ Donation and Medical Assistance in Dying: Ethical and Legal Issues Facing Canada

*Sherri Yazdani, Daniel Z Buchman, Linda Wright & Jennifer A Chandler**

In June 2016, the Government of Canada enacted legislation to regulate the practice of medical assistance in dying (MAID) in response to the Supreme Court of Canada's 2015 decision striking down the prohibition against assisted dying in particular circumstances. One issue that has not been addressed in depth in the Canadian debate is whether those accessing MAID would be eligible to donate organs and tissues, as well as the ethico-legal issues this may pose. This is a challenging question that brings together the controversial introduction of MAID with

En juin 2016, le gouvernement du Canada a promulgué une loi pour réglementer la pratique de l'aide médicale à mourir (AMM) en réponse à l'arrêt de la Cour suprême du Canada en 2015 abrogeant la prohibition contre la mort assistée dans certaines circonstances. Un problème qui n'a pas été abordé en profondeur dans le débat canadien est si ceux qui accèdent à l'AMM seraient éligibles à faire un don d'organes ou de tissus, ainsi que les problèmes éthico-légaux que cela poserait. Il s'agit d'une question difficile rassemblant l'introduction contro-

* Sherri Yazdani, Faculty of Law, University of Ottawa; Member, Canadian Blood Services' Donation Legal Research and Health Policy Working Group (unpaid position). Daniel Z Buchman, University Health Network, Toronto; University of Toronto Joint Centre for Bioethics; Dalla Lana School of Public Health, University of Toronto; Member, Canadian Blood Services' Organ Donation in the Conscious Competent Patient Steering Committee (unpaid position). Linda Wright, University of Toronto Joint Centre for Bioethics; Department of Surgery, University of Toronto; Co-Chair, Trillium Gift of Life Ethics Committee. Jennifer A Chandler, Faculty of Law, University of Ottawa; Bertram Loeb Research Chair, University of Ottawa; Member, Trillium Gift of Life Ethics Committee. The authors gratefully acknowledge the financial support for their research provided by the Canadian National Transplant Research Program and the Bertram Loeb Research Chair. The authors also thank Anna-Lisa Kates for her thoughts, which enriched their thinking on this topic.

Citation: Sherri Yazdani, Daniel Z Buchman, Linda Wright & Jennifer A Chandler, "Organ Donation and Medical Assistance in Dying: Ethical and Legal Issues Facing Canada" (2018) 11:2 McGill JL & Health 59.

Référence : Sherri Yazdani, Daniel Z Buchman, Linda Wright et Jennifer A Chandler, « Organ Donation and Medical Assistance in Dying: Ethical and Legal Issues Facing Canada » (2018) 11 : 2 RD & santé McGill 59.

the ethically sensitive practice of organ donation. This paper analyzes the ethico-legal issues raised in four possible scenarios for donation to occur in the context of MAID: living donation of non-vital organs before MAID, extended living donation of vital organs in anticipation of MAID, posthumous donation following MAID, and MAID by removal of organs. Extended living donation of vital organs and MAID by removal of organs are unlikely to be accepted and, indeed, we recommend against them. However, these possibilities have been raised in the medical ethics literature and we address them as part of a full review of this topic. In conclusion, we provide recommendations to address the combination of organ donation and MAID within what we believe to be acceptable ethical parameters.

versée de l'AMM avec la pratique éthiquement sensible du don d'organes. Cet article analyse les problèmes éthico-légaux soulevés par quatre scénarios de don effectués dans le contexte de l'AMM: le don vivant d'organes non-essentiels avant l'AMM, le don vivant d'organes essentiels en anticipant l'AMM, le don d'organes après décès suite à l'AMM, et l'AMM par enlèvement d'organes. Le don vivant d'organes essentiels en anticipant l'AMM et l'AMM par enlèvement d'organes ont peu de chances d'être acceptés et, effectivement, nous recommandons contre ceux-ci. Cependant, ces possibilités ont été soulevées dans la littérature sur l'éthique médicale et nous les abordons dans le cadre d'une revue complète de ce sujet. En conclusion, nous fournissons des recommandations pour aborder la combinaison du don d'organe et l'AMM dans les limites de ce que nous croyons être des paramètres éthiques acceptables.

Introduction

In June 2016, the Canadian Parliament passed *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)*[1] (the *Act*) to regulate voluntary euthanasia and assisted suicide – together termed medical assistance in dying (MAID). The *Act* was a response to the Supreme Court of Canada's unanimous 2015 ruling in *Carter v Canada (AG)*, which declared the *Criminal Code* provisions prohibiting MAID unconstitutional for competent adults suffering from grievous and irremediable conditions causing intolerable suffering.[2] Prior to *Carter*, only Québec had enacted legislation to address voluntary euthanasia.[3] The *Act* was passed following a protracted national debate over the scope of eligibility for MAID, particularly whether access should be permitted pursuant to an advance request, for mature minors, and for people suffering from mental rather than physical illnesses.[4] Currently, the *Act* does not allow MAID by advance requests or for mature minors. Most people suffering solely from mental illness also appear to be ineligible for MAID due to the eligibility requirement that natural death be reasonably foreseeable, although there has been debate on this point.[5] Parliament has committed itself in the *Act* to further review of these issues.[6]

---

1 SC 2016, c 3 [*MAID Act*]. While both voluntary euthanasia and assisted suicide involve the provision by a medical professional of a substance which causes death, in voluntary euthanasia the substance is administered by the medical professional and in assisted suicide it is self-administered.

2 2015 SCC 5 at para 147, [2015] 1 SCR 331 [*Carter*].

3 See *An Act respecting end-of-life care*, CQLR, c S-32.0001.

4 See Parliament, Special Joint Committee on Physician-Assisted Dying, *Medical Assistance in Dying: A Patient-Centred Approach* (February 2016) at 14, 21, 24 (Joint Chairs: Hon Kelvin Kenneth Ogilvie and Robert Oliphant) (in which the Special Joint Committee of Parliament recommended MAID be available in each of these circumstances).

5 See Jocelyn Downie & Justine Dembo, "Medical Assistance in Dying and Mental Illness under the New Canadian Law", online: (2016) 9 J Ethics Mental Health VI(iv) at 3 <www.jemh.ca/issues/v9/documents/JEMH_Open-Volume_Benchmark_Medical_Assistance_in_Dying_and_Mental_Illness_Under_the_New_Canadian_Law-Nov2016.pdf>.

6 See *MAID Act*, *supra* note 1, Preamble, s 9.1.

The introduction of MAID occurs at a time when Canada is also experiencing a shortage of organs for transplant.[7] The question of whether people accessing MAID would be eligible to donate their organs has not been addressed in depth in the Canadian debate so far. The combination of this controversial change in Canadian law and the ethically sensitive practice of organ donation may give rise to ethical discomfort and legal uncertainty. Throughout the Canadian debate over MAID, concerns have been raised that vulnerable people may be pressured to consent to MAID or that they may consent due to neglect that leaves them little reasonable alternative to relieve unendurable suffering.[8] As will be discussed, issues of vulnerability, coercion, and conflict of interest also arise in the context of organ donation. The combination of MAID and organ donation may raise fears that the decision to seek or provide MAID is influenced by the possibility of benefit to others through organ donation.

In order to reduce the risk that the decision to withdraw life-sustaining treatment might be influenced by the prospect of obtaining transplantable organs, medical and organ donation organization professionals attempt to separate the discussions regarding withdrawal of life-sustaining therapies and donation.[9] However, unlike most other deceased organ donors, MAID patients will be competent immediately before the death and donation and will therefore be able to give first-person informed consent.[10]

---

7 See Canadian Institute for Health Information, *Deceased Organ Donor Potential in Canada* (Ottawa: CIHI, 2014) at 4, online: <www.cihi.ca/web/resource/en/organdonorpotential_2014_en.pdf>.

8 See e.g. Advocacy Centre for the Elderly, "Submission of the Advocacy Centre for the Elderly to the Joint Special Committee on Physician-Assisted Dying" (2 February 2016) at 3, online: <www.advocacycentreelderly.org/appimages/file/PAD%20Submissions%20to%20JSC.pdf>; Council of Canadians with Disabilities, "CCD Submission to Special Joint Committee on Physician Assisted Dying" (28 January 2016), online: <www.ccdonline.ca/en/humanrights/endoflife/SJCPAD-28jan2016>.

9 See Sam D Shemie et al, "Donation after Cardiocirculatory Death in Canada" (2006) 175:8 CMAJ S1 at S10.

10 The legal criteria for valid first-person consent are that the patient be capable and that the consent be voluntary. Under the law, patients are entitled to disclosure of information that is relevant to deciding whether or not to consent to the proposed treatment. See generally Patricia Peppin, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds, *Canadian*

This will allow for careful inquiry into the reasons for their decisions both to request MAID and to donate organs, providing insight into the person's wishes and voluntariness beyond what can be ascertained from the presence or absence of an earlier expressed intention to donate, such as a signed donor card.

Cases of organ donation after MAID are not expected to be common, as some of the medical conditions that may lead people to seek MAID, namely terminal cancer, rule out the possibility of organ donation.[11] However, other conditions such as neurodegenerative diseases are not currently considered an absolute contraindication to transplantation.[12] Neurodegenerative disease transmission through organ donation has not been demonstrated, although there is ongoing debate as to the possibility of disease transmission to the recipient.[13] In addition to the risk of disease transmission, another risk factor crucial to the success of a transplant is the length of time the transplanted organs and tissues are deprived of oxygen, resulting in ischemic damage to the organ.[14] Despite these challenges, requests to donate

---

Health Law and Policy, 4th ed (Markham, Ont: LexisNexis Canada, 2011) 153 at 153–54.

11 See Elizabeth Trice Loggers, Moreen Shannon-Dudley & Frederick R Applebaum, "Implementing a Death with Dignity Program at a Comprehensive Cancer Centre" (2013) 368:15 New Eng J Med 1417 at 1418 (close to 80% of those seeking assisted suicide in Washington and Oregon between 2009 and 2011 had a terminal cancer diagnosis); Julie Allard & Marie-Chantal Fortin, "Organ Donation after Medical Assistance in Dying or Cessation of Life-Sustaining Treatment Requested by Conscious Patients: The Canadian Context" (2017) 43:9 J Med Ethics 601 at 605.

12 See Karim Serri & Pierre Marsolais, "End-of-Life Issues in Cardiac Critical Care: The Option of Organ Donation" (2017) 33:1 Can J Cardiol 128 at 130. For case reports from the US of organ donation by patients with amyotrophic lateral sclerosis, see Shahed Toossi et al, "Organ Donation after Cardiac Death in Amyotrophic Lateral Sclerosis" (2012) 71:2 Ann Neurol 154; Thomas J Smith et al, "Organ Donation after Cardiac Death from Withdrawal of Life Support in Patients with Amyotrophic Lateral Sclerosis" (2012) 15:1 J Palliat Med 16.

13 See Brandon B Holmes & Marc I Diamond, "Amyotrophic Lateral Sclerosis and Organ Donation: Is There Risk of Disease Transmission?" (2012) 72:6 Ann Neurol 832.

14 See AR Manara, PG Murphy & G O'Callaghan, "Donation after Circulatory Death", online: (2012) 108:Suppl 1 Br J Anaesth i108 at i112 <https://acade

organs following MAID have been made and granted in the Netherlands[15] and in Belgium.[16]

The bioethics literature mentions several possible scenarios in which MAID and organ donation may be combined. These scenarios may emerge before, during, or after death by MAID, and include: (1) living donation of non-vital organs before MAID; (2) extended living donation of vital organs in anticipation of MAID; (3) MAID by removal of organs; and (4) post-humous donation following death by MAID. The last scenario, in which donation occurs after cardiac arrest is brought about by MAID, is the most likely option in our view, since the other three encounter significant legal and practical obstacles. This is in fact the practice described in recent Dutch practice guidelines.[17] We seek to contribute to the health law and bioethics literature by offering an ethico-legal analysis of these four options in the order outlined above. We conclude with recommendations for addressing the combination of organ donation and MAID within what we suggest are acceptable ethical parameters. This analysis is timely given the introduction of the *Act* and the fact that patients are already asking to donate following MAID.[18] For policy makers to leave the issue unaddressed is to leave the matter for local health practitioners and hospital bioethicists to decide –

---

mic.oup.com/bja/article/108/suppl_1/i108/237453> (the maximum tolerable period of ischemia varies by organ and tissue type).

15 See AKS van Wijngaarden, DJ van Westerloo & J Ringers, "Organ Donation after Euthanasia in the Netherlands: A Case Report" (2016) 48:9 Transplant Proc 3061; Jan Bollen et al, "Organ Donation after Euthanasia: A Dutch Practical Manual" (2016) 16:7 Am J Transplant 1967 at 1967 [Bollen et al, "Manual"].

16 See D Van Raemdonck et al, "Initial Experience with Transplantation of Lungs Recovered From Donors after Euthanasia" (2011) 15:1 Appl Cardiopulm Pathophysiol 38 at 39; D Ysebaert et al, "Organ Procurement after Euthanasia: Belgian Experience" (2009) 41:2 Transplant Proc 585 at 586; Olivier Detry et al, "Organ Donation after Physician-Assisted Death", Letter to the Editor, online: (2008) 21:9 Transpl Int 915 at 915 <onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.2008.00701.x/full>; Jan Bollen et al, "Legal and Ethical Aspects of Organ Donation after Euthanasia in Belgium and the Netherlands" (2016) 42 J Med Ethics 486 at 486 [Bollen et al, "Legal"].

17 See Bollen et al, "Manual", *supra* note 15 at 1968.

18 See Sharon Kirkey, "Doctors Harvesting Organs from Canadian Patients Who Underwent Medically Assisted Death", *National Post* (20 March 2017),

possibly in urgent circumstances, as was the experience in Belgium when a patient asked to donate her organs the day before her assisted death was to take place.[19]

Since laws are jurisdiction-specific, our legal discussion will be based on the *Act* and Ontario's provincial laws governing organ donation.[20] However, the ethical issues addressed are broadly relevant and the legal analysis may be adapted to other legal jurisdictions as appropriate.

I. Living donation before MAID

A competent adult may seek to make a living donation of non-vital organs – a kidney or part of a liver – in advance of MAID. Allowing living donation before MAID would offer competent patients a way to donate should they wish to do so. There are documented psychological benefits which accrue to living organ donors, and although these benefits will not be long-lasting for a person who will soon die through MAID, it may still be of comfort to know that a donation has indeed gone ahead successfully.[21] This knowledge is evidently impossible in the case of post-mortem donation. There is also a potential benefit from the perspective of medical utility, as organs donated by a living donor do not suffer as much risk of anoxic damage as in post-mortem donation, thereby increasing the chance of a successful transplantation. A living donation also avoids one of the practical difficulties associated with donation after circulatory death (DCD), namely that DCD requires death to occur near an operating room so that organs may be swiftly removed. A living donation could allow a patient to both donate organs and select the location of their death by MAID, which could occur in an unhurried manner with friends or family near.[22]

---

online: <news.nationalpost.com/health/doctors-harvesting-organs-from-canadian-patients-who-underwent-medically-assisted-death>.

19 See Detry et al, *supra* note 16 at 915.

20 *Trillium Gift of Life Network Act*, RSO 1990, c H.20 [*TGLNA*]; *Health Care Consent Act, 1996*, SO 1996, c 2, Schedule A.

21 See e.g. Allison Tong et al, "'It Was Just an Unconditional Gift: Self-Reflections of Non-Directed Living Kidney Donors" (2012) 26:4 Clin Transplant 589 at 597.

22 See Paul E Morrissey & Anthony P Monaco, "Donation after Circulatory Death: Current Practices, Ongoing Challenges, and Potential Improvements"

Legal and ethical considerations

Ontario law permits a mentally competent person who is 16 years old or older to make a living donation, provided the individual gives free and informed first-person consent in writing and donation takes place immediately thereafter.[23] However, the *Act* currently restricts access to competent adults aged 18 years or older.[24]

There do not appear to be legal obstacles to making a living donation ahead of MAID for those 18 years or older in Canada. The standard of capacity for consent to both is likely to be similarly high given the significance of the two decisions. However, it is possible that different capacity assessment procedures for MAID and organ donation may result in divergent opinions on a person's capacity, even if the same standard of capacity is applied. This is because different decision makers and decision-making processes, perhaps producing assessments at different times, may produce divergent results. For example, the *Act* requires that two medical or nurse practitioners independently approve the request and assess the patient's capacity,[25] while no similar duplicative procedure is required for evaluating capacity to consent to living donation in Ontario.[26] Therefore it is possible that a person could be found capable of consenting to one of these procedures, but incapable with respect to the other.

The *Act* excludes minors and the use of advance requests,[27] although these exclusions are sources of controversy,[28] and Parliament has commit-

---

(2014) 97:3 Transplantation 258 at 262–63 (the authors outline the benefits to living donation as an alternative to donation after circulatory death [DCD] following withdrawal of life-sustaining therapies).

23 See *TGLNA*, *supra* note 20, s 3(1).

24 *Supra* note 1, s 3, amending *Criminal Code*, RSC 1985, c C-46, s 241.2(1)(b).

25 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(3)(e).

26 See *TGLNA*, *supra* note 20, s 3.

27 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(1).

28 See e.g. Special Joint Committee on Physician-Assisted Dying, *supra* note 4 at 21, 24 (the Joint Committee recommended that a provision for mature minors come into force within three years of the provisions for adults, and that advance requests be permitted at any time following a diagnosis likely to cause loss of competence or of grievous or irremediable condition; Parliament did not follow either of these recommendations).

ted to further exploring both.[29] Both the Netherlands and Belgium permit MAID for minors,[30] and it is possible that Canada might move to include mature minors in its own legal framework – not least since a total exclusion of mature minors, without regard for their actual circumstances, may impair their rights under section 7 of the *Canadian Charter of Rights and Freedoms* (*Charter*).[31]

Depending on the age of eligibility for MAID, there may be inconsistencies with the age requirements for living donation, which vary across the country.[32] It would be difficult to justify divergent laws that allow a person below 16 years of age to access MAID but not to make a living organ donation. Challenges would also arise if Parliament permits MAID by advance request. For example, if consent to MAID by advance request were permitted, it would follow that MAID could be administered to a person lacking the capacity to consent at the time. Since Ontario law does not permit substitute or advance consent to living donation,[33] this would preclude living organ donation for those whose consent to MAID was given by advance request.

II. Extended living donation before MAID

A more controversial possibility for donation has been raised as an alternative to DCD, namely extended living organ donation.[34] In this scenario,

---

29 See *MAID Act*, *supra* note 1, Preamble, s 9.1.

30 See Giulia Cuman & Chris Gastmans, "Minors and Euthanasia: A Systematic Review of Argument-Based Ethics Literature" (2017) 176:7 Eur J Pediatr 837 at 838.

31 See Constance MacIntosh, "*Carter*, Medical Aid in Dying, and Mature Minors" (2016) 10:1 McGill JL & Health S1 at S22, citing Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [*Charter*].

32 See e.g. *Human Tissue Gift Act*, RSBC 1996, c 211, s 3(1) (establishing 19 as the minimum age for living donation in British Columbia); *The Human Tissue Gift Act*, SM 1987-88, c 39, CCSM c H180, s 10(1) (establishing 16 as the minimum age for living donation in Manitoba); *TGLNA*, *supra* note 20, s 3(1) (establishing 16 as the minimum age for living donation in Ontario); *The Human Tissue Gift Act*, RSS 1978, c H-15, s 4(1) (establishing 18 as the minimum age for living donation in Saskatchewan).

33 See *TGLNA*, *supra* note 20, s 3.

34 See Dominic Wilkinson & Julian Savulescu, "Should We Allow Organ Do-

essential organs are procured from a living person. While this would eventually result in the person's death, death instead occurs before that point due to subsequent removal of life-sustaining treatments, independent of organ procurement.

The literature suggests that living donation of a greater number of organs, including both kidneys, the liver, and pancreas, could be permitted since the donor would die of cardiorespiratory failure resulting from removal of the ventilator, prior to death by loss of organ function.[35] Generally, living donation of essential organs is prohibited by the dead donor rule, an ethical norm which provides the foundation for organ donation law. The dead donor rule stipulates that vital organs can only be procured from persons who are dead.[36] In order to coexist with the dead donor rule, allowing for extended living donation hinges on an understanding of the rule as requiring that the donation *must not cause death* – a subtle variation from the common understanding that the donor *must be dead* before essential organs can be removed.

In theory, these arguments could likewise apply to patients who will undergo MAID. Patients approved for MAID could donate essential organs – including both kidneys, the liver, and the pancreas – the loss of which does not cause immediate death. Provided the procurement of these organs does not cause the patient's death before MAID occurs, this procedure would seem not to violate the dead donor rule, understood as a proscription on causing death by removal of organs.

Legal and ethical considerations

To best uphold law, ethics, and public confidence in the medical system, we strongly recommend against permitting extended living donation before MAID, even where a patient wishes to do this and where it may allow for the greatest protection of organs from anoxic damage.

---

nation Euthanasia? Alternatives for Maximizing the Number and Quality of Organs for Transplantation" (2012) 26:1 Bioethics 32 at 42.

35 See *ibid*.

36 See K Rusinova & J Simek, "Should We Relax the Definition of Death or the Dead Donor Rule?", Letter to the Editor, (2014) 40:6 Intensive Care Med 917 at 917.

An overarching legal problem with extended living donation before MAID stems from the possibility of loss of capacity between the donation and the subsequent administration of MAID. The *Act* requires that immediately before the administration of MAID, a patient be asked to reconfirm their consent.[37] Depending on the interpretation of "immediately before" and the amount of time between the donation and the administration of MAID, a person may have capacity to consent to extended living donation but subsequently lose capacity to give the required confirmation of consent between the donation and MAID. This would leave the medical team that had removed the essential organs in the position of having either inflicted great harm on the donor, who would now require substantial medical support to replace organ function where possible, or having brought about the death of the donor contrary to the *Act* and the established rules relating to organ donation if organ function could not be replaced (as in the case of a liver or pancreas donation).[38]

Furthermore, once essential organs are removed, a person's freedom to change their mind about MAID may cease, depending on whether there are artificial substitutes for the lost organ function. Even if the initial requests for MAID are carefully considered and non-impulsive, people may change their minds.[39] If they have made a living donation of an essential organ, they may no longer be able to change their minds about the timing of their deaths, which could cause great distress for the patients, their families, and the medical teams involved.

From the perspective of trust in the medical and organ donation systems as well as transplant professionals, these kinds of cases would likely be disastrous. Even if the donors intended to undergo MAID, the idea that they would lose the ability to change their minds would be very troubling. The *Act* reveals concern about the stability of decisions to seek MAID, with a legislated delay of 10 days between the request and the administration of MAID[40] and the requirement that consent be reconfirmed immediately be-

---

37 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(3)(h).

38 See Rusinova & Simek, *supra* note 36 at 917. As discussed in more detail in Part III, the dead donor rule in organ donation holds that the removal of organs for transplant must not cause the death of the donor.

39 See Elaine Chen, "Organ Donation after Assisted Suicide: Practically and Ethically Challenging" (2014) 98:3 Transplantation 252 at 252.

40 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(3)(g).

fore MAID is given.[41] Therefore, for the sake of patients, health care teams, and public trust, extended living donation would be most unwise in the context of MAID.

III. MAID by Removal of Organs

Another possible scenario raised in bioethics literature would be to merge MAID and organ donation into a single procedure, whereby death would be caused by the removal of organs from an anaesthetized patient rather than by the administration of lethal medications.[42] This scenario does not fit the traditional distinction between living and posthumous donation, as it brings death and donation together in time. This idea is unlikely to be accepted, given the firm adherence in the organ donation and transplantation community to the dead donor rule. However, we address it here given that it has been raised in the literature as a scenario by which MAID and organ donation could theoretically proceed.

The idea has been proposed as an alternative to DCD following the withdrawal of life-support therapies, under the names "organ donation euthanasia" or "death by donation."[43] Given the language of the *Act*, we adopt the term "MAID by removal of organs." These proposals have not been given wide consideration because they violate the dead donor rule, according to which organ donation must not bring about the death of a person. However, the question that must be asked is whether the dead donor rule should continue to apply in the context of MAID. Are there reasons to insist on the dead donor rule for organ donation in the context of MAID? To put it another way, are there reasons to restrict the manner in which MAID may be administered?

Legal and ethical considerations

The legality of proceeding with MAID by removal of organs is presently uncertain. The rules regulating donation in Ontario differ according to

---

41 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(3)(h).

42 See e.g. Wilkinson & Savulescu, *supra* note 34 at 40–41; Antonia J Cronin, "Death by Donation: Reflections on Individual Authorization, Assisted Suicide and Organ Donation" (2014) 98:3 Transplantation 254 at 254.

43 See Wilkinson & Savulescu, *supra* note 34 at 38; Cronin, *supra* note 42 at 254.

whether the donation is living or posthumous,[44] and as noted above, MAID by removal of organs does not fit either category. If it is to be regarded as a form of posthumous donation, then the legal requirement that the physicians determining death be separate from those recovering organs[45] does not seem possible. Those bringing about death and recovering organs will necessarily be the same, and the determination of death will be made at the same time. If it is considered a form of living donation, as the donor is still living at the moment of donation, then the existing rules governing living donation might be said to apply.

The *Act* defines "medical assistance in dying" as the act of administering, prescribing, or providing "a substance" that causes the patient's death.[46] This seems to preclude bringing about death surgically, although it would perhaps not preclude other methods of bringing about death via the administration of substances that are adapted more specifically to organ donation procedures.

Autonomy and vulnerability

Several authors have argued that the dead donor rule should be abandoned, as it denies some patients the opportunity to donate despite their clearly expressed wishes to do so.[47] For example, patients who consent to donation by DCD may be precluded from donating if they do not die quickly enough after the removal of the ventilator.[48] Truog, Miller, and Halpern argue that organ donation euthanasia should be permitted in order to allow patients in this situation to donate.[49] They contend that the ethics of organ donation should not rest on the dead donor rule but instead on principles of

---

44 *TGLNA*, *supra* note 20, Parts I, II.

45 *Ibid*, s 7(3).

46 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.1.

47 See e.g. Robert D Truog, Franklin G Miller & Scott D Halpern, "The Dead-Donor Rule and the Future of Organ Donation" (2013) 369:14 New Eng J Med 1287 at 1287–88; Wilkinson & Savulescu, *supra* note 34 at 41; Franklin G Miller, "Heart Donation without the Dead Donor Rule" (2014) 97:4 Ann Thorac Surg 1133 at 1134.

48 See Truog, Miller & Halpern, *supra* note 47 at 1287.

49 *Ibid* at 1288.

autonomy and non-maleficence, and that honouring a person's autonomy necessitates providing choices, including the opportunity to donate.[50]

This argument is weaker in the context of MAID than in the context of standard DCD, as death will occur rapidly and predictably, making successful donation more assured than in the case of removal of ventilation. However, a patient may still have an interest in being permitted to pursue MAID by removal of organs: by avoiding the required observation period prior to removal of organs in DCD, the risk of anoxic damage to organs is reduced and the chances of successful transplantation are increased.[51]

One of the persistent worries voiced during Canada's decades-long national debate over MAID is that vulnerable people will be encouraged to request MAID, either directly or by neglect that leaves them with few options.[52] Combining organ donation with MAID might exacerbate these concerns because it introduces a clear benefit for others when someone chooses MAID and so increases the risk of actual or perceived conflict of interest. Organ donation practices, policies, and participating clinicians are already met with distrust by some members of the public[53] and combining MAID and organ donation is unlikely to build trust. Media headlines such as "Doctors Harvesting Organs from Canadian Patients Who Underwent Medically Assisted Death"[54] indicate that the issue is already on the media radar. Given that organ donation via DCD *after* MAID appears to be an ethically and legally permissible option that allows for the dead donor rule to be upheld and for the teams bringing about and determining death to be separated from those recovering organs, it seems that any benefit to permitting MAID by organ removal is not justified by the associated risks.

---

50 *Ibid*.

51 See Wilkinson & Savulescu, *supra* note 34 at 41. The necessity of observing the waiting period before procuring organs is discussed more fully in Part IV below.

52 See e.g. Advocacy Centre for the Elderly, *supra* note 8; Council of Canadians with Disabilities, *supra* note 8 (submissions to the Joint Special Committee on Physician Assisted Dying).

53 See Joshua D Newton, "How Does the General Public View Posthumous Organ Donation? A Meta-Synthesis of the Qualitative Literature" (2011) 11:791 BMC Public Health 1 at 9.

54 Kirkey, *supra* note 18.

IV. Posthumous Donation following MAID

The fourth scenario involves organ donation following MAID via accepted procedures for DCD. This scenario minimizes the risk of anoxic damage to organs, since cardiac arrest occurs rapidly after euthanasia is administered using coma-inducing and muscle relaxant drugs.[55] Donation after DCD also requires MAID occur in or close to a hospital operating room so that organs may be removed swiftly after death, which may or may not be acceptable to patients seeking MAID.

Posthumous donation following MAID is currently practised in Belgium and the Netherlands.[56] The Dutch government indicated its support for organ donation following MAID in 2014, after public controversy had erupted when a man's desire to donate after voluntary euthanasia was initially refused.[57] Bollen and colleagues recently proposed logistical guidelines for combining MAID and organ donation.[58] Proposals for combining MAID and organ donation have also emerged in other countries, including Switzerland, which does not allow donation following assisted suicide primarily for practical reasons.[59] We have not found any reported cases of organ donation following assisted suicide in the American jurisdictions where it is legal.

---

55 See Bollen et al, "Manual", *supra* note 15 at 1968.

56 See *supra* notes 15, 16.

57 See Pieter de Meer, "The Only Thing I Want Is to Donate My Organs" (26 February 2015), *Philosophy, Politics and Economics of Health* (blog), online: <ppeofhealth.weebly.com/blog/archives/02-2015>; Janene Pieters, "Euthanasia Should Lead to Organ Donation: Health Minister", *NL Times* (26 November 2014), online: <www.nltimes.nl/2014/11/26/euthanasia-lead-organ-donation-health-minister/>.

58 "Manual", *supra* note 15.

59 See David M Shaw, "Organ Donation after Assisted Suicide: A Potential Solution to the Organ Scarcity Problem" (2014) 98:3 Transplantation 247 at 247–48 (the author describes the primary practical obstacle as the fact that assisted suicides do not occur at or near a hospital and further notes that Switzerland has not fully developed its DCD capacity).

Legal and ethical considerations

Ontario law permits posthumous organ donation where the donor or the donor's substitute has consented according to the specified procedures.[60] The law further provides that the physicians determining death must be separate from those involved in removing and transplanting the organs.[61] There is no reference in Ontario's organ and tissue donation legislation to MAID and, so long as the requirements for posthumous donation are followed, the law does not appear to prevent donation following MAID.

1. Consent and capacity

Donations following MAID are different from the typical case of posthumous donation in that the potential donor is able to provide first-person informed consent shortly before the donation, directly to the organ and tissue donation coordinator who is not a member of the MAID team. This consent may confirm prior expressed wishes to donate, where an individual earlier signed a donor card, or it may be the first expression of the patient's intention. It is therefore similar in principle to cases in which conscious competent patients – such as those with amyotrophic lateral sclerosis (ALS) or high cervical spine injury – consent to have their ventilators removed, resulting in natural death and followed by organ donation.[62] Given the significance of the decision to seek MAID, the level of capacity required to consent to MAID is likely to be greater than or equal to what is required for first-person consent to posthumous donation.

Indeed, the Ontario legislation does not state any requirement for capacity for first-person consent to posthumous donation, requiring only that the consenting party be 16 years or older.[63] In the usual non-MAID context where a person has registered consent to donate at some point in the past, little or no attention is paid to whether their registered consent was capable or informed. In the case of MAID, the discussion of donation takes place with

---

60 *TGLNA*, *supra* note 20, s 4.

61 *Ibid*, s 7(3).

62 See e.g. Toossi et al, *supra* note 12; Smith et al, *supra* note 12; Gregory Comadira et al, "Do You Have a Right to Decide? Or Do We Have a Right to Acquiesce?" (2015) 28 Aust Crit Care 72.

63 *TGLNA*, *supra* note 20, s 4(1).

a living patient with a high level of capacity, thus providing an opportunity for a more informed discussion than is typically the case with posthumous donation. Physicians and transplant coordinators should therefore provide all necessary information to support informed consent to donation.

An additional consent-related challenge has to do with whether organ donation may put undue pressure on a patient not to change their mind about MAID. This pressure may increase as the process of being assessed as a potential donor moves along. At a minimum, it will be important to be sensitive to this possibility and to reassure patients that any steps taken to prepare for organ donation should not prevent them from changing their minds about both MAID and organ donation. Similar sensitivity is also required for conscious patients with ALS who have requested organ donation following removal of the ventilator.[64]

2. Consent pursuant to an advance request

MAID is not currently available by advance request under Canadian law. However, Parliament has indicated that it will examine this issue in the future.[65] Voluntary euthanasia by advance directive in the case of dementia is legal in the Netherlands.[66] It is worth noting that the Canadian government's Special Joint Committee on Physician-Assisted Dying recommended allowing MAID by advance request when the request is made following the diagnosis of a condition which will cause a loss of competence or of a grievous or irremediable condition.[67] Yet Parliament did not ultimately follow this recommendation.[68]

---

64 See Toossi et al, *supra* note 12 at 154–55.

65 See *MAID Act*, *supra* note 1, Preamble.

66 See Eva E Bolt et al, "From Advance Euthanasia Directive to Euthanasia: Stable Preference in Older People?" (2016) 64:8 J Am Geriatr Soc 1628 at 1628; Marike E de Boer et al, "Advance Directives for Euthanasia in Dementia: How Do They Affect Resident Care in Nursing Homes? Experiences of Physicians and Relatives" (2011) 59:6 J Am Geriatr Soc 989 at 989; Pauline SC Kouwenhoven et al, "Opinions about Euthanasia and Advanced Dementia: A Qualitative Study among Dutch Physicians and Members of the General Public" (2015) 16:7 BMC Med Ethics 1 at 1.

67 *Supra* note 4 at 24.

68 See *MAID Act*, *supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(3)(h).

If Canadian law is changed to allow consent via advance request, MAID could then be administered to a person lacking the capacity to consent at the time of the procedure. This raises questions as to how organ donation would fit within this scenario. Presumably, the current approach to obtaining consent to organ donation in the context of incapable patients would be followed: where the wishes of the patient are unknown, the law allows for substitute consent,[69] and where the wishes of the patient are known through their registered consent, it is the usual practice to ask the patient's substitute decision makers to confirm that consent was not subsequently withdrawn and to authorize the donation.[70] Thus, a procedure is in place regardless of whether the patient has indicated their wishes regarding organ donation. However, it seems preferable to ask all patients who request MAID through an advance request to specify their wishes regarding organ donation. This would promote patient autonomy and potentially reduce distress for families. Where the wishes of the patient are not captured in an advance request, the current practice of consent could be followed.

3. Sequence of decisions on MAID and organ donation

In order to avoid actual or perceived conflict of interest, it is advisable to create a strict separation between the clinical teams providing MAID and those removing organs for transplantation. Ontario law and Canadian practice guidelines for DCD already require that the teams determining death be separate from those who recover organs.[71]

Further, the decision regarding MAID should be taken prior to and independently of the decision to donate organs. This is crucial to avoid the perception that people are being persuaded to consent to MAID in order to obtain organs for transplant.[72] In the usual practice of DCD (i.e., not involving MAID), the decision to withdraw life-sustaining therapies is made prior to any decision regarding donation, in order to ensure that end-of-life decisions are not influenced by the possibility of obtaining organs for trans-

---

69 See *TGLNA*, *supra* note 20, s 5.

70 See Maeghan Toews & Timothy Caulfield, "Evaluating the 'Family Veto' of Consent for Organ Donation", online: (2016) 188:17–18 CMAJ E436 at E436 <www.cmaj.ca/content/188/17-18/E436>.

71 *TGLNA*, *supra* note 20, s 7. See Shemie et al, *supra* note 9 at S8–S9.

72 See Bollen et al, "Legal", *supra* note 16 at 489.

plantation. When families independently raise the possibility of donation before or during discussions about withdrawing life-sustaining therapies, the health care teams for end-of-life care and potential donation are careful to keep the decisions separate.

In the context of MAID, it is advisable that physicians reach a decision with the patient on MAID before any discussion of organ donation is broached, irrespective of whether the patient had earlier registered as an organ donor or not. This is a logical sequence of events that also ensures the focus remains solely upon the patient's interests. Additionally, it would help to assuage public concerns that the possibility of benefiting transplant recipients may encourage MAID. Should a patient independently raise the question of donation in anticipation of MAID, care must be taken to keep the discussions and decisions separate.

4. Should the option of organ donation be raised if the patient does not raise it?

Once a patient's request for MAID has been approved, should a health care team raise the possibility of organ donation? For now, the authors of this paper are divided on the best answer to this question. While some argue that a patient is entitled to know all of the reasonable medical possibilities in order to make a fully informed end-of-life decision, others feel that the request appears to seek benefit for others from a patient's death by MAID.

Bollen and colleagues warn that if a doctor raises the possibility of organ donation in this context, it may put pressure on the patient to consent to it.[73] However, they suggest that it would be acceptable to raise it if the patient were registered as an organ donor.[74] They also note that the promotion of patient autonomy and the possibility that the option to donate may provide comfort both justify raising the option of donation with patients who are not registered donors.[75] Others, however, may consider it inappropriate to raise this with patients who are suffering severely and who may feel pressured to consent or may feel others are seeking to benefit from their death.

---

[73] *Ibid* at 488.

[74] *Ibid*.

[75] *Ibid*.

In Ontario, designated hospitals are currently required to notify the organ donation organization (ODO) when a patient has died or death "is imminent by reason of injury or disease."[76] The ODO then applies screening criteria to determine whether to approach the patient's family regarding donation. The legislation does not address death by MAID and therefore it is unclear whether notification is required in these cases. Practice guidelines could direct hospitals to treat MAID similarly to death by injury or disease. This approach would recognize the opportunity to donate as a meaningful decision to be contemplated by the individual seeking MAID and would respect the individual's full autonomy in making that decision.

Alternatively, it may be argued that in dealing with a patient contemplating MAID, the sensitive judgment of the health care team should be the basis upon which the decision is made of whether or not to raise the topic of organ donation. This approach, while cautious, acknowledges the complexity and uncertainty experienced by health care teams as MAID is introduced in Canada, as well as the voices of those who fear individuals will be pressured too easily to seek MAID for reasons unrelated to their own suffering. During these early days of MAID in Canada, a discretionary approach might be reassuring and a firmer policy recommendation may be formed after experience with MAID increases. Conversely, there is a risk that once the habits of medical practitioners are formed in relation to these cases, it will be challenging to change practice to ensure ODOs are notified of cases of MAID.

5. The waiting period between cardiocirculatory arrest and the removal of organs

The Ontario statute governing transplants requires that death be determined "in accordance with accepted medical practice."[77] In DCD practice in Canada, after a patient experiences cardiac arrest, a no touch period (typically of five minutes) is observed, following which death is declared if the patient has no observable pulse or respiration.[78] The purpose of the waiting and observation period is to verify that death has indeed occurred, so an appropriate period should also be observed in cases of MAID. In MAID, death

---

[76] *TGLNA*, *supra* note 20, s 8.1(1).

[77] *Ibid*, s 7(1).

[78] See Serri & Marsolais, *supra* note 12 at 130; Shemie et al, *supra* note 9 at S6.

is brought about with a combination of drugs that make the death rapid and irreversible. In the usual DCD scenario, the timing of death is uncertain and may take longer.[79] This might suggest that shortening the waiting period is reasonable in the MAID context. However, there is a risk that any movement in this direction could harm public confidence in the donation system.[80] In Belgium and the Netherlands, death following MAID is determined by the same criteria used for any other organ donor and the usual observation period is respected.[81] This seems to be a wise approach, given the sensitivity of bringing organ donation together with the new and controversial practice of MAID.

6. Should recipients be informed that the donor died by MAID?

Another issue that may arise is whether recipients should be entitled to know that their donors died through MAID. The concern is that those who are strongly morally opposed to MAID would not wish to benefit from it, even at the potential cost of their own lives. Presently, only increased medical risks associated with a particular organ must be disclosed to recipients, such as an increased risk of contracting an infectious disease.[82] Medically irrelevant factors – that is, those that are unrelated to increased medical risk,

---

79 See Jeffrey Kirby, "Organ Donation after Assisted Death: Is It More or Less Ethically-Problematic than Donation after Circulatory Death?" (2016) 19:4 Med Health Care Philos 629 at 631–33.

80 See e.g. Tom Rawstorne, "How Doctors Want to Harvest Euthanasia Patients' Organs before They Die: Campaigners Warn of 'Deeply Worrying' Trend as Donors Feel Pressured to End Lives so Others Can Benefit through Their Deaths", *Daily Mail* (8 April 2016), online: <www.dailymail.co.uk/news/article-3530935/How-doctors-want-harvest-euthanasia-patients-organs-die-Campaigners-warn-deeply-worrying-trend-donors-feel-pressured-end-lives-benefit-deaths.html>.

81 See Van Raemdonck, *supra* note 16 at 41; Bollen et al, "Manual", *supra* note 15 at 1970.

82 See The CST/CNTRP Increased Risk Donor Working Group, "Guidance on the Use of Increased Infectious Risk Donors for Organ Transplantation" (2014) 98:4 Transplantation 365 at 367. This is also the approach followed in the US. See United States, Department of Health and Human Services, "Guidance for Donor and Recipient Information Sharing" (17 February 2012), online: Organ Procurement & Transplantation Network <https://optn.transplant.hrsa.gov/resources/guidance/guidance-for-donor-and-recipient-information-sharing>.

including race, religion, or manner of death – are not disclosed, since these factors will not impact the recipient's health and may disclose the donor's identity. Interestingly, Bollen and colleagues take the position that recipients should be able to refuse organs donated by patients who have died by MAID intervention.[83] It strikes us as unwise to make an exception to current Canadian practice of limiting disclosure to information related to increased medical risk. As there is no evidence that organs procured after an assisted death create any additional health risk for the recipient, it is unclear why information about MAID should be treated differently from other facts about donors that recipients may wish to know. For example, recipients may also have a moral objection to suicide (as opposed to MAID), but the fact that a donor died in this way is not currently disclosed.

7. Should patients seeking MAID be permitted to direct their donations to specific recipients?

If directed donation is permitted, a patient may seek MAID in order to donate to a specific person or group of people. Directed posthumous donation occurs when a donor directs their organs, post-mortem, to an identified recipient. While generally accepted in living donation, this is more controversial in posthumous donation as it is inconsistent with the principles of justice, equity, and medical utility, which drive the allocation of organs from deceased donors.[84]

The Canadian Medical Association policy on organ donation and transplantation contemplates directed posthumous donation in limited circumstances,[85] while Ontario permits it when the potential recipient is a family member or relative, or a close friend of the donor or donor family.[86]

---

83 "Manual", *supra* note 15 at 1969.

84 See Antonia J Cronin & James F Douglas, "Directed and Conditional Deceased Organ Donations: Laws and Misconceptions" (2010) 18:3 Med L Rev 275 at 276–77; Canadian Medical Association, "CMA Policy: Organ and Tissue Donation and Transplantation (Update 2014)", s 9, online: <https://www.cma.ca/Assets/assets-library/document/en/advocacy/PD14-08-e.pdf>.

85 *Supra* note 83, s 9.4.

86 See Ontario, Trillium Gift of Life Network, "Clinical Process Instruction Manual: Directed Donation Process Instruction" (2014) [unpublished, archived at TGLN].

Thus, directed donation may be possible in the case of organ donation following MAID if the current practices of living donation or posthumous donation are applied.

However, there is a risk that a conscious, competent adult seeking MAID may be influenced in making those decisions by the desire to help a sick family member or friend. While a directed donation may provide tremendous psychological comfort for a patient in these circumstances, the challenge is to balance the autonomy of patients eligible for MAID and wishing to end their lives earlier than necessary to save a family member or friend with the desire to protect vulnerable patients who may be induced to do so.[87] The psychological screening undertaken to determine eligibility for MAID should explore this possibility in these cases, as the *Act* requires that the request not be made "as the result of external pressure."[88]

8. Would the refusal to consider a medically suitable patient for donation after MAID contravene the patient's rights?

If a patient's request to be considered as an organ donor after MAID were refused for a reason connected to MAID, there is a possible argument that the refusal violates human rights legislation by denying the patient access to the psychological benefits of donation on discriminatory grounds related to disability. We do not develop this argument fully here in part due to space constraints and because this issue is speculative at this point in time. However, it is worth noting that multiple legal claims have been brought across Canada in which claimants have alleged that the refusal of their offer to donate blood constituted discrimination. The majority of these claims argued that the prohibition on donations by men who have had sex with men violates their right to be free of discrimination based on sexual orientation.[89]

To date, none of these claims have been successful. *Canadian Blood Services v Freeman* illustrates some of the complexities and challenges in

---

87 See Bollen et al, "Manual", *supra* note 15 at 1968.

88 *Supra* note 1, s 3, amending *Criminal Code*, *supra* note 24, s 241.2(1)(d).

89 See e.g. *Canadian Blood Services v Manitoba (Human Rights Commission)*, 2011 MBQB 312, 272 Man R (2d) 289; *Neudorf v Canadian Blood Services*, 2005 BCHRT 265, [2005] BCHRTD No 265 (QL).

successfully bringing a claim for discrimination.[90] The claimant argued that Canadian Blood Services' policy of refusing donations from men who have had sex with other men was discriminatory under the *Charter*.[91] The court held that Canadian Blood Services was not a government actor and therefore the *Charter* did not apply.[92] In *obiter*, the court went on to consider the substance of the claim, stating that donation in this context is a gift and not the provision of a service in which discrimination is prohibited by the *Charter*.[93] While the law remains underdeveloped on this point, the existing case law demonstrates that some who wish to donate perceive the refusal of their donation as a harm unjustifiably inflicted upon them.

The language adopted by the Canadian donation and transplantation community is consistent with the idea that denial of the opportunity to donate inflicts harm on a person. The national recommendations on DCD open with the statement that "as an important part of end-of-life care, patients who die should be provided the opportunity to donate organs and tissues."[94] Some Canadian health authorities and organ donation organizations also emphasize a "right" to make the choice to donate.[95] Although these statements are likely intended to encourage health care providers to support organ donation rather than to declare a legally enforceable right for donors, they point to a widely perceived sentiment that it is a benefit to donors and families to have the opportunity to donate.

While this issue remains unsettled, any policy maker proposing a policy to categorically refuse donations following MAID should consider and address the possibility that would-be donors might perceive the refusal as discriminatory.

---

90 2010 ONSC 4885, 217 CRR (2d) 153 [*Freeman*].

91 *Ibid* at para 224, citing *Charter*, *supra* note 31, s 15.

92 *Freeman*, *supra* note 89 at para 3.

93 *Ibid* at para 403.

94 Shemie et al, *supra* note 9 at S1.

95 See e.g. Transplant Manitoba, Gift of Life, "Planning for End-of-Life Decision Making", online: <www.transplantmanitoba.ca/news/read,article/32/planning-for-end-of-life-decision-making>; Saskatoon Health Region, Director for Saskatchewan Transplant Program, "Organ and Tissue Donor Referral Policy", Policy No 7311-60-031 (29 November 2013), online: <https://www.saskatoonhealthregion.ca/about/RWPolicies/7311-60-031.pdf>.

Conclusion and Recommendations

Canadians contemplating MAID are already requesting to donate solid organs and tissues. The issue of organ donation following MAID has been addressed in Belgium and the Netherlands; it would be wise for Canadian policy makers and health care providers to give thoughtful consideration to the combination of these sensitive procedures.

In *Carter*, the Supreme Court of Canada signalled the central importance of patient autonomy in Canadian law.[96] The Court also acknowledged the need to protect the vulnerable from being pressured into MAID, as well as the rights of physicians not to be compelled to provide MAID contrary to their consciences.[97] All of these interests must also be accommodated in determining whether and how organ donation should be incorporated into the practice of MAID as it develops in Canada. In order to ensure that MAID and organ donation are combined in an ethical manner, we propose the following recommendations:

1. Living donation of non-essential organs prior to MAID should be permitted where a competent and medically suitable patient wishes to do so;

2. Posthumous organ donation after MAID should be permitted for competent patients who are medically eligible;

3. If MAID is permitted pursuant to advance requests, posthumous organ donation should also be permitted where the desire to donate was specified within the advance request or where the patient had previously registered their consent to donate;

4. If MAID is permitted pursuant to advance requests and the patient's wishes regarding donation are unknown, current practice should be followed in allowing for substitute consent;

5. The topic of posthumous organ donation should not be raised until after the patient has provided informed consent to MAID;

6. Care should be taken to ensure patients feel free to change their minds about MAID, even after steps have been taken to prepare for organ donation following MAID;

---

96 *Supra* note 2 at paras 64–69.

97 *Ibid* at paras 99, 132.

7. The usual protocols and safeguards in the case of DCD should be applied following MAID, including (1) the separation of the teams involved (a) in bringing about and declaring death and (b) in removing organs and (2) the observation of the specified waiting period between asystole and removal of organs;

8. The fact that the donor died by MAID should be kept confidential and not shared with the organ recipient;

9. In the event that a policy prohibiting posthumous donation following MAID by otherwise medically suitable donors were to be adopted, the perception of discriminatory refusal should be considered and addressed;

10. MAID by removal of organs should not be permitted.

As Canada develops experience assisting patients through the process of MAID, organ donation organizations should collect information about the prevalence of organ donation in this context. In addition, it would be beneficial to conduct further research on the experiences of patients, families, and medical staff in order to more effectively guide policy development in this area.

Recognizing and Legitimizing the Transnational Scientific Governance of Human Gene Editing

*Liam W Harris**

The development of the CRISPR-Cas9 gene editing technique has provoked an international conversation regarding the regulation of human gene editing and the stewardship of humanity's genetic heritage. In the absence of coherent national regulation, non-legal actors at the transnational level may play a key role in regulating the ethical and biological risks raised by these advancements. However, the transnational governance of biotechnology is poorly understood. To further this understanding, the important role played by scientific organizations in transnational governance of these technologies must be examined in greater detail. While a growing literature has examined transnational governance processes and the role of science in these processes, the role of scientific organizations in the transnational governance of science itself has not yet been characterized in depth This paper seeks to understand the role of scientific organizations in the global regulation of scientific practice, by examining the role of the host organizations of the Inter-

Le développement de la technique d'édition génétique CRISPR-Cas9 a provoqué une conversation internationale sur la réglementation de l'édition des gènes humains et la sauvegarde du patrimoine génétique de l'humanité. Dans l'absence de réglementation nationale cohérente, les acteurs non juridiques au niveau transnational peuvent jouer un rôle important dans la réglementation des risques éthiques et biologiques soulevées par ces technologies. Cependant, la gouvernance transnationale de la biotechnologie n'est pas bien comprise. Pour approfondir cette compréhension, le rôle important joué par des organisations scientifiques dans la gouvernance transnationale de ces technologies doit être examiné. Une littérature croissante examine les processus de gouvernance transnationale et le rôle de la science dans ces processus, mais le rôle des organisations scientifiques dans la gouvernance transnationale de la science elle-même n'a pas encore été caractérisé en profondeur. Cet article cherche à comprendre le rôle des organisations scientifiques dans

---

* B.C.L./LL.B. Candidate, McGill University Faculty of Law; B.Sc. I wish to express my gratitude to Prof. Jaye Ellis who supervised this work and provided invaluable insight, as well as to the three anonymous reviewers for their very helpful comments.

Citation: Liam W Harris, "Recognizing and Legitimizing the Transnational Scientific Governance of Human Gene Editing" (2018) 11:2 McGill JL & Health 87.

Référence : Liam W Harris, « Recognizing and Legitimizing the Transnational Scientific Governance of Human Gene Editing » (2018) 11 : 2 RD & santé McGill 87.

national Summit on Human Gene Editing in the regulation of gene editing in humans. This paper argues that the host organizations are in a better position to regulate these technologies than formal legal actors due to the dynamic, transnational, and technical nature of this regulatory task. In addition, this paper examines the inherent legitimacy challenges faced by the host organizations and highlights strengthened discourse between scientific organizations and the public with regards to their policy role as a possible solution.

la réglementation globale de la pratique scientifique en examinant le rôle des organisations hôtes du *International Summit on Human Gene Editing* dans la réglementation de l'édition des gènes humains. Cet article fait valoir que les organisations hôtes sont mieux placées pour réglementer ces technologies que les acteurs étatiques en raison de la nature dynamique, transnationale et technique de cette tâche. En outre, cet article examine les défis de légitimité rencontrés par les organisations hôtes et suggère le renforcement du discours entre les organisations scientifiques et le public concernant leur rôle juridique comme solution.

Introduction

The development and widespread adoption of the CRISPR-Cas9 technique has reinvigorated the international conversation concerning human gene editing. CRISPR[1] allows scientists to manipulate the genome with unprecedented ease and precision, and its low cost and relative simplicity have made it a fixture in laboratories worldwide.[2] There is significant hope that this development will not only fuel better understandings of basic biology but will also lead to a revolution in genetic medicine. However, the power CRISPR offers to edit the genome is accompanied by significant risks, notably the prospect that the genetic makeup of the human species could be altered through inheritable genetic changes.[3] Given its significant potential benefits and risks, CRISPR has revived policy debates about the acceptable limits of scientific research and how to manage humanity's genetic heritage.

This most recent policy challenge builds on previous debates regarding the scientific manipulation of life. Stem cell, cloning, and assisted reproductive technologies have generated significant controversy in preceding decades, leading to the adoption of policies at the national and international levels to manage risks and ethical concerns while minimizing impediments to scientific discovery.[4] The legacy of these debates is a patchwork of highly divergent national laws,[5] coupled with vague and toothless instruments at the international level.[6] The development of CRISPR has revealed that the area of gene editing regulation is characterized by inconsistency and uncertainty.

---

1 In the interests of brevity, the term CRISPR will be used in place of the CRISPR-Cas9 technique. CRISPR refers to the family of DNA sequences used in the technique that, in conjunction with the Cas9 enzyme, can be used to edit genomes.

2 See Jennifer A Doudna & Emmanuelle Charpentier, "The New Frontier of Genome Engineering with CRISPR-Cas9" (2014) 346:6213 Science 1258096 at 1258096-1.

3 See Edward Lanphier et al, "Don't Edit the Human Germ Line" (2015) 519 Nature 410 at 410.

4 See e.g. Heidi Ledford, "The Landscape for Human Genome Editing" (2015) 526 Nature 310 at 311.

5 See *ibid* at 310.

6 See e.g. Carol A Tauer, "International Policy Failures: Cloning and Stem-Cell Research" (2004) 346 Lancet 209 at 210.

It was in the context of this regulatory uncertainty that the leading scientific bodies from the United States, the United Kingdom, and China convened the International Summit on Human Gene Editing (Summit). It brought together hundreds of thinkers from various disciplines to discuss the appropriate uses of CRISPR. The Organizing Committee's conclusions call for a ban on some clinical applications of the technique while approving its relatively unfettered use in basic scientific applications.[7] In addition, an ongoing process set up by the hosts of the Summit (hereafter, collectively referred to as the ISHGE) aims to monitor the technology's development and construct a more detailed guidance framework.[8]

The ISHGE process raises questions about the role of networks of non-state actors in the governance of transnational issues. There is increasing recognition that focusing on states to the exclusion of non-state actors leads to an incomplete understanding of regulation at the international level. National systems of law are complemented by processes occurring across borders, which shape people's behaviour and can therefore be characterized as modes of transnational governance. A growing literature seeks to characterize the role of non-state actors in transnational governance and to examine the consequences of this role on the legitimacy and democratic processes of the governance system.[9] This literature originated in and has largely focused on the regulation of the global economic system. While the role of science in transnational governance processes has been studied in depth, especially in the context of environmental issues, the role of scientific organizations in the transnational governance of science itself is poorly understood.

---

7 Steven Olson, *International Summit on Human Gene Editing: A Global Discussion; Meeting in Brief, 2015* (Washington, DC: National Academies Press, 2016) at 6–7; Andrew R LaBarbera, "Proceedings of the International Summit on Human Gene Editing: A Global Discussion – Washington, D.C., December 1–3, 2015" (2016) 33 J Assist Reprod Genet 1123 at 1126.

8 Olson, *supra* note 7 at 7.

9 See e.g. Alan Brouder, "Introduction" in Christian Tietje & Alan Brouder, eds, *Handbook of Transnational Economic Governance Regimes* (Leiden: Martinus Nijhoff Publishers, 2009) 1 at 5–6; Paul Wapner, "Politics Beyond the State: Environmental Activism and World Civic Politics" (1995) 47:3 World Politics 311; Gregory H Fox & Brad R Roth, eds, *Democratic Governance and International Law* (New York: Cambridge University Press, 2000); Marie-Laure Djelic & Kerstin Sahlin-Andersson, eds, *Transnational Governance: Institutional Dynamics of Regulation* (New York: Cambridge University Press, 2006).

This paper uses the ISHGE process and the regulation of CRISPR gene editing technology as a case study for determining the potential role of transnational scientific networks in the governance of science. This paper also asks how these processes could be optimized, with the goal of more legitimate scientific regulation. I argue that the ISHGE has the potential to play a key role in the regulation of emerging gene editing technology where state-based regulation may be relatively ill-suited. I further argue that the ISHGE, as a private governance actor, faces inherent legitimacy challenges that could be addressed by drawing on the principles of Open Science. Overall, the aim of this paper is to present a framework for understanding transnational scientific governance by examining the significant contemporary regulatory challenge posed by CRISPR.

In Part I, I provide background on the regulatory challenge posed by CRISPR and the details of the ISHGE process. In Part II, I draw on the transnational economic governance literature and the metaphor of regulatory space to conceptualize the challenge of regulating gene editing on a global scale. In Part III, I characterize the ISHGE as a regulatory actor, assess its sources of power, and illustrate how it leverages these resources to affect regulatory outcomes. In Part IV, I survey literature on the legitimacy of non-state governance to assess challenges to the ISHGE's legitimacy and the sources of legitimacy upon which the ISHGE may draw. Finally, in Part V, I consider the relative merits of different mechanisms by which the ISHGE and future transnational scientific governance processes could enhance their legitimacy.

I. Background on CRISPR-Cas9 and the Subsequent International Response

A. CRISPR-Cas9 and the renewed debate on gene editing

Despite deep understanding of the molecular mechanisms of genetics, scientists have struggled to find a way to easily and reliably effect precise point modifications to the genetic code.[10] The power to modify the genome in this way holds immense promise for understanding biological processes, engineering plant and animal species, and developing treatments for genetic diseases.[11]

---

[10] See Doudna & Charpentier, *supra* note 2 at 1258096-5 to 1258096-6.

[11] See *ibid* at 1258096-6.

The CRISPR technique represents a massive improvement over previous gene editing techniques and provides a heightened level of precision and simplicity.[12] The technique is based on a bacterial defence system against viral infection that was first described in 2007.[13] CRISPRs – short pieces of repeating DNA punctuated by sequences obtained from previous viral infections – are transcribed and form complexes with the Cas9 enzyme that cut the foreign DNA at precise locations defined by the DNA sequence of the CRISPR.[14] By combining knowledge of this technique with new understandings of the gene editing potential of transcription activator-like effector nucleases (TALENs), scientists were able to identify the gene editing potential of CRISPR in 2012.[15] By January 2013, at least two separate teams of scientists from Harvard and Massachusetts Institute of Technology had carried out gene modification in cells, including human cells.[16] This discovery stimulated the widespread adoption of the technique, along with a huge volume of study on its applications. Despite some remaining practical challenges, scientists are hopeful that this technique or a related approach to gene editing will revolutionize scientific fields involving genetics, from cell and molecular biology to medicine.[17]

Rumours in early 2015 that a Chinese team from Guangzhou had modified the genome of human zygotes sparked intense debates among scientists and attracted widespread public attention to the technique.[18] The experiment

---

12 See *ibid* at 1258096-5 to 1258096-6.

13 See Rodolphe Barrangou et al, "CRISPR Provides Acquired Resistance Against Viruses in Prokaryotes" (2007) 315 Science 1709 at 1709.

14 See Doudna & Charpentier, *supra* note 2 at 1258096-1 to 1258096-3.

15 See Martin Jinek et al, "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity" (2012) 337 Science 816 at 816.

16 See Le Cong et al, "Multiplex Genome Engineering Using CRISPR/Cas Systems" (2013) 339:6121 Science 819 at 819; Martin Jinek et al, "RNA-Programmed Genome Editing in Human Cells", online: (2013) 2 eLife e00471 at 1 <https://elifesciences.org/articles/00471>; Prashant Mali et al, "RNA-Guided Human Genome Engineering via Cas9" (2013) 339:6121 Science 823 at 823.

17 See e.g. Olson, *supra* note 7 at 1.

18 See Jocelyn Kaiser & Dennis Normile, "Chinese Paper on Embryo Engineering Splits Scientific Community", *Science* (24 April 2015), online: <www.sciencemag.org/news/2015/04/chinese-paper-embryo-engineering-splits-scientific-community>.

was confirmed in an April 2015 publication[19] and, despite designing the study in such a way as to minimize the ethical implications,[20] it generated significant controversy.[21]

The CRISPR technique has the potential to greatly advance our understanding of cellular and developmental processes in humans, which could lead to the treatment of certain diseases. For example, editing the genetic information in a person's cells could alter the receptors that allow the progression of HIV.[22] It could also in theory remove mutations that cause genetic diseases like sickle cell anemia, immune disorders, or cancer.[23] This could be carried out by simply modifying the affected cells ofthe human body.

More controversial is the use of CRISPR for modifying the DNA sequences in germ cells that form human sperm and eggs, thereby affecting the genetics of future generations. In theory, this could completely and permanently remove genes that predispose humans to disease and infertility.[24] In the more distant future, the technique could be applied to enhance human traits; for example, it could be used to make humans more tolerant of certain environments, increase the robustness of the human body, or increase brain function.[25] Germ cell applications are most controversial because they would result in a change to the pool of human genetic information, thereby altering the course of our evolution as a species.[26]

Ethical objections to gene editing range widely. Those who see the modification of natural human reproductive processes as inherently wrong

---

19 Puping Liang et al, "CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes" (2015) 6:5 Protein Cell 363.

20 *Ibid* at 364 (specifically, the authors point out that they use tripronuclear zygotes instead of viable embryos and conclude that clinical applications at this stage would be premature).

21 See e.g. Christopher Scott, "Treading the Line Between Sensational and Groundbreaking Science" (2015) 15:12 Am J Bioeth 1 at 1.

22 See Olson, *supra* note 7 at 2.

23 See *ibid*.

24 See *ibid*.

25 See *ibid*.

26 See Lanphier et al, *supra* note 3 at 410.

categorically oppose germ line editing,[27] echoing concerns expressed in the debates around abortion and artificial reproductive technologies regarding the moral status of the human embryo. Others fear that gene editing technology will exacerbate social inequality.[28] The spectre of eugenics is raised by those who see gene editing as setting us on course to permanently eliminating undesirable features from the human species through the phenomenon of "designer babies."[29] Further, some feel that not enough is known about the technique to proceed without risking significant harm to individuals and the public.[30] Conversely, the strongest proponents argue that the potential to move beyond Darwinian modes of evolution offers considerable benefits, especially as we currently confront the consequences of an increasingly fragile environmental system.[31] Like preceding issues such as stem cell and assisted reproductive technologies, gene editing presents a significant regulatory challenge in balancing uncertain risks and rewards in an area currently devoid of precise legal regulation.

---

27 See e.g. Olson, *supra* note 7 at 4 (contribution of Hille Haker); CBC Radio, The 180 with Jim Brown, "Debating the Ethics of Gene Editing" (6 December 2015), online: <www.cbc.ca/radio/the180/gene-editing-debating-the-usefulness-of-sci-fi-analogies-and-does-more-parental-leave-actually-help-women-1.3351174/debating-the-ethics-of-gene-editing-1.3351261> (position of Margaret Somerville). See also Julian Salvescu, "Gene Editing: A CBC Interview of Margaret Somerville and Julian Salvescu" (7 December 2015), *Practical Ethics* (blog), online: <blog.practicalethics.ox.ac.uk/2015/12/gene-editing-a-cbc-interview-of-margaret-somerville-and-julian-savulescu>.

28 See e.g. *ibid* (contribution of Ruha Benjamin, Françoise Baylis, and Catherine Bliss).

29 Daniel J Kevles, "If You Could Design Your Baby's Genes, Would You?", *Politico* (9 December 2015), online: <www.politico.com/magazine/story/2015/12/crispr-gene-editing-213425>; David King "Editing the Human Genome Brings Us One Step Closer to Consumer Eugenics", Opinion, *The Guardian* (4 August 2017), online: <www.theguardian.com/commentisfree/2017/aug/04/editing-human-genome-consumer-eugenics-designer-babies>.

30 See e.g. Olson, *supra* note 7 at 4 (contribution of Hille Haker).

31 See e.g. *ibid* (contribution of John Harris); John Harris, "Why Human Gene Editing Must Not Be Stopped", *The Guardian* (2 December 2015), online: <www.theguardian.com/science/2015/dec/02/why-human-gene-editing-must-not-be-stopped>.

B. The International Summit on Human Gene Editing

It was in the context of proliferating ethical concern generated by the Chinese human embryo study that the United States National Academy of Sciences and National Academy of Medicine (US National Academies), the United Kingdom-based Royal Society, and the Chinese Academy of Sciences convened the Summit in December of 2015. The aim of the Summit was to begin a conversation about the "scientific, ethical, legal, social, and governance issues" associated with the use of gene editing in humans.[32] Attendees and presenters spanned disciplines and offered a range of perspectives.[33] The Summit itself was video-recorded and broadcast live over the Internet; these videos have now been archived to enhance transparency.[34] Though previous meetings had been held to address the ethical challenges posed by CRISPR,[35] the Summit was unique in that it was hosted by a transnational network of professional organizations and in its unprecedented size and scope.

The Summit was a transnational extension of efforts already undertaken by the US National Academies and other national academies to study and inform lawmakers and the public about human gene editing. The mandate of the US National Academies, a private non-profit organization, is to advise the American government and the public on pressing policy developments in science and medicine.[36] The Royal Society plays an analogous role in the

---

[32] Olson, *supra* note 7 at 1.

[33] See generally LaBarbera, *supra* note 7.

[34] The National Academies of Sciences, Engineering and Medicine, "International Summit on Gene Editing", online: <www.nationalacademies.org/gene-editing/Gene-Edit-Summit> [National Academies, "Summit"].

[35] See e.g. The Netherlands Commission on Genetic Modification, *Symposium Genome on Demand in Retrospect*, (2015), online: <www.cogem.net/index.cfm/en/news/item/symposium-genome-on-demand-in-retrospect>; United Nations Educational, Scientific and Cultural Organization, Press Release, "UNESCO Panel of Experts Calls for Ban on 'Editing' of Human DNA to Avoid Unethical Tampering with Hereditary Traits" (5 October 2015), online: <https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits>.

[36] The National Academies of Sciences Engineering and Medicine, "Who We Are" (2017), online: <www.nationalacademies.org/about/whoweare/index.html> [National Academies, "Who We Are"].

UK and the Commonwealth.[37] Though the Chinese Academy of Sciences fulfills a similar role in the People's Republic, it is not a private entity but rather an arm of the Chinese government and reports to the State Council.[38] The ISHGE represents the latest effort of these organizations to move beyond their national mandates and address scientific issues at the transnational level.

The Summit itself was organized and overseen by the Organizing Committee, appointed by the host organizations. The Organizing Committee was made up of twelve scientists: six from the United States, two from each of the United Kingdom and China, and one from each of Canada and Germany.[39] At the close of the Summit, the Organizing Committee delivered a consensus statement of four conclusions that were endorsed by the presidents of the hosting academies.[40] First, basic preclinical research should proceed relatively unhindered in order to learn more about the technique and its applications, including experimentation on human embryos and germ line modifications. Second, clinical uses of gene editing on somatic (non-germ line) cells should be allowed, since the risks involve only the individual being treated and can therefore be evaluated through existing systems. Third, clinical use of germ line editing should not proceed until the risks are better understood, there is broader societal consensus on its appropriateness, and regulation is in place to oversee developments. Finally, in recognizing the transnational nature of the problem, the Organizing Committee called upon the organizing academies to create an ongoing international body to study the issue further and promote transnational coordination.

In response to the need for more in-depth engagement and recommendations, a 22-member Expert Committee with representatives

---

37 See The Royal Society, "History of the Royal Society", online: <https://royalsociety.org/about-us/history> [Royal Society, "History"].

38 See Chinese Academy of Sciences, "Introduction" (1 March 2016), online: <english.cas.cn/about_us/introduction>; People's Republic of China, "State Council Organization", online: <english.gov.cn/state_council/2014/09/03/content_281474985533579.htm>.

39 See The National Academies of Sciences, Engineering, and Medicine, "International Summit on Human Gene Editing: Statement of Task and Planning Committee", online: <www.nationalacademies.org/gene-editing/gene_167925> [National Academies, "Statement"].

40 Olson, *supra* note 7 at 6–8; LaBarbera, *supra* note 7 at 1126–27.

from eight countries was formed to undertake consultations and author a report.[41]

C. Subsequent events

Meanwhile, research into CRISPR continues at a furious pace. In the months immediately following the Summit, two experiments involving embryonic gene editing received approval. On 14 January 2016, the lab of Dr. Kathy Niakan received approval from the Human Fertilisation and Embryology Authority (HFEA), the UK's regulator of research involving human embryos, to modify human embryos using CRISPR.[42] In approving the study proposal, the HFEA noted the desirable insights to be gained into the development of human embryos and the potential application in treating genetic disease.[43] In the spring of 2015, Fredrik Lanner received institutional review board approval at the Karolinska Institute for a similar project that had already been approved by the Swedish Regional Ethics Board.[44] Meanwhile, another Chinese study in Guangzhou introduced gene edits in non-viable embryos,[45] and in March 2017, a separate team published the first study using CRIPSR in viable human embryos.[46] Interestingly, these studies attracted much less controversy than Liang et al. had in 2015, signal-

---

41 Committee on Human Gene Editing: Science, Medical, and Ethical Considerations, *Human Genome Editing: Science, Ethics, and Governance* (Washington, DC: The National Academies Press, 2017) [Expert Committee].

42 Human Fertilisation & Embryology Authority, *Application for Research License Renewal for Research Project R0162*, License Committee Minutes (14 January 2016), online: Bioetica Web <https://www.bioeticaweb.com/wp-content/uploads/2016/03/33980_ReinoUnido-HFEA_Licence-14012016.pdf>.

43 *Ibid* at 5.

44 See Paul Knoepfler, "Interview with Fredrik Lanner Who Is CRISPR'ing Healthy Human Embryos" (26 September 2016), *The Niche* (blog), online: <https://ipscell.com/2016/09/interview-with-fredrik-lanner-who-is-crispring-healthy-human-embryos>.

45 Xiangjin Kang et al, "Introducing Precise Genetic Modifications into Human 3PN Embryos by CRISPR/Cas-Mediated Genome Editing" (2016) 33:5 J Assist Reprod Genet 581.

46 Lichun Tang et al, "CRISPR/Cas9-Mediated Gene Editing in Human Zygotes Using Cas9 Protein" (2017) 292:3 Mol Genet Genomics 525 at 1.

ling a potential change in attitudes regarding the basic research applications of heritable gene edits following the Summit.

In February 2017, the Expert Committee formed at the close of the Summit released a 200-page report that restated the key conclusions from the event.[47] The report arguably goes even further than the conclusions of the Organizing Committee in stating that clinical application of germ line editing can proceed subject to the restrictions that (1) the research is for a compelling purpose of treating disease and (2) there is stringent oversight in place, among other safeguards.[48] Overall, it seems that the use of human gene editing to treat disease has, at least within the scientific community, become more plausible and more widely accepted since the Summit.

II. Conceptualizing the Regulatory Space

The aim of this Part is to conceptualize the unique challenge posed by the governance of emerging gene editing technology such as CRISPR. First, I will introduce the metaphor of regulatory space from economic governance literature as a conceptual aid to understanding transnational regulation outside the state. I will then consider the particularities of emerging gene editing technology as a regulatory challenge and how this affects the dynamics of the regulatory space. In the final Sub-Parts, I ask how formal legal actors can be expected to act within the defined regulatory space, with reference to the current paucity of regulation in this area. I conclude that state governance structures are poorly situated to regulate emerging gene editing technology, leaving space for informal regulatory actors to wield disproportionate influence.

A. The regulatory space metaphor

Regulation involves the design, implementation, and enforcement of rules through which we organize ourselves as a society.[49] Historically, our thinking about regulation has been focused on the legal rules created by

---

47 *Supra* note 41.

48 *Ibid* at 134–35.

49 See L Hancher & M Moran, "Organizing Regulatory Space" in Robert Baldwin, Colin Scott & Christopher Hood, eds, *A Reader on Regulation* (New York: Oxford University Press, 1998) 148 at 148.

states to tackle problems of public concern, with legislative governance among the most apparent forms of social regulation.[50] In recent years, however, it has become increasingly apparent that formal law is but one of many ways behaviour is regulated within a society. Early work framed the regulatory influence of private institutions as an inherently illegitimate "capture" of the regulatory process.[51] However, institutionalist theories of law have emphasized the blurring of "boundaries between voluntary and mandatory regulations, state and non-state regulations, private and public law, and hard and soft law."[52] Especially in a transnational sphere characterized by an absence of centralized authority, these boundaries become more porous and less important for understanding regulation.

The metaphor of regulatory space, developed as an analytical tool by Hancher and Moran in the context of economic regulation, is useful for understanding the morass of transnational regulation.[53] A regulatory space is defined "by the range of regulatory issues subject to public decision" and is occupied by a wide range of competing regulatory actors.[54] The boundaries of a regulatory space are defined by the particular regulated subject matter at issue and within these different spaces the distribution of resources used by actors to compete with each other varies.[55] Importantly, these actors include not just formal legal actors, but also various sources of authority outside of formal legal structures.[56] Ultimately, the metaphor of regulatory space prompts us to reflect on a power struggle between various actors, both public and private, to "occupy" a space defined by the particular set of regulatory issues and the resources that fuel this struggle.

Key to this model is the idea that actors within a regulatory space possess unequal levels of power due to the uneven distribution of regulatory

---

50 See *ibid* at 150.

51 *Ibid*.

52 Brouder, *supra* note 9 at 19, citing David Vogel, "Private Global Business Regulation" (2008) 11 Annual Rev Political Science 261 at 265.

53 *Supra* note 49.

54 *Ibid* at 153, citing C Crouch, "Sharing Public Space: States and Organised Interests in Western Europe" in J Hall, ed, *States in History* (Oxford: Basil Blackwell, 1986) 177 at 180.

55 See Hancher & Moran, *supra* note 49 at 154–55.

56 See *ibid* at 152.

resources. Scott has identified four key resources: (1) formal legal authority, (2) possession and control of information, (3) possession of wealth, and (4) organizational capacities.[57] Others have added to this list in the context of particular regulatory issues. Of note is work done by Gibbons on the regulation of biobanks, another biomedical regulatory dilemma. She identified (5) the ability to effectively and authoritatively communicate preferences and (6) control over professional education and culture as important resources in this context.[58] These six resources will inform the assessment of the regulatory capacities of formal legal actors later in this Part, as well as the characterization of the ISHGE as a regulatory actor in Part III.

Applying the regulatory space metaphor to emerging gene editing technology requires integrating an additional factor into the model: time. The case of CRISPR demonstrates how scientific innovations can blindside regulators with issues which were previously invisible or non-existent. This mirrors Hancher and Moran's discussion of crisis as a force which induces change in the structure of regulatory space.[59] At the leading edge of technological development, actors are not only competing over known regulatory territory; they must also undertake an occupation of the newly revealed space. Significant understanding of the regulatory space for emerging gene editing technology will be lost if we ignore temporal dynamics.

Here, regulatory space will be deployed as an analytical aid in defining the particularities of the regulatory issue of interest. It will also serve to better understand and contrast formal legal and scientific governance actors and their respective role in this space.

B. Particularizing the regulatory space

The regulatory space identified here encompasses the regulation of emerging gene editing technology in humans. This regulation is targeted primarily at scientists, as they possess the knowledge and capabilities to use

---

57 Colin Scott, "Analysing Regulatory Space: Fragmented Resources and Institutional Design" [Summer 2001] Public L 283.

58 Susan MC Gibbons, "Mapping the Regulatory Space" in Jane Kaye et al, eds, *Governing Biobanks: Understanding the Interplay Between Law and Practice* (Portland: Hart Publishing, 2012) 51 at 83, 89.

59 *Supra* note 49 at 160.

and improve existing techniques, as well as to develop new techniques. It is also targeted at clinicians who may potentially practice human gene editing in a clinical setting. While CRISPR is the focus of this paper, the term gene editing technology encompasses superior techniques that will likely emerge in the coming years. It also reflects the international conversation on this issue, which has so far been dominated by the wider question of gene editing technologies.[60]

There are three major particularities about the regulation of gene editing technology. First, as a scientific practice, it is largely a deterritorialized issue. Science has long been a field where national boundaries mean little. As Jarvie points out, the authority of science is not bounded by national jurisdiction; scientists are by and large working towards the same purportedly universal truth no matter their country of origin.[61] Scientists routinely collaborate transnationally[62] and scientific practices and knowledge are disseminated through journals that circulate around the world. For the purposes of regulating science then, national boundaries are of reduced importance.

When looking specifically at gene editing technology, the risks and benefits involved cannot be limited to a specific national entity; rather, they will be diffused globally. Modifications made in one country would clearly spread around the world in an era where transnational movement is rapid and inexpensive, making patchworks of national legislation ineffective.[63] Uneven bans on reproductive technologies in the past have resulted in the phenomenon of "reproductive tourism," where individuals travel abroad to undergo therapies that are banned in their own country.[64] Furthermore, the

---

60 See e.g. Olson, *supra* note 7.

61 Ian Jarvie, "Science in a Democratic Republic" (2001) 68:4 Philosophy Science 545 at 560, 563.

62 See Diane Stone, *Knowledge Actors and Transnational Governance: The Private-Public Policy Nexus in the Global Agora* (Basingstoke, UK: Palgrave Macmillan, 2013) at 43–45.

63 See Noëlle Lenoir, "Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level" (1998) 30 Colum HRLR 537 at 541.

64 Debora Spar, "Reproductive Tourism and the Regulatory Map" (2005) 352:6 N Engl J Med 531 at 533.

human genome is widely seen as the common heritage of humanity; everyone has a stake in its stewardship regardless of nationality.[65] Regulation in specific territorialized subsections of the regulatory space are therefore likely to be ineffective at protecting this shared heritage.

Second, this regulatory space is fraught with uncertainty and a paucity of information. Our understanding of genetics and genomics has evolved rapidly in the sixty years since DNA was identified as the molecule carrying genetic information between generations. While the discovery of CRISPR has opened up a new avenue for scientific advancement, it also brings a new shadow of uncertainty and risk.[66] Regulating complex risk requires that a great deal of information be gathered and examined through an expert lens.[67] For example, the regulation of the risks associated with climate change involved a global process to evaluate and scrutinize evidence through the International Panel on Climate Change (IPCC).[68] In such settings, control over information – one of Scott's four key resources – is of prime importance, since those who can claim to better understand the risk can make more authoritative pronouncements about the direction regulation should take.[69] Additionally, without sufficient information and expertise, it becomes impossible to tell whether scientists are actually complying with imposed regulations.

Third, the regulatory space for emerging gene editing technologies is inherently dynamic. As described above, game-changing scientific discoveries like CRISPR arise without warning and alter the regulatory landscape, forcing actors to react. Actors who possess speed and flexibility in adapting to changes in the regulatory space may therefore be best suited to regulating at the leading edge of technological development.

---

65 See *Universal Declaration on the Human Genome and Human Rights*, UNESCO General Conference, 11 November 1997, art 1 (endorsed by GA Res 152, UNGAOR, 53rd Sess, UN Doc A/53/625/Add 2 (1998)) [*UDHGHR*].

66 See Olson, *supra* note 7 at 6.

67 See Jacqueline Peel, *Science and Risk Regulation in International Law* (New York: Cambridge University Press, 2010) at 3–4.

68 See *ibid* at 321.

69 *Supra* note 57 at 285.

C. The place of law

Having particularized the regulatory space, I now consider the actors who may populate it. It is particularly useful to consider what role formal legal actors will play in the regulation of emerging gene editing technologies before moving on to consider the role of the ISHGE as an informal governance actor. For our purposes, formal legal actors include the three branches of the state: the executive, legislators, and judiciary, as well as their formally delegated agents.

Actors who wield the formal legal authority of states hold several obvious advantages, both practical and normative, within regulatory space. In the practical sense, modern states are usually highly organized entities that are capable of enforcing rules by means of physical force within their defined territory. In the normative sense, the exercise of this force is legitimized by the concept of sovereignty and the historical dominance of states, which has entrenched them as the "presumed locus of all regulatory power and activity."[70] These unique qualities make it possible for legal actors to wield considerable regulatory influence, exemplified by the fact that they alone hold the first in Scott's list of key resources: formal legal authority.[71]

It is important not to fall into the trap of equating this influence with unlimited power to exclude other regulatory actors. Informal actors can still wield greater influence where formal legal actors are unable or unwilling to regulate over a particular issue due to the nature of the regulatory space.[72] For example, formal legal actors may lack awareness of the issue to be regulated or may not prioritize it. The law may not be sufficiently precise to completely cover the field, so regulation from informal actors may fill in the neglected space. Alternatively, the gaps in overly detailed regulation can be revealed when technologies change and outgrow the precisely targeted language. In other cases, covert non-compliance with formal legal rules by the targets of the regulation may allow informal actors to exclude states from regulatory space.[73] I argue that the nature of the regulatory space

---

70 Gibbons, *supra* note 58 at 56.

71 *Supra* note 57 at 6.

72 See Gibbons, *supra* note 58 at 80, 83, 90.

73 See Martin Herberg, "Bringing Professions Back In: A Fresh Look at the Dynamics of Institution-Building in (World) Society" in Christian Joerges & Josef

under consideration here is one in which formal legal actors are particularly maladapted.

First, formal legal actors are generally ineffective at tackling transnational problems. Since legal authority flows from states with defined territorial boundaries, this authority is inherently tied to specific geographic space. The ability of states to exercise jurisdiction beyond their borders has been the topic of considerable discussion, but it seems clear that even the most powerful states cannot make legitimate claims to legislate activity that occurs on the sovereign territory of another, in all but the narrowest of circumstances involving human rights violations.[74] States could be considered to informally influence the practice of science outside their borders by attaching conditions to funding of extraterritorial research but, in reality, this form of control is only available to the wealthiest states, like the United States. Furthermore, the failure of states and state-based international organizations to comprehensively address transnational issues, whether they be economic or environmental, is well documented.[75] As discussed above, the challenges posed by gene editing technology are inherently transnational. A state's ability to regulate only within a defined territory therefore weakens its ability to cover the regulatory space.

Second, states possess inadequate information and expertise about emerging scientific issues. As explored above, control over information is a key regulatory resource, especially in the context of the high risk and uncertainty that accompanies gene editing. While states may generally have the wealth and capacity to gather information, legal decision makers rarely have the kind of technical expertise to foresee and address regulatory dilemmas, relying instead on independent bodies of experts.[76] Legal actors often rely on the opinions of experts in making their decisions but the process of translating scientific discourse for a policy audience is riddled with difficulties.

Falke, eds, *Karl Polanyi, Globalization and the Potential of Law in Transnational Markets* (Oxford: Hart Publishing, 2011) 107 at 115.

74 See e.g. *R v Hape*, 2007 SCC 26 at paras 66–69, [2007] 2 SCR 292; Anthony J Colangelo, "A Unified Approach to Extraterritoriality" (2011) 97:5 Va L Rev 1019 at 1025.

75 See e.g. Olaf Dilling, "Enclosed Solutions for Common Problems?: Uncertainty, Precaution and Collective Learning in Environmental Law" in Joerges & Falke, *supra* note 73, 131 at 152; Brouder, *supra* note 9 at 2.

76 See Peel, *supra* note 67 at 51.

While organizations like the IPCC demonstrate the ability of intergovernmental institutions to amass and interpret large quantities of information, the translation challenges make this a costly and time-consuming process.[77] States, with finite resources, must prioritize the issues of which they wish to be informed. Staying abreast of the kind of "blue sky" research from which CRISPR emerged is unlikely to be a priority.

Finally, formal legal institutions struggle to adapt quickly to changing regulatory landscapes. Lawmaking is a process which takes significant time. For public administrative bodies, rule making is prolonged by procedural requirements, bureaucratic elements, and political influence.[78] Legal pronouncements from courts only occur once the right case is litigated, which can take years. In both cases, political actors must be sufficiently informed in order to take decisive regulatory action but, as considered above, the necessary information gathering, interpretation, and translation processes require significant time. The result is significant incongruence between the law and the state of science. Incongruence can take the form of loopholes in permissive regulation that renders it ineffective against new technology or the unintentional application of overly prophylactic restrictions on emerging technologies.[79] In both cases, the law is maladapted to the technological landscape.

The notion that law lags behind technological and scientific development has been much discussed. Ogburn argued that the cultural institutions of law and science develop at uneven paces, such that the former will always lag behind the latter.[80] This has been attributed not only to the practical

---

77 See Peel, *supra* note 67 at 335–36. The IPCC is an intergovernmental organization endorsed by the United Nations General Assembly to produce reports on climate change. The IPCC Panel is made up of government and organizational appointees, usually with expertise relevant to its mandate, who summarize peer-reviewed scientific literature carried out outside the IPCC.

78 See Cornelius M Kerwin & Scott R Furlong, "Time and Rulemaking: An Empirical Test of Theory" (1992) 2:2 J Public Administration Research & Theory 113 at 116.

79 See generally Peter J Rugg-Gunn et al, "The Challenge of Regulating Rapidly Changing Science: Stem Cell Legislation in Canada" (2009) 4:4 Cell Stem Cell 285 at 287–88; Gary E Marchant & Douglas J Sylvester, "Transnational Models for Regulation of Nanotechnology" (2006) 34:4 J Law Med Ethics 714 at 715.

80 See Sheila Jasanoff, "Making Order: Law and Science in Action" in Edward J Hackett et al, eds, *The Handbook of Science and Technology Studies*, 3rd

constraints mentioned above but also to the fact that law is culturally geared towards looking back to judicial precedents and enacted rules, while science is designed to overwrite its previous conclusions when challenged by new information in a continuous cycle of innovation and discovery.[81]

Though the notion that law generally lags behind scientific developments is widely accepted in legal literature, emerging work challenges the simplicity of this proposition. Sheila Jasanoff points out that, through the concept of co-production, law does not simply react to scientific developments in a linear pathway, but rather the two institutions work together to structure our understanding of the social and natural worlds.[82] In addition, the concept of technological "deviancy" suggests that the newness of a technology results not from science but from the legal practice of targeting technologies which violate existing law as the subject of new regulation.[83] Under this conception, "new" technologies do not exist outside of current law, but rather are defined by it from the beginning.[84] It is therefore important not to oversimplify the phenomenon of law lag.

Additionally, states may adopt regulatory strategies that do not necessarily need to be adapted to each new technological innovation. For example, instead of focusing on regulations that target specific practices and technologies that represent the state of the art at the time of drafting, states can craft risk-based legal regimes that are adaptive and forward-looking. While it is impossible to predict the future, an approach that takes the focus off specific technologies may leave less of a legal vacuum as science progresses.

That said, and as explored in more depth below, CRISPR and gene editing are clear examples of areas where existing legal regulation has yet to adapt to the features of the scientific landscape. Regulation, where it exists, was created to regulate technology as it stood decades ago and formal

---

ed (Cambridge: Massachusetts Institute of Technology Press, 2008) 761 at 768 [Jasanoff, "Making Order"], citing William F Ogburn, "Cultural Lag as Theory" (1957) 41 Sociol Social Res 167 at 167.

81 See Jasanoff, "Making Order", *supra* note 80 at 768.

82 *Ibid* at 772, 775.

83 See Francis Lord, "The Legal Interpretation of Technology" (2016) [unpublished] at 30.

84 See *ibid* at 34.

legal actors have yet to react to the emerging issues around gene editing.[85] Through the lens of technological deviancy, we might say that while formal legal actors have largely ignored the discovery of CRISPR – in other words, have not identified it as deviant – the ISHGE network, by starting a conversation around gene editing technology, is performing the legal practice of identifying novel technology requiring updated regulation. Therefore, even if it is true that identifying the novelty of a technology is a legal exercise, here it has been carried out by the scientific community rather than formal legal actors.

With a technology that raises significant health risks like CRISPR, it seems inevitable that formal legal regulation will eventually be applied.[86] However, as explored above, there are several reasons to expect that formal legal actors will be relatively weak within the regulatory space surrounding emerging gene editing technology. Confined within national borders, informationally disadvantaged, and facing delays in responding to emerging technology, formal legal actors may struggle to shape the practice of emerging gene editing technology through regulation. Without the ability to quickly, precisely, and comprehensively fill the newly opened space, gaps will inevitably emerge, allowing for informal regulation to exert disproportionate influence.

D. The state of the law

Examining the current state of legal regulation of gene editing technology illustrates the theoretical weaknesses laid out above. A recent survey of gene editing regulations carried out by the Centre of Genomics and Policy at McGill University describes a patchwork of national regulations which vary in form from outright bans, to permissive guidelines, to nothing at all.[87] Even where gene editing is covered by broad bans on genetic and reproductive technology, such as those adopted in Germany and Canada,

---

85 See R Isasi, E Kleiderman & BM Knoppers, "Editing Policy to Fit the Genome?: Framing Genome Editing Policy Requires Setting Thresholds of Acceptability" (2016) 351:6271 Science 337.

86 See Nicholas Wade, "Scientists Seek Moratorium on Edits to Human Genome That Could Be Inherited", *New York Times* (3 December 2015), online: <https://www.nytimes.com/2015/12/04/science/crispr-cas9-human-genome-editing-moratorium.html>.

87 Isasi, Kleiderman & Knoppers, *supra* note 85.

there is little practical effect because the vagueness of the language and the references to obsolete technologies leave gaping loopholes.[88] This ambiguity is aggravated by enduring confusion about the meaning of basic terms critical to human gene editing, such as "human embryo" or "reproductive cells."[89] In addition, the enforcement of state regulations with criminal sanctions, where they exist, is made difficult by an unclear requirement of intentionality.[90] Meanwhile, in countries like China, Japan, and India, governments only have non-binding guidelines which forbid certain practices in this area.[91] Indeed, it was China where the genomes of human embryos were first modified, despite non-binding guidelines discouraging the practice.

It is important to note that this regulation, where it exists, results from historical waves of political concern over older technologies: stem cell research and human cloning.[92] The fact that the current regulatory landscape reflects these older technologies exemplifies the lag effect described earlier in Sub-Part C, especially considering these waves of legal regulation followed several years after the development of the targeted technology. Consequently, formal legal regulation of emerging gene editing technology is incongruent with the challenges being faced today. The combined effect of this incongruence, the inherent ambiguity and unenforceability of these regulations, and the diversity of national approaches to what is an inherently transnational issue results in its diminished importance to the practices and behaviour of scientists.

III. The International Summit on Human Gene Editing as a Regulatory Actor

Part III builds on the regulatory space framework developed in Part II by characterizing the ISHGE as an actor within this space. Drawing on literature that examines the social, legal, and political power of scientific

---

88 See *ibid* at 337.

89 *Ibid* at 339.

90 See *ibid* at 337.

91 See Motoko Araki & Tetsuya Ishii, "International Regulatory Landscape and Integration of Corrective Genome Editing into In Vitro Fertilization" (2014) 12:108 Reprod Biol Endocrinol 1 at 8.

92 See Ledford, *supra* note 4 at 310.

bodies, as well as the sociology of professions, I will evaluate which regulatory resources the ISHGE has at its disposal. I will then examine how well adapted the ISHGE is to the specific regulatory challenge of emerging gene editing technology. I argue that the ISHGE is particularly well adapted to this deterritorialized, highly technical, and dynamic regulatory environment and consequently has the potential to wield significant power over the practice of gene editing.

It is important to clarify the composition of the actor itself. The name of the ISHGE is used here for simplicity, although the Summit was an event rather than an institution. The true actor here is the network, composed of the scientific academies that organized the Summit and mediate the ongoing deliberations. As mentioned in Part I, the policy documents generated by this network are authored by committees appointed by the constituent academies. The Organizing Committee wrote the policy conclusions at the close of the Summit[93] and a separate Expert Committee subsequently prepared more detailed guidelines.[94] Though these are two different groups, I will consider all policy activity undertaken within the collaboration framework set up by the academies to be attributable to a single actor, the ISHGE. Having clarified the composition of this actor, I will move on to consider the regulatory resources at its disposal.

A. Expertise and control of information

The ISHGE can claim a substantial amount of one regulatory resource: expertise and information relevant to the understanding of gene editing technologies. The academies count among their membership scientists who have expertise across a range of fields relevant to gene editing. This is the natural result of considering scientific expertise as a prerequisite to academy membership.[95] Moreover, the ISHGE committee members were chosen for their specific expertise relevant to gene editing technologies, which extends

---

93 Olson, *supra* note 7 at 6–7.

94 *Supra* note 41.

95 See The National Academy of Sciences, "Membership Overview", online: <www.nasonline.org/membership> [National Academy, "Membership"]; The Royal Society, "Elections", online: <https://royalsociety.org/fellows/elections> [Royal Society, "Elections"]; Academic Division of the Chinese Academy of Sciences, "Brief Introduction", online: <english.casad.cas.cn/au/bi>.

beyond scientists to include legal and bioethics experts.[96] In short, the ISHGE was able to quickly gather a large amount of information on this subject and evaluate it through an expert lens. Through their ongoing discussions and report preparations, the ISHGE continues to amass information and study this issue in unprecedented depth.

The regulation of science by scientific organizations like the ISHGE is essentially an exercise in self-regulation. Self-regulation can offer significant benefits in technical fields like gene editing due to the inherent expertise of the regulator and the ease of access to information on the subject of regulation. Herberg highlights that professions may operate in "[s]ituations of complexity, uncertainty, instability and uniqueness," and that, as a result, the members of these professions are well placed to reflect upon and solve the particular problems in their domain.[97] Gene editing is arguably exemplary of this kind of situation. Self-regulation generally means that the cost of standard formulation and interpretation is low compared to external regulatory schemes, as resources need not be spent gathering expertise and information that is already internal to the regulator. Further, when the regulator and the regulated share a common expertise, the standards can be more precisely formulated and more accurately interpreted by relying on common understanding and vocabulary.[98] For these reasons, expertise native to the profession – in this case, science – is often essential to its regulation, which is why Herberg suggests that professional regulation cannot simply be left to bureaucratic or market forces, but rather requires some degree of self-regulation.[99]

Inherent expertise and access to information also allows the ISHGE to benefit from reduced costs of measuring compliance and enforcing standards. The monitoring and enforcement of guidelines is less costly where there is significant understanding of the subject of the guidelines, since information is readily available and comprehensible to the regulator.[100] In this context, that means not just being aware of the various projects on gene edit-

---

96 See National Academies, "Statement", *supra* note 39.

97 *Supra* note 73 at 119–20.

98 See Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Portland: Hart Publishing, 2005) at 30–31, citing Anthony Ogus, "Rethinking Self-Regulation" (1995) 15 Oxford J Leg Stud 97 at 97–98.

99 *Supra* note 73 at 121.

100 See Schepel, *supra* note 98 at 30, citing Ogus, *supra* note 98 at 97–98.

ing being conducted around the world, but also possessing the scientific literacy to identify when projects deviate from the expected standards. While covert non-compliance can be employed by professions to resist external regulation, non-compliance is more likely to be identified from within the scientific community itself.[101] As a result, the ISHGE as a scientific organization can be expected not only to draw on scientific expertise to create more precise and functional regulation, but also to more effectively monitor compliance with this regulation.

It is also important to consider the ability of the ISHGE and its constituent academies to control the flow of information. It is not insignificant that the Royal Society and the National Academy of Sciences publish some of the world's most prestigious scientific journals, nor that the ISHGE is currently leading the international effort to amass and analyze data on the topic of gene editing.[102] Controlling the dissemination of information is a key source of power for networks of knowledge actors like the ISHGE in that it allows the regulatory challenge to be presented in a way that can structure future discourse on the topic. Not only does the ISHGE have expertise in gene editing, it also plays an ongoing and important role in characterizing the technology and its associated challenges to legal audiences.

In summary, the ISHGE, as a scientific organization regulating scientific practice, benefits from inherent expertise and access to information – two regulatory resources that are of particular importance in this regulatory space. Guidance flowing from the unprecedented concentration of multidisciplinary expertise at the ISHGE will carry more weight, not only because of its perceived quality and accuracy, but also because of the ease with which this expert body can identify work that diverges from its guidelines. In addition, the ISHGE holds influence over information flow that is used by others to conceptualize the techniques and associated challenges of gene editing.

B. Authoritative communication and prestige

A second major source of regulatory power for the ISHGE is its ability to draw on elite status and reputation to communicate its policy preferences.

---

101 See Herberg, *supra* note 73 at 115, 121.

102 The Royal Society publishes *Proceedings of the Royal Society A & B*, as well as *Philosophical Transactions of the Royal Society A*, while the National Academy of Sciences publishes *Proceedings of the National Academy of Sciences*.

As mentioned in Part II, Gibbons highlights the importance of status and reputation as a key regulatory resource in biomedical spaces where scientists are accustomed to making value judgements based on authoritativeness.[103] Scientists may be particularly receptive to appeals to prestige since success in science, via high-impact publications and awards, is dependent on acceptance by the established members of the broader scientific community. Therefore, the ability to communicate authoritatively is a significant regulatory resource within the gene editing regulatory space.

Though the ISHGE is a new partnership without a prestigious narrative of its own, it can draw prestige both from its constituent organizations and the composition of its committees. The constituent academies of the ISHGE are self-selecting organizations where membership is based on scientific excellence. Scientific organizations emphasize this excellence and their historical contributions to their field in order to build their authoritative voice on scientific issues.[104] Indeed, the Royal Society and the US National Academies are quick to emphasize their illustrious histories and their roles in shaping the scientific enterprise as it exists today. The Royal Society can claim to have started the phenomenon of scientific publishing and to have published works as important as Newton's laws of physics and Benjamin Franklin's famous kite experiment.[105] The National Academy of Sciences also uses history to emphasize its prestige, emphasizing the fact that President Lincoln signed the congressional charter that created the organization.[106] The Chinese Academy, as a state agency in a communist society, can make a strong claim to represent the scientific community in the People's Republic, even though its history may not be as long or illustrious as its counterparts. Combining their mandates over three of the largest and most prestigious scientific communities worldwide, these three bodies can credibly claim to represent the global scientific elite.

In addition, the individual members of the ISHGE's committees represent preeminent members of the scientific community. The Chair of the Organizing Committee, David Baltimore, is not only the President Emeritus of the California Institute of Technology, but is a Nobel laureate, along with

---

103 *Supra* note 58 at 83, 89.

104 See *ibid* at 83; Stone, *supra* note 62 at 47.

105 See Royal Society, "History", *supra* note 37.

106 National Academies, "Who We Are", *supra* note 36.

fellow committee member Paul Berg.[107] Jennifer Doudna, one of the discoverers of the CRISPR technique and a likely pick for a future Nobel Prize,[108] has a seat, as do other highly accomplished scientists and bioethicists. On both institutional and individual levels, the ISHGE's normative pronouncements are delivered by voices which project significant prestige within the scientific community and may accordingly have a stronger impact on the behaviour of scientists.

C. Control over scientific culture

In addition to expertise and prestige, the ISHGE can draw on the role its constituent academies play in controlling scientific culture to affect regulatory outcomes. As professional organizations, the academies that make up the ISHGE are positioned as the guardians of independence from both the state and the market.[109] These organizations work continuously to define the professional community and defend it by fostering a shared identity among members of that profession. This is reflected in the academies' mandates to protect and promote scientific culture and values. Transnational scientific organizations like the ISHGE take this to another level. By bringing together scientists from around the world and engaging them in a conversation that involves not only data but values, the ISHGE process could be seen as part of a larger effort by national academies to foster a transnational scientific culture.

As a network of these guardians of scientific professionalism, the ISHGE may exercise significant control over scientific practice. Empirical research done on scientific organizations in the biobanking context demonstrates that the inculcation of professional culture has significant impacts on the attitudes and day-to-day practices of scientists.[110] Though, admittedly, the cultural impact of the ISHGE is unlikely to be as strong as a national academy, the ISHGE taps into the larger, growing phenomenon of international

---

107 See National Academies, "Statement", *supra* note 39; LaBarbera, *supra* note 7 at 1123.

108 See Julie Steenhuysen, "Nobel Prize Predictions See Honors for Gene Editing Technology", *Reuters* (24 September 2015), online: <https://www.reuters.com/article/us-nobel-predictions-thomsonreuters-idUSKCN0RO0BB20150924>.

109 See Herberg, *supra* note 73 at 120.

110 See Gibbons, *supra* note 58 at 83.

scientific culture. It has created a space to embody and communicate the norms of this culture in the specific context of gene editing in order to affect scientific practice.

D. Transnational reach

Though not a resource per se, the transnational reach of the ISHGE has important implications for its effectiveness as a regulatory actor in this space. As discussed in Part II, the governance of gene editing technology, as with other scientific practices, requires a transnational approach in order to overcome coordination problems and to protect the genome as the common heritage of humanity.

Transnational networks of national academies like the ISHGE have the potential to play a critical role in the transnational organization of science. International networks of scientists create venues where national identity matters little, leading to the erosion of national identity in favour a transnational professional identity.[111] Face-to-face meetings like the Summit that began the policy process under consideration here may be particularly important for this development. The ISHGE not only taps into the existing transnational identity of science, but it has also helped to foster it in the context of gene editing by bringing together scientists from around the world. We can therefore expect its policy guidance to be effective across borders.

The transnational nature of the ISHGE can also be gleaned by looking at its constituent academies. As some of the oldest and best funded national academies worldwide, the Royal Society and the US National Academies already have significant global impacts in terms of the publication of scientific research and science policy initiatives on their own. The inclusion of China is an important signal of the truly transnational nature of the ISHGE, broadening its reach beyond the Global North. In addition, the inclusion of representatives from other countries on the committees exemplifies the ISHGE's attempt to speak for the scientific community beyond the national constituencies of its host academies. The importance of transnational inclusiveness in the ISHGE process was highlighted in the Organizing Committee's conclusions to the Summit,[112] echoing the *Universal Declaration on*

---

[111] See Stone, *supra* note 62 at 49.

[112] Olson, *supra* note 7 at 7.

the Human Genome and Human Rights in its commitment to the idea of the human genome as the common heritage of all.[113] The ISHGE purports to speak with a truly transnational voice and is likely to be heard not just in the home countries of its constituent academies, but worldwide.

E. Dynamism

It is also worth briefly assessing the ability of the ISHGE to react dynamically to changes in the regulatory landscape. As noted previously, in regulatory space characterized by emerging technologies, the ability to respond and adapt to scientific developments is of significant importance. The constituent academies of the ISHGE have the organizational capacity to quickly develop flexible networks that are focused on a particular regulatory issue. The decision to engage in an ongoing monitoring and expert study process shows how the academies continue to adapt the ISHGE process to the policy needs of the gene editing issue. In addition, the kind of guiding principles penned by the Organizing Committee do not require the same formalism as the adoption of formal legal instruments. This precise monitoring of developments in gene editing, paired with the relatively informal adoption procedures for its guidelines, provides the ISHGE and related networks with the ability to adapt to dynamic policy issues like gene editing.

To conclude, the ISHGE has several key resources at its disposal within the regulatory space for emerging gene editing technologies. It has the advantage of unparalleled expertise and control over information, significant prestige, and the ability to embody global scientific culture (at least within this narrow regulatory space). Recalling the particularities of the regulation of emerging gene editing technology, the ISHGE appears particularly well adapted to this environment. Specifically, it has the transnational reach required to address the problem and the ability to authoritatively pronounce on its technical aspects. Since its members were already well versed in the underlying mechanics of gene editing, and because of its informal nature, the ISHGE process has been dynamic, on track to produce detailed guidelines less than two years after the first human embryo experiments brought attention to the issue. Consequently, the ISHGE is positioned as a key actor in the regulation of emerging gene technology.

---

[113] *Supra* note 65, art 1.

F. Mechanisms of action

It is worth briefly examining the mechanisms and pathways through which the ISHGE can leverage its resources to affect regulatory outcomes. These mechanisms can be classified into two broad categories. First, the ISHGE can mobilize these resources to influence scientific practice directly at the level of individual scientists, research institutions, and review boards. Second, the same resources could indirectly affect regulatory outcomes by influencing the development of formal legal regulation. I argue that both pathways are important to understanding the ISHGE's regulatory role.

Direct mechanisms of action have been alluded to earlier in Part III. The most visible pathway towards regulating scientific practice involves issuing best practices and other explicit policy guidance. The ISHGE did this at the close of the Summit[114] and with its release of the report by the Expert Committee.[115] These guidance documents explicitly provide scientists with indications about what is and is not acceptable to the ISHGE committees and, by extrapolation, to the international scientific community.

Less visible are the impacts the ISHGE process has had on scientific culture around CRISPR technology. The inculcation of a professional culture around normative frameworks is a key regulatory resource, especially in the biomedical context.[116] Beyond mere norm generation, regulatory actors regulate behaviour by exerting control over, and integrating regulated persons into, cultures. Beyond the consensus text, the Summit brought together many thinkers who engaged in a broad and complex conversation about CRISPR's acceptable uses and dangers. This is likely to affect the practice of science by having exposed scientists to alternative narratives and concerns and taking the first steps towards consensus building among the scientific community. Therefore, while the cultural impacts on the practice of science are more difficult to track and measure, it is important to recognize that the direct impacts of the Summit go beyond its consensus text.

As mentioned in Part II, it is widely expected that states will eventually adapt formal regulation to reflect new gene editing techniques – a development that is in fact encouraged by the Organizing Committee's consensus

---

114 Olson, *supra* note 7 at 6–7.

115 *Supra* note 41.

116 See Gibbons, *supra* note 58 at 83.

document.[117] However, the increased regulation via formal legal processes in the regulatory space will not necessarily render the normative action of the ISHGE moot. Not only would the ISHGE process in this scenario generate interim policy guidance, but it could also influence the ultimate form of formal regulation. Indeed, the World Medical Association's *Declaration of Helsinki* provides a striking example of the extent to which states are willing to incorporate non-binding expert declarations in their legislation.[118]

This pathway can be conceptualized through a framework from political science known as "discourse coalitions."[119] Under this approach, actors organize themselves into coalitions to achieve certain policy goals by first shaping the public understanding and discourse around the issue and later influencing government responses.[120] This control of the public discourse constrains perceptions of other actors in a phenomenon known as "discourse structuration."[121] As the discourse becomes more deeply entrenched, it moves towards being accepted as truth by regulatory institutions in a process called "discourse institutionalization," though this is not inevitable and involves contestation between alternate discourses.[122] Institutionalized discourses shape public decision making until they are replaced or overwritten by new conceptualizations, continuing the cycle.

As an early and authoritative voice in the conversation on the regulation of gene editing technology, the ISHGE has the opportunity to structure how this problem is perceived. This position gives the ISHGE the potential to affect the form and content of future regulation at national and international levels. Indeed, the separation highlighted in the consensus statement

---

117 Olson, *supra* note 7 at 6–7.

118 See Delon Human & Sev S Fluss, "The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives" (2001) [unpublished] at 2, online: Semantics Scholar <https://pdfs.semanticscholar.org/acde/7253a068d3eb2c738f3a90fc0d4eec1db243.pdf>.

119 Stone, *supra* note 62 at 50, citing Maarten A Hajer, "Discourse Coalitions and the Institutionalization of Practice: The Case of Acid Rain in Great Britain" in Frank Ficher & John Forester, eds, *The Argumentative Turn in Policy Analysis and Planning* (London: Duke University Press, 1993) 43 at 45.

120 See *ibid* at 47–48.

121 Stone, *supra* note 62 at 50.

122 *Ibid*.

between basic research and clinical approaches[123] represents a new conceptualization of the problem. Much of the discussion in the lead-up to the Summit concerned the appropriateness of germ line modification compared to somatic cell modification.[124] Under the Summit conclusions, however, both somatic and germ line modification are deemed acceptable in the basic research context; only the clinical applications of germ line modification are discouraged.[125] Under this framework, the study on human embryos that provoked backlash would actually be acceptable, since it would be classified as basic research, despite the fact that the germ line is being modified. Something as simple as the structure of the meeting's conclusions may insulate basic science from over-zealous restriction and could cement this outcome if the structure is replicated in formal legal regulation.

G. Lessons from the United Nations Declaration on Human Cloning

The *United Nations Declaration on Human Cloning* provides an interesting historical example of the influence of normative declarations from transnational scientific actors on formal legal outcomes.[126] When France and Germany went to the United Nations General Assembly looking for a simple declaration banning the practice of reproductive human cloning, the initiative was relatively uncontroversial.[127] However, the conversation was unexpectedly steered by a coalition including the United States and the Holy See towards a wider ban of all human cloning, including stem cell research.[128] The scientific community was caught off guard and scrambled to counter-mobilize. Another network of scientific academies, the InterAcademy Panel on International Issues (IAPII), called for a ban on reproductive cloning while opposing a wider ban.[129] While the declarations of the IAPII held significant weight in watering down the wording such that

---

123 See Olson, *supra* note 7 at 6–7.

124 See e.g. Lanphier et al, *supra* note 3; Wade, *supra* note 86.

125 Olson, *supra* note 7 at 6–7.

126 GA Res 280, UNGAOR, 59th Sess, UN Doc A/59/280 (2005).

127 See Mahnoush H Arsanjani, "Negotiating the UN Declaration on Human Cloning" (2006) 100:1 Am J Intl L 164 at 166.

128 See *ibid* at 172.

129 See *ibid* at 174.

nothing was effectively banned, the resulting non-binding document was not at all clear[130] and accomplished very little for the regulation of stem cell research.[131]

This example not only shows that networks of scientific academies can shape formal legal instruments at the international level, it also demonstrates room for improvement. This process taught the scientific community that taking a passive approach to the regulation of emerging technology could have negative consequences for science and for effective public policy. By the time scientific organizations got involved in the human cloning debate, the conversation had been framed in moral and religious terms, rather than in ways that were more favourable to the scientific agenda.[132] With gene editing, by contrast, the ISHGE was quick to start the policy conversation in a form and arena that was better adapted to its policy priorities. As a result, we can expect that future formal legal regulation will conform more closely with the preferences of scientists.

The ISHGE is an important actor within the regulatory space of emerging gene editing technology. Drawing on scientific expertise and information about the emerging technology, the prestige of its constituent institutions and committee members, its role in shaping scientific culture, and possessing both a transnational reach and a dynamic, flexible structure, the ISHGE is well placed to affect regulatory outcomes in this area. Outcomes can be effected both through direct impacts on the scientific community, such as explicit guidelines and implicit cultural development, as well as indirectly by shaping the policy discourse in the lead-up to eventual formal regulation. The extent to which the ISHGE utilizes this power and the actual impact this will have on the scientific practice of gene editing remain to be seen.

IV. Assessing the Legitimacy of Transnational Scientific Governance

Having characterized the ISHGE's role in the regulatory landscape of gene editing technology and the ways in which it impacts regulatory outcomes, I now turn to examine the legitimacy of the exercise of this power.

---

130 See *ibid* at 177.

131 See Channah Jarell, "No Worldwide Consensus: The United Nations Declaration on Human Cloning", Note, (2006) 35:1 Ga J Intl & Comp L 205 at 208.

132 See Arsanjani, *supra* note 127 at 174, 173.

Assessing the legitimacy of non-state actors is critical to understanding transnational governance.[133] As generally democratic states are increasingly forced to share the regulatory space with a multitude of non-state actors, observers have expressed concerns about technocracy and a loss of democratic accountability more generally.[134] Yet our conceptual tools for evaluating legitimacy were developed in the context of states and may not be suitable to the evaluation of non-state actors.[135] In this Part, I consider what it means to be a legitimate actor in transnational regulatory space, before evaluating the major challenges to the ISHGE's legitimacy by virtue of its status as a private, scientific body. I argue that despite inherent challenges, scientific governance bodies like the ISHGE retain the potential to claim legitimate authority over the regulation of emerging gene editing technology.

A. Legitimate authority outside the state

The concept of legitimacy has been the focus of numerous works across a variety of legal and non-legal disciplines. Central to many of these definitions is the notion that legitimacy is the property that turns the exercise of mere power into the exercise of authority.[136] While power can motivate individuals to accept laws or rules because of coercion or cost-benefit calculations, legitimate authority motivates individuals to accept those rules simply because they see the espoused norm as binding.[137] Legitimacy is often used as a prescriptive concept to evaluate the appropriateness of the use of power, but Weber argued that it can also be employed as a descriptive concept to explain the social fact that subjects accept a given governance

---

133 See Brouder, *supra* note 9 at 6.

134 See e.g. Ngaire Woods, "The Challenge of Good Governance for the IMF and the World Bank Themselves" (2000) 28:5 World Development 823; Robert O Keohane, "Global Governance and Democratic Accountability" in David Held & Mathias Koenig-Archibugi, eds, *Taming Globalization: Frontiers of Governance* (Cambridge: Polity Press, 2003) at 125.

135 See Jens Steffeck, "The Legitimation of International Governance: A Discourse Approach" (2003) 9:2 European J Intl Relations 249 at 251.

136 See Brouder, *supra* note 9 at 28; A Claire Cutler, Virginia Haufler & Tony Porter, eds, *Private Authority and International Affairs* (Albany: State University of New York Press, 1999) at 5.

137 See Steffeck, *supra* note 135 at 254–55.

scheme.[138] Here, I examine various sources of legitimacy to assess why and in what contexts the public would accept regulation by private scientific bodies as binding.

Discussion of legitimacy is particularly important when examining informal governance actors like the ISHGE network. In contrast to states, most informal actors cannot mobilize the coercive force necessary to motivate individuals to follow their rules and guidelines through domination.[139] Instead, informal actors are expected to rely more on the persuasiveness of their norms in affecting individual behaviour, something that is likely affected by their perceived legitimacy. Therefore, while the legitimacy of a state is a normative element of its governance, the legitimacy of many informal actors like the ISHGE is a necessary precondition to playing an active role within the regulatory space.

The concept of legitimacy has received renewed attention in the 21st century in the context of globalization and the rising influence of non-state actors.[140] Yet, as Steffeck indicates, merely applying notions of state legitimacy to the non-state level is problematic.[141] For Steffeck, the emerging literature on legitimacy has focused too much on democratic participation and ignores other sources of legitimacy which exist in the absence of democratic institutions.[142] While an in-depth literature review on this topic is outside the scope of this paper, I will briefly outline three proposed sources of legitimacy before specifically examining the legitimacy of the ISHGE.

First, democratic participation theories of legitimacy are based around the idea that involving the governed in the acts of governance will make those acts more acceptable to them.[143] This version of legitimacy is based

---

138 See *ibid* at 253, citing Max Weber, *Economy and Society* (Berkeley: University of California Press, 1978) at 31.

139 See Steffeck, *supra* note 135 at 259.

140 See Peel, *supra* note 67 at 13.

141 *Supra* note 135 at 251.

142 *Ibid* at 256–57.

143 See e.g. Christopher Lord & David Beetham, "Legitimizing the EU: Is There a 'Post-Parliamentary Basis' for Its Legitimation?" (2001) 39:3 J Common Market Studies 443; John S Dryzek, *Deliberative Global Politics: Discourse and Democracy in a Divided World* (Cambridge: Polity Press, 2006) at 62 [Dryzek, *Deliberative Global Politics*].

in the Lockean concept of the consent of the governed.[144] According to this theory, legitimate governance flows from institutions which were set up by a social contract between individuals and therefore involves the governed in the decision-making process.

This theory forms the basis for the declaration of a "democracy deficit" in transnational governance. The perceived growth in the impact of non-state actors is seen by some as a shift in power from generally democratic states to entities that are not directly accountable to the public.[145] This has spurred calls for the opening up of governance bodies to a more diverse group of civil society actors, with the aim of creating an environment of deliberative democracy.[146] Greater input from outside actors is seen by some authors as an important way to restore the legitimacy of transnational institutions.[147] However, Steffeck points out that considering only the democratic aspects of legitimacy at the international level fails to explain the existence of non-democratic international institutions, like the United Nations, whose rule making is nonetheless considered legitimate.[148]

Another source of legitimacy is the result achieved by a governance structure, rather than the processes that went into making those rules as considered above. This distinction was drawn by Scharpf using the concepts of input and output legitimacy.[149] Whereas input legitimacy is concerned with public participation as discussed above, output legitimacy asks whether the policy outcomes for the public are favourable. In the specific case of regulation, Majone has argued that the public's perception of the quality of regulation, along with transparency and accountability mechanisms, fosters legitimacy in these settings.[150] Specifically, rather than require that

---

144 See Steffeck, *supra* note 135 at 256.

145 See Peel, *supra* note 67 at 42.

146 See e.g. Jan Aart Scholte, "Civil Society and Democracy in Global Governance" (2002) 8:3 Global Governance 281.

147 See e.g. *ibid* at 281; Peel, *supra* note 67 at 357–58.

148 *Supra* note 135 at 257.

149 Fritz W Scharpf, *Governing in Europe* (Oxford: Oxford University Press, 1999) at 2.

150 Giandomenico Majone, "The Regulatory State and Its Legitimacy Problems" (1999) 22:1 Western European Politics 1 at 22–23.

regulatory bodies become politicized and deliberative to gain legitimacy, Majone's argument is that legitimacy can be earned when it is apparent to the public that those bodies are the most appropriate venues for the regulatory task at issue.[151]

Conceptions of output legitimacy, while useful in expanding the concept of legitimacy beyond the democratic institutions of the state, are not without criticism. For instance, measuring the impacts of rules and understanding how this contributes to their legitimacy remains unclear in practice.[152] Whereas democratic participation is fairly easy to define, at least quantitatively, the quality of output is value-based and difficult to measure empirically. Different measures of desirable output may rise as others fall, making it difficult to gain a holistic assessment of a given actor's legitimacy. Further, reducing the quality of regulation to a simple cost-benefit calculation does not appear to capture true legitimacy, recalling that legitimate authority is contrasted with incentive structures as an alternate motivation for rule acceptance.[153]

Finally, a third approach proposed by Steffeck sees legitimacy outside the nation-state as the product of communicated rationality, or discourse. According to this argument, legitimacy at the international level has its basis in public agreement on the normative reasoning that will underlie governance.[154] Legitimacy can therefore only be won if this reasoning enters the public discourse, where the rationality can be scrutinized and challenged. In this public forum, a consensus can be built where the regulator and the public achieve normative congruency as to the reasons for the acceptability of a given rule.[155] In this framework, it is not the direct public contribution to the decision making that is important, nor even that the outcome be favourable, but rather that the rationale for the decision is normatively accepted.

Discourse theory shares many parallels to the idea of "throughput legitimacy." Rather than measuring public participation or outcome, this approach measures the "accountability, transparency and efficacy" of the

---

151 *Ibid* at 22.

152 See Steffeck, *supra* note 135 at 257.

153 See *ibid*.

154 See *ibid* at 263–64.

155 See *ibid* at 264.

decision-making process itself.[156] These features contribute positively to the ability of an institution to communicate the rationale for decisions to the public. Therefore, both discourse theory and throughput legitimacy focus on the process of decision making, which is a source of legitimacy where it is shown to be rational and efficient.

Importantly, the notion of discourse goes further than mere transparency. Legitimacy in a discourse framework requires meaningful engagement between the rule-making party and the public in order to generate the required normative agreement. This agreement extends beyond the reasons behind the actual regulatory decisions to include agreement on the scope and guiding principles of the regulatory regime itself.[157] Legitimacy is therefore a function of a justificatory discourse which results in rational agreement on these points by the public.

According to this analysis, legitimacy may find its source from the inputs, outputs, and throughputs of governance, as well as how the throughput is communicated and received in public discourse. Ultimately, claiming legitimate transnational governance depends on the public perception of the normative acceptability of the governance structure and its conclusions as a result of the combination of these factors. I will now consider how this applies to the ISHGE's legitimacy as a regulator of gene editing technology.

B. Challenges to the legitimacy of private actors

The ISHGE faces an inherent challenge to its legitimacy as a private body. Unlike democratic public institutions, private institutions cannot claim a mandate from the public. The ISHGE was convened by private scientific bodies rather than elected governments and the committee members chosen to investigate more detailed guidelines were experts, not elected officials.[158] Under an approach solely focused on input legitimacy, the ISHGE's governance would be irreparably illegitimate and a sign of the "legitimacy deficit."

---

156 Vivien A Schmidt, "Democracy and Legitimacy in the European Union" in Erik Jones, Anand Menon & Stephen Weatherill, eds, *The Oxford Handbook of the European Union* (Oxford: Oxford University Press, 2012) 661 at 661.

157 See Steffeck, *supra* note 135 at 267.

158 See Olson, *supra* note 7 at 1; LaBarbera, *supra* note 7.

However, in the absence of a world government, it is overly simplistic to suggest that private actors are illegitimate while states and state-based institutions are legitimate. At the transnational level, states also have a "private" character in the sense that they do not represent the international public but rather a specific national interest.[159] Moreover, the public knows relatively less about their state's policies at the international level than at the domestic level[160] and these issues are rarely determinative in elections.[161] The public can be said to participate less in setting policy priorities for states within transnational regulatory spaces.

Additionally, it can be argued that the ISHGE and its constituent bodies are not purely private actors. As its constituent organizations are largely funded by public money,[162] it may be more accountable to the elected political bodies that make decisions regarding this funding and therefore take on a quasi-public character.

Nevertheless, it is impossible to ignore the impact that a lack of democratic accountability can have on an institution's legitimacy in the eyes of the public. Recent anti-European Union discourse provides a stark example of the lack of trust the public can harbour for transnational governance actors, compared to their nationally elected governments.[163] Regardless of outcome or process, lack of democratic accountability is a powerful image that can have a significant impact on public acceptance of governance processes and consequently their legitimacy.

---

159 See Brouder, *supra* note 9 at 11.

160 See *ibid*.

161 See e.g. Lawrence R Jacobs & Benjamin I Page, "Who Influences US Foreign Policy?" (2005) 99:1 Am Poli Sci Rev 107 at 121.

162 See The Royal Society, "Trustee's Report and Financial Statements" (2015) at 81, online: <https://royalsociety.org/~/media/Royal_Society_Content/about-us/reporting/2013-11-20-Trustees-Report.pdf?la=en-GB>; National Academy of Sciences, "Report of the Treasurer of the National Academy of Sciences for the Year Ended December 31, 2015" (2016) at 51, online: <https://www.nap.edu/23558>; Chinese Academy of Sciences, "2013 Annual Report" (2013) at 72, online: <english.cas.cn/about_us/reports>.

163 See e.g. Klaus Armingeon & Besir Ceka, "The Loss of Trust in the European Union during the Great Recession since 2007: The Role of Heuristics from the National Political System" (2013) 15:1 European Union Politics 82.

C. Challenges to the legitimacy of scientific actors

The interaction of science and policy has attracted a great deal of attention as authors try to come to grips with the high uncertainty and regulatory challenges in the biomedical field and beyond.[164] While scientific information has been increasingly called upon to create policy in these areas, there is disagreement about how to mediate the boundary between law and science. Scientific institutions carry with them distinct normative values and processes that complicate their interaction with both political actors and the public.[165] Consequently, we would expect that the scientific nature of the ISHGE would affect its claim to legitimate authority.

First, the input legitimacy of scientific bodies is negatively affected by the fact that participation in meaningful scientific discourse is limited to scientists and does not extend to the general public. Like other professions, membership in scientific institutions is restricted to a self-selecting elite[166] and, in reality, participation in scientific debate and discourse is limited to those who have earned an advanced degree in their field. Members of the constituent academies of the ISHGE must be elected by those who are already members upon recognition of their scientific accomplishments.[167] This requirement of scientific expertise and self-selection impedes the ISHGE from claiming input legitimacy given the severe limitation this places on public participation.

Exclusivity of membership also impacts legitimacy from a discourse perspective. This exclusivity can have a negative impact on the communication and reception of rationales for governance decisions.[168] Whereas

---

164 See Peel, *supra* note 67 at 10.

165 See Jaye Ellis, "Logics of Science, Politics, and Law in International Environmental Protection: The Role of Boundary Organisations" (2015) [unpublished] at 1, online: SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2661750>.

166 See Gibbons, *supra* note 58 at 83.

167 See Royal Society, "Elections", *supra* note 95; National Academy, "Membership", *supra* note 95; Academic Divisions of the Chinese Academies of Science, "Statutes for Membership of the Chinese Academy of Science", online: <english.casad.cas.cn/au/re>.

168 See Steffeck, *supra* note 135 at 265.

argumentation within fully inclusive institutions will be formulated, necessarily, in a way that is comprehensible to the entire polity, argumentation within exclusive institutions will be geared towards an exclusive audience and may therefore not resonate as strongly with the wider public. Steffeck points to exclusivity as the reason that rules created at the United Nations General Assembly are seen as more legitimate than those created by the G8.[169] By analogy, organizations whose membership is limited to the scientific community may communicate rationales which are not congruent with the normative frames of the wider public.

That analogy is not perfect, however, as unique features of science as a discipline seem to have a positive impact on discourse legitimacy. Science claims to espouse universal truths and speaks a language of rationality that, according to discourse theory, should earn it legitimacy. The replacement of divine claims to legitimacy with rationality in the modern era has secured the place of science within contemporary political discourse – a process that has been extensively characterized within Science and Technology Studies (STS).[170] The patina of objectivity carried by scientific organizations may, as with expertise in general, create the perception that regulatory outputs are "right" and therefore legitimate based on notions of output legitimacy. Similarly, the public may be more willing to accept outcomes that are justified by scientific rationale or espoused by scientific organizations as legitimate.

However, there exist significant limitations to the ability of science to leverage its claims to objectivity in the policy context. Scientific actors face an inherent danger of politicization at the boundary between science and policy.[171] The power of scientific actors is derived from their claims to produce credible, objective knowledge,[172] which is threatened where they are seen to make judgments based on values rather than observation and logic. This risk is greater in cases of scientific uncertainty, where revealing these professional disagreements to the public within the context of policy arguments erodes the notion that science espouses objective truth.

---

169 *Ibid*.

170 See *ibid* at 262; Alan Irwin, "STS Perspectives on Scientific Governance" in Hackett et al, *supra* note 80, 583 at 583; Jasanoff, "Making Order", *supra* note 80 at 762.

171 See Ellis, *supra* note 165 at 1.

172 See *ibid* at 3.

Unfortunately, it is in these areas of uncertainty – for example, risk regulation – that science is increasingly called upon as a policy tool.[173] There has therefore been a call for the development of "boundary organizations" to mediate between the science and policy realms, in order to protect the integrity of the normative orders.[174]

Recasting this dilemma within a discourse theory framework, the legitimacy of scientific organizations is under threat where the communicated rationale of their regulatory decisions incorporates subjective values and beliefs rather than the objective facts expected by the public. In conditions of uncertainty, scientific organizations face the challenge of maintaining legitimacy without being able to appeal to purely objective truth. Even where phenomena are well understood, regulatory decisions ultimately involve a judgment about acceptable levels of risk, which is subjective.[175] When this subjectivity is revealed in public discourse it opens up science to claims of corruption and illegitimacy.

In addition, an important challenge to the legitimacy of scientific organizations in the regulation of science is the appearance of a vested interest in a deregulated research landscape. Scientists may be perceived to have two sets of interrelated interests in deregulation: (1) material interests flowing from research on or the commercialization of new technologies and (2) a general interest in the advancement of scientific knowledge. While material interests will generally only be held by individual scientists with proprietary interests in the new technology or its spinoffs, the legitimacy of scientific organizations is compromised to the extent that they rely heavily on input from these experts, at tension with their institutional role in espousing expert opinions. Furthermore, even scientists without a material interest in a particular technology may be ideologically predisposed to deregulation given that their goals as scientists is to advance the state of knowledge. The proximity of scientists to the technology being regulated is an important regulatory resource, but may also generate the appearance of self-interest that could undermine legitimacy.

---

173 See Peel, *supra* note 67 at 4.

174 Ellis, *supra* note 165 at 2; Maria Carmen Lemos & Christine Kirchhoff, "Boundary Organizations" in Jean-Frédéric Morin & Amandine Orsini, eds, *Essential Concepts of Global Environmental Governance* (New York: Routledge, 2015) 16 at 17.

175 See Peel, *supra* note 67 at 106–07.

The literature on legitimacy outside the nation-state provides for the possibility that the regulatory activities of the ISHGE can be legitimate even without a democratic mandate. However, as a network of private, scientific organizations, the ISHGE faces several challenges to its legitimacy. First, as a private actor with exclusive membership, it cannot, without major restructuring, rely on democratic participation as a source of legitimacy. Second, the exclusivity of its membership and of membership in the wider scientific community impairs its ability to frame its policy discourse in a way that will be recognized as legitimate by the public. Finally, while the perceived objectivity of science endows these organizations with legitimacy when making ontological claims, this legitimacy is endangered where it appears that these actors are making decisions based on subjective assessments of risk, subjective preferences, or self-interest. It is therefore clear that there are significant inherent challenges to the ISHGE's legitimacy and, consequently, that the sustainability of the regulatory processes begun by the ISHGE regarding gene editing is at risk. In the next Part, I consider the steps taken by the ISHGE to address these challenges and what can be done to increase the legitimacy of this scientific governance process in the future.

V. Legitimizing Scientific Governance

In this final Part, I assess various methods through which the ISHGE and related organizations could legitimize their regulatory role. First, I examine the possibility of increasing public participation in the decision-making process. While this strategy holds potential for strengthening both input and output legitimacy, I argue that its application in the case of the ISHGE would undermine the regulatory resources that allow it to influence policy outcomes in the first place. Second, I consider good governance principles, in particular, transparency, as an alternative legitimation strategy. While transparency is undoubtedly part of the solution, it carries certain dangers in the context of the scientific organizations that could be addressed by improving communication and discourse around the distinct policy role of these organizations.

A. Public participation and democratization

One of the most frequently cited ways to increase the legitimacy of transnational governance structures is to encourage broader participation from a wider array of stakeholder groups in decision-making processes. This plays off the notion that legitimacy increases where the public is able

to contribute to the development of the regulation that will affect them.[176] Several authors have proposed that opening up governance in this way can transform otherwise private structures into sites for deliberation of a transnational public.[177] In doing so, transnational governance could in theory become a way to engage and foster a global governance community, rather that removing governance from the public sphere.

The rationale for greater public participation is not, however, limited to discussion of input legitimacy. Widening participation may allow the public to feel more connected to the decision-making process while also leading to better policy outcomes,[178] thereby linking to notions of output legitimacy. Dryzek suggests that increased participation would occur by integrating different stakeholder perspectives, refocusing on the public interest, and incorporating feedback or accountability.[179] In a post-modern world where there is increasing doubt about our ability to uncover objective truths, unquestioningly following the guidance of experts has become unfeasible in practice.[180] Reforming processes of negotiation and including democratic validation mechanisms have been proposed as a way to achieve the goals of greater public participation.

The regulation of science and technology has not escaped such calls for wider participation. For example, Peel, in her discussion of risk regulation, argues that we can no longer overestimate the universal validity of science compared to non-scientific approaches.[181] In STS, the traditional narrative that the public is deficient in scientific knowledge is being replaced by the notion of co-production, which highlights the role that non-scientists play in the collaborative process of scientific knowledge creation.[182] While co-production is more descriptive than prescriptive, it has been the basis for the

---

176 See Steffeck, *supra* note 135 at 256.

177 See e.g. Peel, *supra* note 67 at 371.

178 See John Dryzek, "Global Deliberative Democracy" in Morin & Orsini, *supra* note 174, 76 at 76.

179 *Ibid* at 76–77.

180 See Schepel, *supra* note 98 at 26; Jasanoff, "Making Order", *supra* note 80 at 775.

181 *Supra* note 67 at 8.

182 See Irwin, *supra* note 170 at 589.

call for hybrid forums where the public can interact with scientific experts to foster this process.[183]

While the ISHGE demonstrates certain features of public participation and is demonstrative of an evolving attitude in the scientific community towards public involvement, public participation was not a controlling feature of the process. Explicit effort was made to recruit non-scientific experts and stakeholders to participate and share their points of view at the Summit; however, it was ultimately the Organizing Committee of mostly scientific experts that drafted and summarized these perspectives in the consensus statements. While that committee called on the work following the Summit to be inclusive of "a wide range of perspectives,"[184] both expert and non-expert, all committee members who authored the report have an advanced degree of some kind, the vast majority being PhDs, MDs, or JDs.[185] Therefore, while the wider public was to be consulted in theory, the control of the process was still very much in the hands of experts.

Despite the potential of public participation for the legitimation of governance, there are important limits to the desirability of its application, especially in the context of transnational scientific actors like the ISHGE. One concern is that opening up regulatory processes to the wider public could undermine the very scientific credibility that is the source of its power as a regulatory actor. As explored in Part III, the regulatory force of the ISHGE flows in large part from its claims to expertise and its cultivated elite status. This power is undermined where non-experts are involved in decision making and have control over policy outcomes. Increasing legitimacy in this way would be for naught if it were to result in the erosion of the actor's regulatory power.

In addition, broader public participation in decision making could undermine the ISHGE's ability to embody and protect scientific culture. Losing its position as a defender of the scientific profession could have negative consequences for the ability of ISHGE guidelines to shape the day-to-day

---

183 See *ibid* at 593.

184 Olson, *supra* note 7 at 7.

185 See The National Academies of Science, Medicine and Engineering, "Committee Members", online: <www.nationalacademies.org/gene-editing/consensus-study/committee/index.htm>.

behavior of scientists.[186] By inviting other stakeholders to have a determinative role in transnational scientific organizations, the scientific community would lose its ability to use these organizations to express their unique, though not universally true, perspective on policy that affects their community. Accordingly, while the broader public engagement that occurred at the Summit is undoubtedly valuable, pushing for greater public involvement at the decision-making stage risks undermining the role of scientific networks in this regulatory space.

B. Good governance and transparency

An alternate approach to legitimizing transnational regulation focuses not on the actors who contribute to regulatory decisions, but rather on the process of making regulatory decisions. Recalling the discourse and throughput sources of legitimacy considered in the previous Part, legitimacy can be gained by increasing the integrity and transparency of the process behind a decision.

Insight into ensuring that reasoning is communicated and is acceptable to the public can be gained by examining the good governance principles from the regulation literature, namely consistency, transparency, accountability, targeting, and proportionality.[187] Consistency is necessary to demonstrate to the public that there is a relatively stable rationality underlying regulatory decisions. Transparency of the decision-making process is necessary for the rationale to be verifiable, and accountability implies that this rationale can be challenged and additional justification can be requested. Targeting and proportionality ensure that the impacts of the decision affect the specific phenomenon being regulated and minimize other effects. Governance systems that claim conformity to these principles are more likely to be able to rationalize their regulatory decisions in ways that will be accepted by the public and can therefore claim legitimacy according to discourse and throughput conceptions.

---

186 See Gibbons, *supra* note 58 at 83.

187 See e.g. UK, Better Regulation Task Force, *Principles of Good Regulation* (London: Her Majesty's Stationery Office, 2003), online: <webarchive.nationalarchives.gov.uk/20091111121217/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>.

Transparency is of particular interest in discussions of legitimacy, since it is necessary in order for the public to make a genuine assessment of the rationales and process behind regulatory decisions. Transparency has held a privileged place in the literature on "new" governance approaches that offer an alternative to democratization.[188] In theory, opening up regulatory processes to scrutiny creates an alternative mechanism of public input without compromising expert control over decision making and therefore protects a key source of power as described above.

The values of transparency and accountability are also gaining normative weight in the scientific community itself. The growth of the Open Science movement has advanced the idea that science should be more broadly comprehensible and collaborative.[189] Though the focus of Open Science is usually on knowledge generation rather than policy making, its rise demonstrates that the pull towards transparency and accountability exists within the scientific community. These values are reflected in growing demand for transparency in some of the world's most venerable expert bodies, such as the World Medical Association in its stewardship of the *Declaration of Helsinki* principles on human experimentation.[190]

The ISHGE process demonstrates a conscious effort to increase the transparency of its decision making. The Summit was broadcast online to thousands and presentation slides and video from the conference remain openly available online.[191] The conclusions of the Organizing Committee were accompanied by a summary of the Summit proceedings that presented diverging viewpoints on the usefulness and risks of gene editing.[192] The work of the Expert Committee was not accessible while they were prepar-

---

188 See Irwin, *supra* note 170 at 596.

189 See Benedikt Fecher & Sascha Friesike, "Open Science: One Term, Five Schools of Thought" in Sönke Bartling & Sascha Friesike, eds, *Opening Science: The Evolving Guide on How the Internet Is Changing Research, Collaboration and Scholarly Publishing* (Heidelberg: SpringerOpen, 2014) 17 at 19–25.

190 See Michael DE Goodyear, Karmela Krleza-Jeric & Trudo Lemmens, "The Declaration of Helsinki: Mosaic Tablet, Dynamic Document, or Dinosaur?" (2007) 335 BMJ 624 at 625.

191 See Olson, *supra* note 7 at 1; National Academies, "Summit", *supra* note 34.

192 Olson, *supra* note 7.

ing their findings, though their meetings and the speakers and stakeholder groups in attendance were openly publicized.[193]

The ISHGE's exercise in openness can be contrasted with events like the secret genome synthesis meeting that occurred around the same time at Harvard University.[194] This group met behind closed doors, with the hundreds of attendees pledged to secrecy about the proposed project which involved the chemical synthesis of a human genome. The public backlash once the meeting was inevitably outed was significant and demonstrates that the level of transparency witnessed at the Summit is not yet the norm. The scientific community must resist historical impulses to organize in the shadows and embrace emerging norms of transparency and public accountability if they are to be seen as legitimate regulatory actors.

It is worth noting, however, that increased transparency could have negative consequences for the credibility of governance processes if it lays bare the weakness of governance structures. When mistakes and inconsistencies become apparent to the public, the credibility of the governance process as a whole suffers, whether or not the outcome of the process is actually affected.[195] Some insight into the aforementioned phenomenon can be gleaned from the controversy, dubbed "Climategate," where emails between scientists working within the IPCC process were leaked.[196] The leak led to

---

193 See Lauren Scrudato, "Debate on Gene Editing Continues at Expert Committee Meeting", *Laboratory Equipment* (14 July 2016), online: <www.laboratoryequipment.com/news/2016/07/debate-gene-editing-continues-expert-committee-meeting>.

194 Interestingly, the meeting was much more controversial in foreign media than it was in the United States. Compare Andrew Pollack, "Scientists Talk Privately about Creating a Synthetic Human Genome", *New York Times* (13 May 2016), online: <https://www.nytimes.com/2016/05/14/science/synthetic-human-genome.html>; Pete Shanks, "Genome Games: A Secret Meet and a Controversy", *Deccan Chronicle* (22 May 2016), online: <www.deccanchronicle.com/technology/in-other-news/220516/genome-games-a-secret-meet-and-a-controversy.html>.

195 See e.g. Reiner Grundmann, "The Legacy of Climategate: Revitalizing or Undermining Climate Science and Policy?" (2012) 3 WIREs Climate Change 281 at 284 [Grundmann, "Legacy"]; Sheila Jasanoff, "Testing Time for Climate Science" (2010) 328 Science 695 at 696.

196 Reiner Grundmann, "'Climategate' and the Scientific Ethos" (2011) 38:1 Sci Technol Human Values 67 at 68–72.

widespread criticism and emboldened climate-denier groups, who used the emails to undermine the broadly accepted conclusion of scientific consensus regarding anthropogenic climate change.[197] Though this was the result of a leak, the same dangers could be imagined if processes are intentionally made transparent.

Conversely, it is perhaps even more dangerous for scientists and scientific organizations to attempt to pass off difficult judgment calls as objective truth in the hopes of maintaining credibility. In an increasingly interconnected world, it is inconceivable that scientific decision-making processes could be entirely hidden from public scrutiny, as the Climategate scandal helps to illustrate. Part of what made the leak so damaging was the sense of betrayal felt by the public at having been sold a story about the IPCC's objective rigor, and the objective rigor of science in general, when science cannot meet these expectations in a "post-normal" world, where "facts are uncertain, values in dispute, stakes high, and decisions urgent."[198] In short, while increased transparency in scientific decision-making processes carries the danger of undermined credibility, so too do futile attempts to seal away these processes from public scrutiny. Transparency, then, seems at best a partial solution to the legitimation of transnational scientific governance.

C. Embracing a policy role for scientific organizations

A critical consideration in the legitimation of the regulatory functions of scientific organizations is open communication, not just of the rationale behind policy choices but also regarding the organizations' policy-making role. If it is ineffective to simply open up scientific decision making and unsustainable to completely insulate it from this scrutiny, the only option is to more carefully mediate how the rationales for scientific decisions are communicated to the public. As demonstrated in the preceding Parts of this paper, scientific organizations have a key role to play in the regulation of emerging gene editing technologies. Scientific organizations should embrace this regulatory role, but they must explicitly communicate *why* they are doing so.

Specifically, scientific organizations need to communicate two distinct sets of additional rationale. First, it is important to clarify the distinct nature

---

197 See Grundmann, "Legacy", *supra* note 195 at 283.

198 *Ibid* at 286.

of their policy role. While scientists are accustomed to communicating purportedly neutral observations of the natural world,[199] in regulatory contexts they must openly communicate that their role is a subjective assessment of the desired policy outcomes from the perspective of the scientific community. In other words, when the scientific community voices its perspective on a policy issue, it must communicate that this is a *perspective* rather than a scientific truth. By separating their two roles in this way, scientific organizations may better insulate themselves from the accusation that they are passing off value-laden policy preferences as scientifically determined fact.

Second, these organizations must effectively communicate to the public the reasons for which the scientific perspective should be privileged within the particular regulatory space. This relates to Majone's conclusion that the legitimacy of non-state governance actors depends on their ability to foster public belief in their appropriateness for the regulatory tasks they undertake.[200] In this way, scientific organizations can maintain their authoritative position in the regulatory space despite having revealed their role as subjective regulatory actors. For instance, a persuasive case can be made, for all the reasons outlined in previous Parts, that the regulatory conclusions of scientific organizations should be taken seriously within the realm of gene editing, but this may be less true in contexts where scientific expertise is judged by the public to be less relevant.

The legitimacy of scientific organizations would be enhanced through the effective communication of these points to the public. As explored above, a key source of legitimation is discourse that builds normative consensus between policy makers and the public. This consensus can only be achieved if the role of the policy maker is also subject to the same rational assent.[201] By carving out an explicit policy role for science and justifying this role to the public, scientific actors can emerge from the black box and find their voice as legitimate regulatory actors. Of critical importance to this exercise is the ability of these organizations to effectively communicate with the public but, unfortunately, research shows that this has been a challenge.[202]

---

199 See Jasanoff, "Making Order", *supra* note 80 at 762.

200 *Supra* note 150 at 22.

201 See Steffeck, *supra* note 135 at 267.

202 See Alexander Gerber, "Science Caught Flat-Footed: How Academia Struggles with Open Science Communication" in Bartling & Friesike, *supra* note 189, 73 at 78.

The Open Science movement has awakened scientists to the need to revolutionize the way it communicates its role with the public. While data sharing and the absence of patent protection often take centre stage within the paradigm, the goal of the movement to strengthen science's public interface are equally important.[203] Open Science is about giving the public the tools to evaluate the conclusions of scientific work and about better communicating the details of the scientific process.[204] It has sparked conversation about increasing public accessibility and comprehensibility in science.[205] This extends to its policy role, where the scientific community must openly communicate to the public how it arrived at its policy conclusions, including non-objective factors, and in so doing provide the tools to engage in meaningful discourse.

Beyond public participation, good governance, and transparency, an alternative route to legitimation is the active and frank communication by scientific organizations of their policy role within the public discourse. In order to achieve this legitimation, the scientific community must improve its communication with the public. As the Open Science movement and the ISHGE itself demonstrate, there is renewed focus on improving this communication. This bodes well for the future role of transnational scientific organizations as legitimate regulatory actors.

Conclusion

The case of the ISHGE and emerging gene editing technology provides fertile ground for examining the role of transnational scientific organizations as regulatory actors. As presented here, the regulatory space for this technology is particularly ill-suited to formal legal regulation because of its transnational, highly technical, and dynamic character. I have argued that the ISHGE, in contrast, has the potential to be an important regulatory actor in the case of gene editing. Recognizing the role that scientific organizations play is critical to understanding the regulation of these emerging technologies.

The potential importance of scientific organizations in transnational governance is a phenomenon that deserves deeper engagement and study. In

---

203 See Fecher & Friesike, *supra* note 189 at 44.

204 See *ibid* at 25.

205 See *ibid* at 19.

particular, while the focus here has been on contrasting the ISHGE with formal legal actors, a complete understanding of this regulatory space requires a more comprehensive cataloguing of regulatory actors and their dynamics and interactions. In addition, while I have often spoken of the ISHGE or the scientific community as a cohesive regulatory actor, further insight could be gained from examining internal regulatory competition between different scientific actors. There is more to be done in bringing together transnational governance and sociology of science literature to understand biomedical regulation.

I have argued the ISHGE guiding principles and the Expert Committee's report may not only shape the behavior of scientists directly but may indirectly impact future formal legal regulation in this area through the phenomenon of discourse structuration. I have highlighted historical lessons from the *United Nations Declaration on Human Cloning*, which may have empowered the scientific community to strengthen this indirect pathway. However, only time will reveal the actual impacts of the ISHGE process on both scientific behavior and formal regulation and these impacts will provide important evidence for refining the theoretical assessment laid out here.

I have also argued that, like other informal regulatory actors, the ISHGE must inevitably confront challenges to its legitimacy, especially given its private, non-democratic nature. Building a conceptualization of legitimacy outside the state is an ongoing exercise and one to which the consideration of scientific actors brings unique insights that are inherent to the science-policy interface.

In order to confront these challenges, I have outlined and evaluated several potential strategies the ISHGE and similar actors could adopt. In this context, increasing public participation and transparency in order to increase legitimacy are unideal and incomplete solutions, respectively. I have argued that focusing on improving the public communication of the role and rationale behind scientific organizations as regulatory actors is an important element of legitimation that deserves additional attention. In particular, there is difficult work to be done in carving out an explicit policy role for scientific organizations and communicating the parameters of this role to the public in a way that enhances legitimacy, while preserving regulatory power. The effort to develop and improve communication across the science-public interface connects to the goals and principles of the Open Science movement, a link that deserves further exploration. Ultimately, while the degree to which the ISHGE and other scientific organizations will be successful in optimizing and sustaining their regulatory role remains to be seen, their work holds significant promise for the transnational regulation of science.

La fin des petits cigares au punch tropical : le Canada est-il exemplaire pour contrer les astuces de l'industrie du tabac?

*Marie-Eve Couture Ménard et Marie-Lynda Pierre-Louis**

L'industrie du tabac utilise depuis des décennies une panoplie d'additifs ayant des propriétés aromatiques ou autres, qu'elle incorpore à ses produits pour les rendre plus addictifs et plus attractifs, fidélisant ainsi ses consommateurs et en s'assurant une relève. Pour contrer cette pratique et protéger les jeunes du tabagisme, le Canada fut le premier pays dans le monde à interdire les additifs aromatisants dans certains produits du tabac, perpétuant sa réputation de pays exemplaire dans la réglementation des produits tabagiques. Mais alors qu'un foisonnement de nouvelles normes sur les additifs s'observe actuellement aux niveaux provincial et international, nous posons la question suivante : le Canada fait-il encore preuve d'exemplarité ? Nous démontrons que la portée de la loi canadienne fédérale est plus limitée que celle recommandée par les directives internationales élaborées après son

For decades, the tobacco industry has tactically manipulated the composition of its products by using additives of all kinds, including flavor additives, to make them more addictive and more appealing to consumers. To counter this practice and uphold public health, Canada was the first nation in the world to ban flavour additives in certain tobacco products, thereby upholding its reputation as an exemplary leader in the regulation of these products. Yet given the considerable proliferation of new provincial and international additive standards, we question whether Canada is still as exemplary as it once was. We demonstrate that the scope of the present federal law is more limited than international guidelines recommend. Moreover, and contrary to other regulations, it is reactive to industry practices which could undermine efforts to protect youth from smoking. However, re-

* Marie-Eve Couture Ménard, Professeure agrégée, Faculté de droit, Université de Sherbrooke. Marie-Lynda Pierre-Louis, avocate, diplômée de la maîtrise en Droit et politiques de la santé, Université de Sherbrooke. Nous tenons à remercier Fernand Lafleur, nos collègues Marie-Claude Desjardins et Mélanie Bourassa Forcier, ainsi que les examinateurs, pour leurs précieux commentaires.

Référence : Marie-Eve Couture Ménard et Marie-Lynda Pierre-Louis, « La fin des petits cigares au punch tropical : le Canada est-il exemplaire pour contrer les astuces de l'industrie du tabac? » (2019) 11 : 2 RD & santé McGill 141.

Citation: Marie-Eve Couture Ménard & Marie-Lynda Pierre-Louis, "La fin des petits cigares au punch tropical : le Canada est-il exemplaire pour contrer les astuces de l'industrie du tabac?" (2019) 11:2 McGill JL & Health 141.

adoption. De plus, contrairement à d'autres réglementations, la loi canadienne obéit à une logique réactive face aux pratiques de l'industrie, ce qui pourrait miner la protection des jeunes contre le tabagisme. Toute fois, les récentes mesures provinciales, à l'instar de la *Loi concernant la lutte contre le tabagisme* du Québec, compensent les faiblesses de la loi fédérale et contribuent à maintenir la réputation de chef de file du Canada.

cent provincial measures, such as Québec's new *Tobacco Control Act*, compensate for the gaps in the federal law and contribute to maintaining Canada's reputation as a leader in the wake of recent regulatory evolution.

Introduction

Le tabagisme est responsable de plus de sept millions de décès chaque année au niveau planétaire[1], dont environ 37 000 au Canada[2] et près de 13 000 au Québec[3], constituant la principale cause de décès évitables[4]. En 2012, le tabagisme était responsable de 5,7 % des dépenses mondiales en soins de santé et grugeait l'équivalent de 1,8 % du produit intérieur brut mondial[5]. Au Canada, la même année, les coûts associés au tabagisme étaient évalués à 17 milliards de dollars, dont 4,4 milliards en coûts directs de soins de santé[6]. Malgré leurs effets nocifs connus, les produits du tabac continuent d'être consommés. Selon les dernières données disponibles, près de 4,6 millions de canadiens fument[7]. Au Québec, ce nombre serait actuellement de plus de 1,4 million[8].

Usant de toute la créativité dont elle est capable, l'industrie du tabac manipule depuis longtemps la composition de ses produits pour les rendre plus addictifs et plus attractifs en y ajoutant des additifs de toutes sortes, fidélisant ainsi ses consommateurs et en s'assurant une relève. D'ailleurs,

---

1 Organisation mondiale de la Santé, « Tabagisme » (9 mars 2018), en ligne : <www.who.int/mediacentre/factsheets/fs339/fr/>.

2 Santé Canada, *Des assises solides, un objectif renouvelé : Aperçu de la Stratégie fédérale de lutte contre le tabagisme du Canada 2012-2017*, 23 janvier 2014 à la p 2, en ligne : <www.canada.ca/content/dam/canada/health-canada/migration/healthy-canadians/publications/healthy-living-vie-saine/tobacco-strategy-2012-2017-strategie-tabagisme/alt/tobacco-strategy-2012-2017-strategie-tabagisme-fra.pdf> [Santé Canada, « Des assises solides »].

3 Institut national de santé publique du Québec, « Le tabagisme au Québec », en ligne : <www.inspq.qc.ca/lutte-contre-le-tabagisme> [INSPQ, « Tabagisme »].

4 Organisation mondiale de la Santé, *WHO Report on the Global Tobacco Epidemic*, *2015: Raising Taxes on Tobacco*, Luxembourg, World Health Organization, 2015 à la p 15, en ligne : <apps.who.int/iris/bitstream/10665/178574/1/9789240694606_eng.pdf?>.

5 Mark Goodchild, Nigar Nargis et Edouard Tursan d'Espaignet, « Global Economic Cost of Smoking-Attributable Diseases » (2018) 27 : 1 Tobacco Control 58 aux pp 61–62.

6 Santé Canada, « Des assises solides », *supra* note 2.

7 *Ibid*.

8 INSPQ, « Tabagisme », *supra* note 3.

84 % des Canadiens qui ont déjà fumé l'ont fait avant l'âge de 18 ans et les trois quarts d'entre eux deviendront des fumeurs à vie[9]. En 2005, le Canada fut désigné comme ayant l'un des meilleurs régimes de réglementation des produits du tabac[10]. Parmi les pratiques exemplaires du pays, on a souligné le pouvoir du gouvernement fédéral de réglementer la fabrication des produits du tabac, incluant celui d'établir des normes pour les ingrédients s'y retrouvant[11], prévu dans la *Loi sur le tabac et les produits de vapotage*[12] fédérale. Perpétuant sa réputation de chef de file, le Canada est ensuite devenu en 2009 le premier pays au monde à interdire la présence d'additifs aromatisants dans certains produits du tabac[13], modifiant à cette fin sa *Loi sur le tabac*[14]. Par cette action, le Parlement du Canada visait à protéger les jeunes du tabagisme en réagissant à la mise en marché massive de petits cigares aux arômes de fruits, de chocolat, de gomme et de punch tropical, dont les ventes au pays sont passées, entre 2001 et 2008, de 53 millions d'unités à 469 millions d'unités, soit une augmentation de près de 900 %[15].

Depuis ce temps, des directives internationales ont été élaborées sous l'égide de l'Organisation mondiale de la Santé (OMS) concernant la réglementation des additifs contenus dans les produits du tabac[16]. De plus, les in-

---

9 Avis aux parties intéressées : Projet de décret modifiant l'annexe de la *Loi sur le tabac* (Menthol), (2016) Gaz C I, 1149 [Projet de décret, 2016].

10 Voir Organisation mondiale de la Santé, Groupe d'étude de l'OMS sur la réglementation des produits du tabac (TobReg), *Réglementation des produits du tabac : Rapport du Canada*, Organisation mondiale de la Santé, 2005 à la p v, en ligne : <apps.who.int/iris/bitstream/10665/43518/1/9242593958_fre.pdf>.

11 Voir *ibid* à la p 3.

12 LC 1997, ch 13 [*Loi sur le tabac*].

13 Voir *Décret modifiant l'annexe de la Loi sur le tabac*, CP 2015-753, (2015) Gaz C II, 149 [*Décret* 2015].

14 Voir *Loi modifiant la Loi sur le tabac*, LC 2009, c 27 ; *Loi sur le tabac*, *supra* note 12, arts 5.1, 5.2, Annexe 1.

15 « Projet de loi C-32, Loi modifiant la loi sur le tabac », 2e lecture, *Débats de la Chambre des communes*, 40e parl, 2e sess, vol 144, n° 066, (2 juin 2009), à la p 4079 [*Débats* 2009] ; Santé Canada, « Loi modifiant la Loi sur le tabac : Foire aux questions » (31 mars 2010), en ligne : <www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/federal/amend_faq-modif-fra.php#q3> [Santé Canada, *Foire aux questions*].

16 Organisation mondiale de la Santé, *Convention-cadre de l'OMS pour la lutte*

itiatives réglementaires en la matière se sont multipliées dans le monde : les États-Unis[17], l'Australie[18], le Brésil[19], l'Éthiopie[20], l'Union Européenne[21], la

---

antitabac : Directives pour l'application de l'article 5.3 ; de l'article 8 ; des articles 9 et 10; de l'article 11 ; de l'article 12 ; de l'article 13 ; de l'article 14, Organisation mondiale de la Santé, 2013, en ligne : <apps.who.int/iris/bitstream/10665/80515/1/9789242505184_fre.pdf> [OMS, *Directives partielles*].

17 Voir *Family Smoking Prevention and Tobacco Control Act*, Pub L No 111-31, § 907(a)(1)(A), 123 Stat 1775 (2009) (codifié tel que modifié dans plusieurs sections du 15 USC et du 21 USC) [*Family Smoking Act*]. Pour plus de détails, voir aussi les pp 159 et 164–65, ci-dessous. Concernant les initiatives américaines infranationales, voir Michael Freiberg, « The Minty Taste of Death: State and Local Options to Regulate Menthol in Tobacco Products » (2015) 64 : 4 Cath U L Rev 949 aux pp 958–74. La validité de certaines de ces normes demeure incertaine.

18 Pour un tableau présentant les différentes initiatives réglementaires australiennes jusqu'en 2011, voir Andrew Mitchell et Tania Voon, « Regulating Tobacco Flavors: Implications of WTO Law » (2011) 29 : 2 BU ILJ 383 à la p 423.

19 Voir Brésil, Ministério da Saúde, Agência Nacional de Vigilância Sanitária, *Resolução da diretoria colegiada – RDC n°14, de 15 de março de 2012*, 15 mars 2012 [Brésil, *Resolução da diretoria colegiada*]. Pour plus de détails, voir aux pp 163–64, ci-dessous.

20 Voir Ethiopian Food, Medicine and Healthcare Administration and Control Authority, *Tobacco Control Directive*, mars 2015, art 10(3), en ligne : <www.tobaccocontrollaws.org/files/live/Ethiopia/Ethiopia%20-%20Tobacco%20Ctrl.%20Dir.%20No.%2028_2015%20-%20national.pdf>. Voir aussi Organisation mondiale de la Santé, Groupe d'étude de l'OMS sur la réglementation des produits du tabac (TobReg), *Advisory Note: Banning Menthol in Tobacco Products*, Organisation mondiale de la Santé, 2016 à la p 49, en ligne : <apps.who.int/iris/bitstream/10665/205928/1/9789241510332_eng.pdf?ua=1> [TobReg, *Advisory Note*] (l'Éthiopie a interdit en 2015 la vente et la distribution de tout produit du tabac aromatisé, incluant les produits mentholés).

21 Voir CE, *Directive 2014/40/UE du Parlement européen et du Conseil du 3 avril 2014 relative au rapprochement des dispositions législatives, réglementaires et administratives des États membres en matière de fabrication, de présentation et de vente des produits du tabac et des produits connexes, et abrogeant la directive 2001/37/CE*, [2014] JO, L 127/1 à la p 2. La directive oblige les États membres à interdire, à partir de mai 2016, la mise sur le marché de produits du tabac contenant un « arôme caractérisant ». Pour le moment, cette interdiction ne vise que la cigarette et le tabac à rouler. La directive interdit également la mise sur le marché de produits du tabac contenant certains types d'additifs

Turquie[22] et le Chili[23] ont emboité le pas du Canada. Au sein même du Canada, depuis 2015, six provinces ont adopté des mesures législatives concernant les additifs dans les produits du tabac[24]. Au vu de ces développements législatifs foisonnants, nous posons la question suivante : le Canada est-il toujours un pays exemplaire en matière de réglementation de la composition des produits du tabac ? Nous entendons ici, par l'exemplarité, le respect des plus hauts standards de réglementation des additifs, tels que recommandés par les directives internationales en la matière, ou même l'adoption de mesures innovantes allant au-delà de ces recommandations.

À la lumière de ce questionnement, nous effectuons d'abord une analyse juridique et une critique de la *Loi sur le tabac* fédérale (ci-après la loi canadienne), législation centrale dans la reconnaissance de l'exemplarité du

---

ayant des propriétés colorantes, associés à la vitalité (par exemple la taurine) ou ayant des effets bénéfiques sur la santé (par exemple les vitamines). Par ailleurs, une période transitoire se terminant en 2020 est prévue pour étendre ces interdictions aux produits dont la part de marché est supérieure à 3 %, comme c'est le cas pour les cigarettes mentholées. Enfin, la directive rend possible l'interdiction éventuelle de produits contenant des additifs augmentant leur toxicité et leur pouvoir addictif. Au sein de l'Union européenne, la France avait déjà interdit depuis 2009 la vente, la distribution et l'offre de cigarettes aromatisées contenant certains ingrédients leur donnant une saveur sucrée ou acidulée, lorsque ces ingrédients sont présents en quantité supérieure à celle autorisée par la loi (voir *Décret n° 2009-1764 du 30 décembre 2009 relatif à la composition des cigarettes aromatisées dont la vente, la distribution ou l'offre à titre gratuit est interdite*, JO, 31 décembre 2009, 23309, art 1).

22 Voir TobReg, *Advisory Note*, *supra* note 20 à la p 50 (la Turquie interdira à compter de 2019 la fabrication de cigarettes et de tabac à rouler mentholés, une interdiction qui sera étendue à la vente de ces produits en 2020).

23 Voir *ibid* aux pp 49–50 (au Chili, un projet de loi interdisant la vente de tout produit du tabac mentholé a obtenu l'approbation du Sénat, mais nécessite l'aval de l'autre chambre et la signature du Président).

24 Il s'agit des provinces de Québec (2015), de l'Ontario (2015), du Nouveau-Brunswick (2015), de la Nouvelle-Écosse (2015), de l'Alberta (2015) et de l'Île-du-Prince-Édouard (2016). Voir *Loi concernant la lutte contre le tabagisme*, RLRQ c L-6.2, art 29.2 ; *Loi favorisant un Ontario sans fumée*, LRO 1994, c 10, art 6.1 ; *Loi sur les ventes de tabac et de cigarettes électroniques*, LN-B 1993, c T-6.1, art 2.1 ; *Tobacco Access Act*, SNS 1993, c 14, art 7(c)(d) ; *Tobacco and Smoking Reduction Act*, SA 2005, c T-3.8, art 7.4(2) ; *Tobacco and Electronic Smoking Device Sales and Access Act*, SPEI 1988, c T-3.1, art 3.1.

Canada en 2005 et en 2009. Malgré son titre de pionnière, la loi canadienne demeure peu étudiée dans la littérature eu égard aux mesures qu'elle prévoit en matière d'additifs contenus dans les produits du tabac. Outre une présentation éclairante mais sommaire de sa portée[25] et de son contexte d'adoption[26], elle a été étudiée dans une perspective de droit international du commerce[27]. Le regard que nous portons sur elle contribue quant à lui à mieux connaître cette réglementation dans une perspective de santé publique. Nous démontrons ainsi que sa portée en matière de contrôle des additifs est actuellement plus limitée que celle recommandée par les normes internationales. Aussi, contrairement à d'autres réglementations, elle obéit à une logique réactive face aux pratiques de l'industrie, ce qui pourrait s'avérer contreproductif pour protéger les jeunes du tabagisme. Cependant, les récentes mesures provinciales, à l'instar de la nouvelle loi québécoise, compensent les faiblesses de la loi canadienne et contribuent à perpétuer la réputation de chef de file du Canada.

Notons que le tabagisme, tout comme la santé plus généralement, ne fait pas l'objet d'une attribution constitutionnelle spécifique ; tant le Parlement que les législatures provinciales peuvent intervenir en la matière, dans leurs champs de compétences respectifs[28]. Ainsi, la Cour suprême du Canada a conclu que la *Loi sur le tabac* fédérale, prévoyant notamment des interdictions relatives à la publicité et à la promotion des produits du tabac, était un exercice valide de la compétence du Parlement en matière criminelle, visant à protéger les Canadiens des effets nocifs du tabac sur leur santé[29]. Dans une autre affaire, la Cour suprême a conclu qu'une loi provinciale pouvait chevaucher la *Loi sur le tabac* fédérale, en l'occurrence prévoir elle-aussi des interdictions en matière de promotion des produits du tabac, pour autant

---

25 Voir Barbara Von Tigerstrom, « Tobacco Control and the Law in Canada » dans Nola M Ries, Tracey M Bailey et Timothy Caulfield, dir, *Public Health Law and Policy in Canada*, 3e éd, Markham (Ont), LexisNexis, 2013, 355.

26 Voir Rob Cunningham, « Canada: Ban on Flavours » (2010) 19 : 1 Tob Control 4 (News Analysis) aux pp 4–5.

27 Voir Mitchell et Voon, *supra* note 18 ; Raphael Lencucha, Jeffrey Drope et Ronald Labonte, « Rhetoric and the Law, or the Law of Rhetoric: How Countries Oppose Novel Tobacco Control Measures at the World Trade Organization » (2016) 164 Social Science & Medicine 100.

28 Voir *RJR-MacDonald Inc c Canada (PG)*, [1995] 3 RCS 199 au para 32, 127 DLR (4e) 1 [*RJR-MacDonald*].

29 Voir *ibid*.

qu'il soit possible de se conformer aux deux textes de loi et que la loi provinciale n'entrave pas la réalisation de l'objet de la loi fédérale[30]. En outre, une loi provinciale peut être plus restrictive que la loi fédérale, afin de renforcer la réalisation de son objet.

Dans une première partie, nous abordons brièvement les pratiques de l'industrie du tabac relatives à l'utilisation d'additifs dans ses produits, avant d'examiner, dans une seconde partie, les normes internationales découlant de la *Convention-cadre de l'OMS pour la lutte antitabac* en matière de réglementation des additifs. Nous nous attardons ensuite à la loi canadienne, en cernant sa portée et l'approche qu'elle sous-tend dans le contrôle des additifs. Enfin, dans une quatrième partie, nous analysons la loi québécoise afin d'illustrer l'apport des mesures provinciales dans la réglementation de la composition des produits du tabac et dans le maintien de la réputation de chef de file du Canada en la matière. Notre analyse porte avant tout sur la cigarette traditionnelle, mais un aperçu de la réglementation entourant la cigarette électronique au Québec nous permet d'enrichir notre réflexion sur l'encadrement des additifs contenus dans les produits du tabac.

I. L'UTILISATION D'ADDITIFS PAR L'INDUSTRIE DU TABAC

La manipulation de la composition des produits du tabac pour moduler les habitudes tabagiques des consommateurs est une pratique de l'industrie qui a été découverte à la suite des grands procès américains contre les cigarettières survenus dans les années 1990, qui ont débouché sur la signature du *Master Settlement Agreement*[31] en 1998. Cet accord a permis aux autorités publiques d'accéder aux documents gardés secrets par l'industrie[32] et de

---

30 En cas d'incompatibilité entre les deux lois, la loi provinciale devient inopérante selon la doctrine de la prépondérance des lois fédérales. Voir *Rothmans, Benson & Hedges Inc c Saskatchewan*, 2005 CSC 13 aux paras 22, 25, [2005] 1 RCS 188 [*Rothmans*].

31 « Master Settlement Agreement » (1998), Public Health Law Center, en ligne : <http://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf> (accord signé par les 51 procureurs généraux américains et les six plus grandes compagnies de tabac de l'époque).

32 L'Université de Californie fait partie des institutions ayant publié ces données. Voir University of California San Francisco, *Truth Tobacco Industry Documents*, en ligne : <www.industrydocumentslibrary.ucsf.edu/tobacco/>.

constater l'incidence de la manipulation des produits du tabac sur la dépendance au tabagisme.

En outre, l'industrie manipule les propriétés des feuilles de tabac elles-mêmes en modifiant par exemple leur teneur en nicotine. Elle utilise aussi de nombreux additifs, c'est-à-dire des substances autres que le tabac qui ne sont pas essentielles à la fabrication de ses produits. L'ammoniaque, par exemple, permet d'augmenter la quantité de nicotine absorbée par le fumeur et d'en accroître la vitesse d'absorption, renforçant ainsi le pouvoir addictif des produits du tabac[33]. Toutefois, la majorité des additifs sert d'arômes[34] utilisés pour accroître le pouvoir attractif des produits de manière à impulser ou à faciliter les premières consommations. Parmi ces additifs, on retrouve, par exemple, des colorants, des vitamines, des saveurs et des arômes tels que fruit, bonbon, vanille, chocolat. Certaines de ces substances masquent les désagréments liés à l'usage des produits du tabac, notamment en supprimant le goût âpre ou en adoucissant l'irritation causée par la fumée[35]. Certains additifs, notamment le cacao et le menthol, pourraient même augmenter les pouvoirs attractif et addictif des produits du tabac[36]. Le menthol est un additif de longue date qui fait d'ailleurs l'objet d'une littérature abondante concernant ses effets sur les habitudes de consommation du tabac. À l'instar d'autres études[37], l'OMS souligne le rôle important que joue le

---

33 Voir Semira Gonseth et Jacques Cornuz, « Modification de la composition des cigarettes durant le XXe siecle : rôle de l'industrie du tabac et effet sur la dependance tabagique » (2009) 5 Rev Med Suisse 1468 à la p 1469 ; Jack E Henningfield, James F Pankow et Bridgette E Garrett, « Ammonia and Other Chemical Base Tobacco Additives and Cigarette Nicotine Delivery: Issues and Research Needs » (2004) 6 : 2 Nicotine Tob Res 199 à la p 203 (l'ammoniaque dilate les voies aériennes et facilite l'inhalation).

34 Voir Institut national de santé publique du Québec, *Projet de loi 44 : Lois concernant la lutte contre le tabagisme : Mémoire déposé à la Commission de la santé et des services sociaux*, par Annie Montreuil et al, Gouvernement du Québec 2015 à la p 35 [INSPQ, *Mémoire*].

35 Voir *ibid*.

36 Voir Natasha A Sokol, Ryan David Kennedy et Gregory N Connolly, « The Role of Cocoa as a Cigarette Additive: Opportunities for Product Regulation » (2014) 16 : 7 Nicotine Tob Res 984 à la p 984 ; Freiberg, *supra* note 17 à la p 954.

37 Voir par ex Coalition québécoise pour le contrôle du tabac, « Aromatisation des produits du tabac : camoufler les dangers mortels du tabac à l'aide de saveurs

menthol eu égard à l'attractivité des produits du tabac pour les jeunes et d'autres groupes cibles[38].

Par l'ajout d'additifs, l'industrie du tabac a donc une influence non négligeable sur les habitudes des consommateurs et sur le fléau du tabagisme[39]. La réglementation de la composition des produits du tabac, en l'occurrence des additifs utilisés par l'industrie, est donc une avenue incontournable de la lutte contre le tabagisme[40].

II. LES NORMES INTERNATIONALES EN MATIÈRE D'ADDITIFS

Les normes internationales relatives à la réglementation des additifs contenus dans les produits du tabac sont énoncées dans la *Convention-cadre de l'OMS pour la lutte antitabac* (*CCLAT*)[41] et ses directives. La *CCLAT* est un traité négocié sous l'égide de l'OMS en 2003, dont 181 états sont actuellement parties[42]. Il constitue un cadre contraignant pour la mise en œuvre de mesures de lutte antitabac par les États parties[43] et comporte à ce titre deux articles concernant la réglementation de la composition des produits du tabac. L'article 9 énonce que :

> *La Conférence des Parties*, en consultation avec les organismes internationaux compétents, *propose des directives* pour

---

agréables et amusantes » (janvier 2015), en ligne : <www.cqct.qc.ca/Documents_docs/DOCU_2015/DOCU_15_01_22_Aromatisation.pdf>.

38 Organisation mondiale de la Santé, Groupe d'étude de l'OMS sur la réglementation des produits du tabac (TobReg), *Rapport sur les bases scientifiques de la réglementation des produits du tabac : quatrième rapport d'un groupe d'étude de l'OMS*, 2012 aux pp 17–18, en ligne : <apps.who.int/iris/bitstream/10665/78071/1/9789242209679_fre.pdf>.

39 Voir *ibid* à la p 13.

40 Voir Organisation mondiale de la Santé, « Réglementation des produits du tabac », en ligne : <www.who.int/tobacco/industry/product_regulation/fr/>.

41 21 mai 2003, 2302 RTNU 167, art 10 (entrée en vigueur : 27 février 2005) [*CCLAT*].

42 Voir Organisation mondiale de la Santé, « Liste complète des signataires et des Parties à la Convention-cadre de l'OMS pour la lutte antitabac » (25 octobre 2017), en ligne : <www.who.int/fctc/signatories_parties/fr/>.

43 Voir *CCLAT*, *supra* note 41, arts 3, 5.

> les tests et l'analyse de la composition et des émissions des produits du tabac, et *pour la réglementation de cette composition* et de ces émissions. *Chaque Partie, adopte et applique*, sous réserve de l'approbation des autorités nationales compétentes, *des mesures* législatives, exécutives, administratives ou autres mesures efficaces concernant ces tests et analyses et *cette réglementation* [nos italiques][44].

Puis, selon l'article 10 de la Convention, chaque État partie doit adopter et appliquer des mesures exigeant des fabricants et des importateurs de produits du tabac qu'ils « communiquent aux autorités gouvernementales les informations relatives à la composition et aux émissions des produits du tabac »[45]. Également, selon cet article, chaque État partie doit prendre des mesures efficaces pour que le public soit informé sur les constituants toxiques des produits du tabac[46]. Les articles 9 et 10 de la *CCLAT* énoncent ainsi une marche à suivre à deux volets pour les États parties, mais nous nous concentrons sur le premier, à savoir la réglementation des pratiques de l'industrie eu égard à la composition de ses produits.

Pour mieux guider les États parties dans la mise en œuvre de ces deux articles, des directives ont été adoptées en 2010[47], soit les *Directives partielles pour l'application des articles 9 et 10 de la Convention-cadre de l'OMS pour la lutte antitabac*[48] (ci-après les *Directives partielles*). Bien que bonifiées en 2012[49], les directives sont toujours qualifiées de « partielles », car la tâche du groupe de travail chargé de les rédiger n'est pas achevée. Dans leur facture actuelle, elles abordent trois aspects reliés au contrôle de la composition des produits du tabac (article 9 de la *CCLAT*), à savoir : le potentiel incendiaire des cigarettes, les informations exigées des fabricants

---

44 *Ibid*, art 9. La Conférence des Parties est l'organe directeur de la Convention créé par l'article 23 du texte conventionnel. Elle regroupe tous les États parties à la *CCLAT*. Elle est chargée de promouvoir la mise en œuvre de la Convention par une action normative.

45 *Ibid*, art 10.

46 Voir *ibid*.

47 Voir Organisation mondiale de la Santé, « Quatrième session de la Conférence des Parties à la Convention-cadre de l'OMS pour la lutte antitabac », en ligne : <www.who.int/fctc/cop/sessions/fourth_session_cop/fr/>.

48 *Supra* note 16 à la p 33 et s.

49 *Ibid* à la p 33, n 1.

et la réglementation des additifs, laquelle nous intéresse plus particulièrement.

Ainsi, en ce qui concerne la réglementation des additifs, les *Directives partielles* énoncent des recommandations à l'égard des *ingrédients*[50] augmentant le *pouvoir attractif*[51] des produits du tabac. Elles recommandent que les États parties : (1) limitent ou interdisent l'utilisation d'ingrédients pouvant servir à améliorer le goût des produits du tabac (par exemple sucres, arômes comme le menthol, épices) ; (2) limitent ou interdisent l'utilisation d'ingrédients ayant des propriétés colorantes dans les produits du tabac ; (3) interdisent l'utilisation dans les produits du tabac d'ingrédients pouvant donner l'impression que ces produits ont un effet bénéfique sur la santé (par exemple vitamine C, extraits de fruits, oméga-3) ; et (4) interdisent l'utilisation dans les produits du tabac d'ingrédients associés à l'énergie et à la vitalité, tels que des composants stimulants (par exemple caféine, taurine)[52]. Ces recommandations ne font pas état d'une liste exhaustive d'ingrédients à contrôler, mais bien de catégories inclusives, en donnant des exemples d'ingrédients qui s'y retrouvent. De plus, les *Directives partielles*

---

50 *Ibid* à la p 35, art 1.3 (les ingrédients englobent le tabac lui-même, les composants comme le papier et le filtre, ainsi que les matériaux utilisés pour fabriquer ces composants, les additifs, les aides à la fabrication, les substances résiduelles laissées dans le tabac à la suite du stockage et du traitement et les substances qui migrent de l'emballage dans le produit, mais les contaminants ne font pas partie des ingrédients).

51 *Ibid* à la p 35, art 1.3 (l'attractivité « désigne des facteurs comme le goût, l'odeur et d'autres propriétés sensorielles, la facilité d'emploi, la souplesse du système de dosage, le coût, la réputation ou l'image, les risques ou les avantages présumés et d'autres caractéristiques d'un produit destinées à en encourager l'utilisation »).

52 *Ibid* aux pp 40–42, arts 3.1.2, 3.1.2.2. Voir aussi *ibid* aux pp 53–54, Appendice 3 (les *Directives partielles* énoncent ensuite une série de recommandations concernant la mise en œuvre de telles mesures; elles prodiguent, par exemple, les méthodes d'analyse nécessaires pour détecter, dans les produits du tabac, la présence d'ingrédients devant faire l'objet d'interdictions ou de limitations) ; *ibid* aux pp 46–48, arts 4.1-4.6 (d'autres recommandations concernent la nécessité de prévoir l'infrastructure et le budget nécessaires pour assurer le respect de la réglementation, ainsi que l'importance de prévoir des délais limites de conformité à une nouvelle réglementation ou encore des mesures d'inspections, de tests et d'échantillonnage) ; *ibid* à la p 46, art 4.1 (aussi, selon ces *Directives partielles*, les États devraient faire peser sur les fabricants et importateurs une responsabilité juridique en cas de violation des normes).

recommandent d'interdire ou de limiter ces catégories d'ingrédients dans les *produits du tabac*, c'est-à-dire sans distinction entre les différents produits disponibles tels que les cigarettes, les cigares, les cigarillos, la chicha, les feuilles d'enveloppe, le tabac à rouler, etc. Les normes internationales ont donc une très large portée quant aux ingrédients de type attractif que l'industrie utilise actuellement ou pourrait utiliser dans l'avenir et quant aux produits dans lesquels ceux-ci se retrouvent ou pourraient se retrouver éventuellement.

Les États parties devraient par conséquent adopter des réglementations très restrictives face aux pratiques de l'industrie, tant en termes d'additifs visés (de type attractif) que de produits du tabac ; cependant, ils bénéficient d'une certaine latitude. À l'égard des ingrédients pouvant améliorer le goût des produits ainsi que des colorants, les États parties peuvent interdire ou simplement limiter leur utilisation. S'agit-il de limiter la quantité d'un ingrédient donné ou encore d'interdire seulement certains ingrédients ? Les *Directives partielles* ne donnent pas de précision à ce sujet. Elles indiquent aussi que « [l]es Parties devraient introduire les mesures décrites dans la présente section [ingrédients (réglementation)], conformément à leur législation nationale et en tenant compte de leur situation et de leurs priorités nationales »[53]. Cela laisse une marge de manœuvre certaine aux États parties dans la portée qu'ils peuvent donner à leur réglementation. À cela s'ajoute le fait que les *Directives partielles* constituent seulement des « éléments d'orientation »[54], soit des normes non contraignantes. Les articles de la *CCLAT* sont quant à eux contraignants, mais l'article 9 oblige les États parties à adopter des mesures pour réglementer la composition des produits du tabac sans indiquer la manière précise de le faire. Dès lors, tout en se conformant à son obligation conventionnelle de réglementer la composition des produits du tabac, un État partie peut bien choisir quels ingrédients seront interdits ou limités et dans quels produits du tabac, s'en remettant à sa discrétion aux recommandations des *Directives partielles*. Une telle latitude laissée aux États parties les soumet à l'influence des groupes d'intérêts, en particulier de l'industrie du tabac. Néanmoins, *a contrario*, les États parties peuvent adopter des mesures qui vont au-delà des recommandations énoncées dans les directives[55].

---

53 *Ibid* aux pp 40–42, art 3.1.2.

54 *Ibid* à la p 34, art 1.2.1.2.

55 Voir par ex Brésil, *Resolução da diretoria colegiada*, *supra* note 19 aux arts 4, 6 (allant au-delà des recommandations internationales, la résolution brésilienne établit une quantité maximale de goudron, de nicotine et de monoxyde de car-

Par ailleurs, les *Directives partielles* sont muettes quant aux additifs qui augmentent le *pouvoir addictif* et la *toxicité* des produits du tabac et ne prévoient donc aucune recommandation concernant les additifs tels que l'ammoniaque. Elles indiquent toutefois que les substances de cette nature feront l'objet de recommandations ultérieurement[56]. Les défis scientifiques et les enjeux idéologiques entourant la réglementation des substances nocives contenues dans le tabac peuvent expliquer ce vide normatif. Comme l'indique von Tigerstrom :

> *It might seem that reducing the harm caused by tobacco products must be a good thing, but in fact the matter is not so clear. Since tobacco products have multiple toxic constituents and harmful effects, designing a product that reduces the overall health impact significantly is likely to be difficult. Even if a genuinely harm-reducing product could be developed, some experts fear that attempts to reduce the harm of tobacco consumption could undermine the central and ultimate goal of decreasing its prevalence*[57].

En effet, au-delà des défis scientifiques liés à la fabrication de produits du tabac moins nocifs, l'idée de rendre les produits du tabac moins dangereux ou moins addictifs ne fait pas l'unanimité, car l'application de l'approche de réduction des méfaits en matière de tabagisme[58] est controversée[59]. Par

---

bone que les cigarettes peuvent contenir et interdit la commercialisation de tout produit du tabac contenant de l'ammoniaque).

56 OMS, *Directives partielles*, *supra* note 16 à la p 34, arts 1.2.1.2–1.2.1.3.

57 Von Tigerstrom, *supra* note 25 à la p 356. Voir aussi Matthew L Myers, « Could Product Regulation Result in Less Hazardous Tobacco Products? » (2003) 3 : 1 Yale J Health Pol'y L Ethics 139.

58 Voir Denis Choinière, Byron Rogers et Murray J Kaiserman, « Concepts liés à la réduction des méfaits dans la lutte au tabagisme » (2007) 6 : 1 Drogues, santé & société 317 (l'approche de réduction des méfaits en matière de tabagisme se définit par le maintien de la consommation tabagique et par la limitation des risques de maladies liées au tabagisme).

59 Voir par ex David Sweanor et Adam R Houston, « Rethinking Nicotine: The Role of Public Health Law in Ending an Epidemic » (2015-16) 47 : 2 Ottawa L Rev 419 ; Mark Parascandola, « Tobacco Harm Reduction and the Evolution of Nicotine Dependance » (2011) 101 : 4 Am J Public Health 632 à la p 638 ; Sweanor et Grunberger, « The Basis of a Comprehensive Regulatory Policy for Reduced Harm Tobacco Products » (2008) 11 : 1 J Health Care L & Pol'y 83 à

exemple, l'élimination ou la limitation de la nicotine dans les produits du tabac, afin de contrer leur caractère addictif, soulève des doutes ; certains craignent que les fumeurs déjà dépendants consommeront davantage afin de compenser leur besoin de nicotine[60]. La Conférence des Parties de la *CCLAT* a d'ailleurs demandé au groupe de travail chargé de l'élaboration des *Directives partielles* de poursuivre son mandat par un processus étape par étape, « à mesure que de nouvelles expériences de pays et de nouvelles données scientifiques, médicales et autres deviendront disponibles »[61]. Notons que le Canada fait partie de ce groupe de travail, avec le Brésil, l'Union européenne et la Turquie[62].

---

la p 85 ; Laura Eggerston, « Harm Reduction Over Morals to Reduce Smoking Deaths » (2016) 188 : 1 CMAJ E16 ; Lynn T Kozlowski et David B Abrams, « Obsolete Tobacco Control Themes Can be Hazardous to Public Health: The Need for Updating Views on Absolute Product Risks and Harm Reduction » (2016) 16 : 1 BMC Public Health 1.

60 Voir Von Tigerstrom, *supra* note 25 à la p 357. Voir aussi Henningfield, Pankow et Garrett, *supra* note 33 à la p 130 (concernant la réglementation de la nicotine dans les produits du tabac).

61 Organisation mondiale de la santé, *Poursuite de l'élaboration des directives partielles pour l'application des articles 9 et 10 de la Convention-cadre de l'OMS pour la lutte antitabac : Rapport du groupe de travail*, 5e sess, FCTC/COP/5/9 (2012) 1 en ligne : <apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5_9-fr.pdf>. Il est également spécifié que le progrès dans la rédaction des directives dépendra de la validation des méthodes d'analyse chimique pour tester et analyser la composition et les émissions des cigarettes. Le progrès dépendra aussi des autres travaux entrepris par le groupe de travail chargé de la rédaction de directives relatives à l'application de l'article 13 de la *CCLAT*, concernant la publicité en faveur du tabac, la promotion et le parrainage (OMS, *Directives partielles*, *supra* note 16 à la p 34, n 3). Les liens entre les directives relatives aux article 9 et 10 et celles relatives à l'article 13 ne sont pas expliqués. Parmi les sections qui demeurent incomplètes au sein des *Directives partielles*, on retrouve notamment celles intitulées : « pouvoir addictif » (risque dépendogène), « toxicité », « constituants » (emploi des termes), « constituants » (information à communiquer), « constituants » (réglementation), « émissions », « surveillance », et « évaluation ».

62 Voir Organisation mondiale de la Santé, *Composition of the Intersessional Groups Currently Mandated by COP*, 2013, en ligne : <www.who.int/entity/fctc/treaty_instruments/Composition_WGs_after_COP5_24March2013_revOct2013.pdf?ua=1>.

III. LA LOI CANADIENNE : UNE ODEUR DE COMPROMIS

Depuis sa modification en 2009, la *Loi sur le tabac* interdit de fabriquer[63], d'importer, de distribuer et de vendre[64] au Canada des produits du tabac contenant des additifs énumérés en annexe de la loi[65]. La loi contient en effet une annexe où figure un tableau énumérant, dans une première colonne, treize additifs ou catégories d'additifs[66] et énumérant, dans une seconde colonne, les produits du tabac dans lesquels ces additifs sont interdits (voir en annexe). Par exemple, il est interdit de fabriquer, d'importer, de distribuer ou de vendre des cigarettes, des feuilles d'enveloppe ainsi que certains types de cigares qui contiennent un additif qualifié d'aromatisant par le Comité mixte FAO/OMS d'experts des additifs alimentaires. Il est également interdit, par exemple, de fabriquer, d'importer, de distribuer ou de vendre des cigarettes, des petits cigares[67], des feuilles d'enveloppe et un

---

63 Fabriquer « [e]st assimilé à l'acte de fabriquer le produit du tabac ou le produit de vapotage le fait de le distribuer, de l'importer, de l'emballer ou de l'étiqueter pour le vendre du Canada ». *Supra* note 12, art 2.

64 Vendre est « le fait de mettre en vente ou d'exposer pour la vente ». *Ibid*.

65 *Ibid*, arts 5.1, 5.2 (la loi proscrit aussi l'emballage des produits du tabac concernés d'une manière qui laisse croire qu'ils contiennent un des additifs visés en annexe de la loi) ; art 23.1 (il en va de même de la vente de produits emballés de cette façon).

66 *Ibid*, Annexe 1 (il s'agit des additifs ou catégories d'additifs suivants : (1) additif qui a des propriétés aromatisantes ou qui rehausse l'arôme ; (2) acides aminés ; (3) caféine ; (4) agents colorants ; (5) acides gras essentiels ; (6) fruits, légumes et tout produit obtenu par leur transformation ; (7) glucuronolactone ; (8) probiotique ; (9) épices, aromates et herbes ; (10) sucres et édulcorants ; (11) taurine ; (12) vitamines ; (13) minéraux nutritifs).

67 Petit cigare est défini comme:

> Rouleau ou article de forme tubulaire qui remplit les conditions suivantes :
>
> a) il est destiné à être fumé ;
>
> b) il comporte une tripe composée notamment de tabac naturel ou reconstitué ;
>
> c) il comporte soit une sous-cape et une cape, soit une cape qui sont composées notamment de tabac naturel ou reconstitué ;
>
> d) il comporte un bout-filtre de cigarette ou pèse au plus 1,4 gramme, sans le poids des embouts.

certain autre type de cigares qui contiennent de la caféine, de la taurine, des sucres ou encore des épices, et des fruits et des légumes[68].

A. La portée de la loi

La loi canadienne, dans son annexe, règlemente chacune des catégories d'ingrédients énoncées dans les *Directives partielles* de la *CCLAT* au niveau international[69], à savoir les ingrédients relatifs au goût (aromatisants), les colorants, ceux pouvant créer une impression que le produit a des effets bénéfiques sur la santé et ceux associés à l'énergie et à la vitalité. On note que la loi ne comporte aucune interdiction ni limite concernant les additifs augmentant la toxicité ou le pouvoir addictif des produis du tabac, comme l'ammoniaque ou le goudron[70] et ne s'inscrit donc pas dans une approche de réduction des méfaits ; d'ailleurs les normes internationales ne font aucune recommandation à cet égard pour le moment. Par conséquent, la portée de la loi canadienne en termes de catégories d'additifs visés semble aussi large que celle recommandée par les normes internationales. Deux nuances s'imposent toutefois.

Premièrement, certains arômes font l'objet d'une exception dans la loi[71]. Les arômes communément attribués au porto, au vin, au rhum ou au whisky

---

La présente définition vise aussi les produits du tabac que les règlements désignent comme des petits cigares. *Ibid*, art 2.

68 *Ibid*, Annexe 1.

69 OMS, *Directives partielles*, *supra* note 16 aux pp 40–42, art 3.1.2.2 (les ingrédients utilisés pour améliorer le goût : ceux ayant des propriétés colorantes, ceux pouvant créer l'impression que le produit a des effets bénéfiques sur la santé et ceux associés à l'énergie et à la vitalité).

70 La portée de la loi fédérale pourrait toutefois être élargie dans l'avenir pour s'étendre à ce type d'additifs, grâce au pouvoir réglementaire octroyé au gouvernement par l'article 5 de la *Loi sur le tabac*, *supra* note 12 : « Il est interdit au fabricant de fabriquer ou de vendre un produit du tabac qui n'est pas conforme aux normes établies par règlement. » Bien qu'à ce jour, aucun règlement n'ait été adopté en ce sens, l'article 7 indique que : « Le gouverneur en conseil peut prendre des règlements : a) établissant des normes concernant les caractéristiques des produits du tabac et de leurs émissions, notamment (…) concernant les quantités et concentrations des substances que peuvent contenir les produits et leurs émissions (…) ».

71 Voir *ibid*, Annexe 1, item 1.1.

sont permis dans un certain type de cigares[72]. Les normes internationales ne reconnaissent pourtant aucune exception à l'égard des ingrédients permettant d'améliorer le goût des produits du tabac. Aussi, jusqu'en octobre 2017, tout produit du tabac mentholé était d'ailleurs autorisé bien que cet additif était donné en exemple par les normes internationales à titre d'ingrédient à interdire ou à limiter. Cette exception a été réduite par un décret modifiant l'annexe de la loi en conséquence[73]. À la suite de ce décret de 2017, le menthol sera interdit dans la fabrication et la vente des cigarettes, des feuilles d'enveloppe et de la plupart des cigares[74]. Il faudra toutefois attendre la sanction du projet de loi S-5, en mai 2018, pour que le menthol soit finalement interdit dans *tous* les produits du tabac[75].

Deuxièmement, alors que les normes internationales en matière d'additifs visent tous les produits du tabac sans distinction, la loi canadienne vise certains produits (par exemple cigarettes, petits cigares, feuilles d'enveloppe et autres types de cigares). Ainsi, un produit qui n'est pas énoncé à l'annexe de la loi échappe aux interdictions prévues en matière d'additifs. Cela laisse une marge de manœuvre certaine à l'industrie, qui en a d'ailleurs profité par le passé. En effet, il fut noté que suite à l'adoption de la loi en 2009, l'industrie s'est stratégiquement soustraite à son application en fabriquant d'autres types de produits du tabac non visés dans l'annexe, mais contenant les mêmes arômes que ceux interdits[76]. Dans la vision de

---

72 Voir *ibid*.

73 Voir Santé Canada, *Initiative de réglementation : Décret visant à modifier l'annexe de la Loi sur le tabac (menthol) : Plan prospectif de la réglementation 2016-2018*, Ottawa, Santé Canada, 2017, en ligne : <www.canada.ca/fr/sante-canada/programmes/consultation-modifications-apporter-loi-tabac-qui-concerne-menthol/decret-modifiant-lannexe-loi-tabac-menthol.html >.

74 Voir *Décret modifiant l'annexe de la Loi sur le tabac (menthol)*, CP 2017-256, (2017) Gaz C II, 151 [*Décret* 2017] (« Cela entraînera l'interdiction de l'utilisation de ces additifs de menthol dans la fabrication des cigarettes, des feuilles d'enveloppe et de la plupart des cigares (petits cigares, cigares munis d'un papier de manchette, cigares munis d'une cape non apposée en hélice et cigares pesant plus de 1,4 g mais moins de 6 g, sans le poids des embouts) et de leur vente. Le retrait de l'exception pour le menthol signifiera également que l'interdiction de la promotion des additifs du menthol sur les emballages de produits de tabac sera applicable »).

75 *Loi sur le tabac*, *supra* note 12, Annexe 1, item 1.2.

76 Voir *Décret* 2015, *supra* note 13. Voir aussi INSPQ, *Mémoire*, *supra* note 34 ;

« protéger les jeunes des incitations à l'usage du tabac en réduisant encore plus la disponibilité de cigares aromatisés »[77], l'annexe de la loi canadienne a donc été modifiée en 2015[78] pour assujettir certains cigares aux interdictions visant les additifs, alors qu'ils y échappaient jusque-là faute d'entrer dans la définition de « petits cigares » au sens de la loi (lesdits cigares étant un peu plus gros)[79].

Bien qu'elle comporte des limites certaines, la portée de la loi canadienne demeure somme toute assez large comparativement à d'autres réglementations adoptées ailleurs dans le monde. Aux États-Unis, par exemple, seuls les additifs *aromatisants* sont interdits et ce, uniquement dans les cigarettes et ses parties constituantes. Lorsqu'ils sont présents en quantité suffisante pour être considérés comme des « characterizing flovor of tabacco product or tobacco smoke »[80], les additifs aromatisants sont interdits dans les cigarettes et leurs constituants ; autrement dit, leur quantité dans le produit ne devrait pas donner à ce dernier un goût prononcé autre que celui du tabac, comme un goût de fruit ou de bonbon[81]. Tout arôme ou saveur, artificiel ou naturel, autre que ceux du tabac, les herbes et les épices sont visés par

---

Décret modifiant l'annexe de la Loi sur le tabac, « Résumé de l'étude d'impact de la réglementation », (7 mars 2015) Gaz c I, vol 149, nº 10.

77 *Décret* 2015, *supra* note 13.

78 Voir *ibid* ; *Loi sur le tabac*, *supra* note 12, art 7.1(1) (« [l]e gouverneur en conseil peut, par décret, modifier l'annexe par adjonction, modification ou suppression :

a) du nom ou de la description d'un additif ou d'un produit du tabac;

b) d'une mention générale visant tous les produits du tabac, avec ou sans exception »).

79 *Décret* 2015, *supra* note 13. Avant le décret, seuls les « petits » cigares étaient visés par les interdictions concernant les arômes (voir *Loi sur le tabac*, *supra* note 12, art 2 pour la définition de « petit cigare »). Depuis le décret, les cigares munis d'une cape non apposée en hélice et les cigares avec papier de manchette sont également visés. Les caractéristiques physiques de ces nouveaux cigares les rendent semblables aux petits cigares ou aux cigarettes.

80 *Family Smoking Act*, *supra* note 17.

81 Voir Reinskje Talhout, Suzanne van de Nobelen et Anne S Kienhuis, « An Inventory of Methods Suitable to Assess Additive-Induced Characterizing Flavours of Tobacco Products » (2016) 161 Drug & Alcohol Depend 9 à la p 10.

cette interdiction[82], sauf le menthol[83]. Quant aux États membres de l'Union européenne, ils doivent interdire, depuis le mois de mai 2016, la mise sur le marché de produits du tabac contenant un « arôme caractérisant », ce qui rappelle la formulation américaine. Pour le moment, cette interdiction ne vise que la cigarette et le tabac à rouler ; une période transitoire est toutefois prévue jusqu'en 2020 pour étendre ces interdictions aux produits dont la part de marché est supérieure à 3 %, comme c'est le cas des cigarettes mentholées. Contrairement à la loi américaine et à la directive européenne, la loi canadienne n'exige pas que les additifs aromatisants interdits soient considérés comme « caractérisant » le produit dans lequel ils se retrouvent. De plus, les interdictions prévues à la loi canadienne concernent un éventail plus large de produits du tabac.

La portée actuelle de la loi canadienne demeure tout de même moins large que ne le recommandent les normes internationales. Or, comme l'indiquent ces dernières, les États parties adoptent des mesures en conformité avec leurs législations nationales, en tenant compte de leur situation et de leurs priorités nationales[84]. Nous pouvons considérer que ces contraintes façonnent une « approche » propre à chacun.

B. L'approche canadienne

Les limites à la portée de la loi canadienne découlent de la recherche d'un compromis entre deux intérêts, à savoir : la protection des jeunes contre le tabagisme[85] et la protection des droits individuels des fumeurs adultes, en l'occurrence leur liberté de choisir les produits qu'ils consomment. Le

---

82 Voir *Family Smoking Act*, *supra* note 17 (la loi donne des exemples d'additifs interdits, qui incluent notamment la fraise, le raisin, l'orange, le clou de girofle, le cacao, le chocolat, la cannelle, la cerise et le café).

83 Voir Freiberg, *supra* note 17 à la p 955. À l'origine, l'exception concernant le menthol serait issue d'un compromis nécessaire pour obtenir un appui suffisant pour adopter la législation fédérale; elle ne serait donc pas liée à un argument de santé publique. Cependant, cette exception serait aussi chargée politiquement, considérant qu'environ 75 % des fumeurs afro-américains consomment des cigarettes mentholées. Certains ont donc évoqué que cette exception est discriminatoire, envoyant le message que les jeunes afro-américains ont moins de valeur que les jeunes de race blanche.

84 Voir OMS, *Directives partielles*, *supra* note 16 aux pp 40–42, art 3.1.2.

85 Voir *Débats* 2009, *supra* note 15 à la p 4079.

gouvernement canadien indique expressément que l'exception concernant les arômes de whisky, de porto ou de vin – permis dans certains types de cigares – est prévue pour limiter l'effet de la loi sur la liberté de choix des adultes[86]. Lors de la modification de l'annexe de la loi en 2015, le gouvernement mentionnait d'ailleurs que « [l]e Décret permettra de faire face aux problèmes soulevés de la manière la plus efficace possible, tout en permettant aux adultes d'avoir accès aux cigares traditionnels aromatisés »[87].

Fondée sur un raisonnement similaire, l'exception qui visait le menthol jusqu'en octobre 2017 s'expliquait par le fait que la loi vise à protéger les jeunes en se concentrant sur les nouveaux produits du tabac aromatisés aux fruits et aux bonbons, comme les petits cigares, qui pourraient les inciter à fumer. Les cigarettes mentholées, qui sont sur le marché depuis longtemps (1920) et sont consommées par près de 2 % des fumeurs au pays, ont donc échappé jusqu'à tout récemment à cette logique[88]. D'ailleurs, lors des travaux parlementaires entourant l'adoption de la loi en 2009, il était mentionné que les connaissances scientifiques sur le rôle du menthol dans le renforcement des habitudes tabagiques étaient encore limitées[89]. Cependant, en 2016, dans son projet de décret visant à supprimer l'exception concernant le menthol, le gouvernement a affirmé que l'usage de cigarettes mentholées chez les jeunes était une source de préoccupation ; il a fait référence aux *Directives partielles* de la *CCLAT*, qui indiquent que cette substance est utilisée pour favoriser et entretenir le tabagisme[90]. Le gouvernement a également indiqué qu'une enquête menée en 2012-2013 révélait que l'usage de produits du tabac mentholés était le plus répandu chez les jeunes Canadiens qui sont déjà des fumeurs[91].

Nul doute que dans son décret de 2017 venant limiter les produits mentholés, le gouvernement réaffirme son objectif de protection des jeunes, dont le corollaire équivaut à permettre les additifs qui n'attirent pas cette partie

---

86 Voir *Décret* 2015, *supra* note 13.

87 *Ibid*.

88 Voir Santé Canada, *Foire aux questions*, *supra* note 15, Réponse 7.

89 Voir « Projet de loi C-32, Loi modifiant la loi sur le tabac », 3e lecture, *Débats de la Chambre des communes*, 40e parl, 2e sess, vol 144, n° 077 (17 juin 2009) à la p 4749.

90 Projet de décret, 2016, *supra* note 9 à la p 1150.

91 Voir *ibid*.

de la population et à respecter ainsi la liberté des fumeurs adultes de choisir le produit qu'ils souhaitent consommer. La crainte de s'exposer à une contestation judiciaire pour une possible violation de la *Charte canadienne des droits et libertés*[92] et, ce faisant, celle de retarder l'application des mesures pourrait bien expliquer ce choix législatif qui résulte en une portée plus limitée de la loi[93] ; de surcroit, ce choix pourrait aussi s'expliquer par le souci d'éviter une contestation judiciaire au niveau international[94]. Mais l'on peut se questionner également sur la possibilité qu'il dissimule en réalité un souci de ne pas brimer outre mesure les intérêts de l'industrie. Quoiqu'il en soit, le compromis que sous-tend la loi nous apparaît dangereux, car il implique de départager les substances et les produits du tabac qui attirent les jeunes de ceux qui ne le font pas, donnant ainsi une occasion à l'industrie de mettre sur le marché de nouveaux produits pour lesquels il n'existe pas encore de données concernant leur pouvoir attractif chez les jeunes. Dans un document explicatif portant sur la modification de la loi en 2009, le gouvernement indique que :

> L'interdiction des arômes (sauf le menthol) dans les petits cigares, les cigarettes et les feuilles d'enveloppe touche une part importante du marché des produits aromatisés et envoie un message important aux fabricants de produits du tabac à l'effet que le marketing *visant les jeunes* ne sera pas toléré. *Santé Canada continuera de surveiller les nouvelles tendances* en ce qui concerne les autres produits du tabac et prendra les mesures qui s'imposent [nos italiques][95].

Comme ce passage en témoigne, le compromis sous-jacent à la loi canadienne tend à favoriser une logique réactive face aux pratiques innovan-

---

92 *Charte canadienne des droits et libertés*, partie I de la *Loi constitutionnelle de 1982*, constituant l'annexe B de la *Loi de 1982 sur le Canada* (R-U), 1982, c 11 [*Charte*].

93 *Débats* 2009, *supra* note 15 à la p 4087. La députée du NPD Judy Wasylycia-Leis, très influente dans l'élaboration du projet de loi, a mentionné que : « [l]'une des lacunes a trait au fait qu'il [le projet de loi] vise la plupart des saveurs, mais pas le menthol, puisque le menthol existe depuis les années 1920. Nous aurions bien voulu que le projet de loi bloque toutes [sic] les échappatoires (…) mais nous devons avancer. Nous ne pouvons simplement nous contenter d'argumenter sans rien faire. »

94 Voir par ex Mitchell et Voon, *supra* note 18 à la p 385.

95 Santé Canada, *Foire aux questions*, *supra* note 15, Réponse 8.

tes de l'industrie. Dans le souci de protéger la liberté des fumeurs adultes, il est nécessaire de surveiller les tendances de l'industrie pour n'agir que lorsqu'elles affectent les jeunes, c'est-à-dire par à-coups. Cela laisse une marge de manœuvre à l'industrie, qui a le loisir de mettre sur le marché de nouveaux produits et d'attendre que le gouvernement réagisse. Cette approche réactive s'est traduite dans le choix d'interdire les additifs seulement dans *certains* produits du tabac et d'en ajouter de nouveaux à la liste en annexe, au besoin ; la loi confère d'ailleurs au gouverneur en conseil le pouvoir de modifier l'annexe de la loi au moyen d'un décret[96]. La logique de protection des jeunes sur laquelle se fonde la loi peut donc nuire elle-même aux efforts de prévention du tabagisme chez cette population, comme cela a été constaté lors de la mise en marché de cigares aromatisés qui échappaient aux interdictions de la loi entre 2009 et 2015.

Ailleurs dans le monde, d'autres réglementations traduisent une logique plus proactive, permettant d'appliquer la loi *de facto* aux nouvelles pratiques de l'industrie. Au Brésil, par exemple, une résolution de l'Agência Nacional de Vigilância Sanitária (ANVISA) a interdit en 2012 la commercialisation de tout produit fumigène dérivé du tabac contenant un ou des additifs proscrits par celle-ci[97]. Les différentes catégories d'additifs de type attractif qui y sont énumérées[98] couvrent en totalité celles des *Directives partielles* de la *CCLAT* au niveau international[99] et sont tout aussi inclusives, ne se limitant pas à une liste exhaustive d'ingrédients interdits. Le Brésil est d'ailleurs le premier pays au monde à avoir interdit le menthol comme additif[100]. De

---

96 Voir *Loi sur le tabac*, *supra* note 12, art 7.1.

97 Voir Brésil, *Resolução da diretoria colegiada*, *supra* note 19.

98 *Ibid*, art 6. Cette interdiction vise autant la commercialisation de produits du tabac fabriqués au pays que de produits importés. Les additifs proscrits incluent : (1) les substances synthétiques ou naturelles avec des propriétés de saveur ou arôme de produit ; (2) les technologies de soutien pour les arômes et les saveurs ; (3) les additifs avec des propriétés nutritionnelles (par exemple les acides aminés, les vitamines et les acides gras essentiels) ; (4) les additifs associés à de supposées propriétés stimulantes ou revigorantes (par exemple la caféine et la taurine) ; (5) les colorants ; (6) les fruits et végétaux ; (7) les édulcorants ; (8) les assaisonnements, herbes, et épices ; (9) les substances qui améliorent le goût ; et (10) l'ammoniaque.

99 OMS, *Directives partielles*, *supra* note 16 aux pp 40–42, arts 3.1.2, 3.1.2.2.

100 Voir Tobacco Control Legal Consortium, « Brazil and Chile Pass Historic Laws Prohibiting Flavored Additives in Tobacco Products », *Legal Update* (Print-

plus, la résolution brésilienne prévoit que les additifs de type attractif sont interdits dans tout produit fumigène dérivé du tabac[101], ne faisant donc aucune distinction entre les produits comme la cigarette, le tabac à rouler ou autres. Cette formulation large permet d'inclure *de facto* les produits fumigènes dérivés du tabac, actuels et futurs. Ladite résolution a d'ailleurs fait du Brésil un chef de file en matière d'interdiction d'additifs dans les produits du tabac. Bien que l'industrie du tabac ait contesté la résolution et que celle-ci ait été suspendue temporairement en 2013 par la Cour suprême[102], cette dernière a finalement rendu jugement en février 2018, décidant en faveur du maintien de la résolution brésilienne[103].

Par ailleurs, depuis 2009 aux États-Unis, un fabricant doit obtenir une autorisation de la Food and Drug Administration (FDA) préalablement à la commercialisation de tout nouveau produit du tabac ou de tout produit du tabac existant mais ayant subi une modification, notamment lorsque cette nouveauté ou cette modification est associée à l'utilisation d'un ingrédient (« *premarket application* »)[104]. Dans le cadre de son processus d'évaluation

---

emps 2013) 2, en ligne : <www.publichealthlawcenter.org/sites/default/files/resources/tclc-legal-update-spring-2013.pdf>.

101 Brésil, *Resolução da diretoria colegiada*, *supra* note 19, art 6 (la cigarette électronique est toutefois exclue).

102 Voir TobReg, *Advisory Note*, *supra* note 20 à la p 49. Voir aussi Tânia Maria Cavalcante et al, « Brazil: Balance of the National Tobacco Control Policy in the Last Decade and Dilemmas » (2017) 33 : 3 Cadernos de Saúde Pública, à la p 7, en ligne : <www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-311X2017001503001&lng=en&nrm=iso&tlng=en>.

103 Voir Tobacco Control Laws, *National Confederation of Industry (Confederaçao Nacional da Industria) v. ANVISA, Litigation by Country*, en ligne : <www.tobaccocontrollaws.org/litigation/decisions/br-20180201-national-confederation-of-indu> (« Although the decision is not binding because of a lack of quorum, it is unlikely that subsequent challenges to the regulation would be decided differently »).

104 *Family Smoking Act*, *supra* note 17, § 910. La loi définit un « new tobacco product » comme suit :

> A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
>
> (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constitu-

préalable, la FDA vérifie si ledit produit respecte certaines exigences de santé publique pour décider d'en autoriser la commercialisation ou non[105]. Le processus d'évaluation commence par l'envoi par un fabricant d'une demande au secrétaire de la FDA, qui dispose d'un délai maximum de 180 jours pour analyser ladite demande. Trois choix s'offrent alors au secrétaire de la FDA : il peut émettre une ordonnance selon laquelle le nouveau produit peut être introduit sur le marché américain ; il peut prévoir des restrictions sur la vente et la commercialisation du nouveau produit, tout en autorisant sa mise en marché ; enfin, il peut émettre une ordonnance selon laquelle le nouveau produit ne peut pas être introduit sur le marché dans l'une au l'autre des situations suivantes :

> *A. [T]here is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;*
>
> *B. the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);*
>
> *C. based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or*
>
> *D. such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.*[106]

---

ent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

105 Voir US Food and Drug Administration, « The Facts on the FDA's New Tobacco Rule, New Hampsire: USFDA » (16 juin 2016), en ligne : <www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm> (pour plus d'informations sur l'autorisation de mise en marché des nouveaux produits du tabac). Voir aussi Corinne G Husten et Lawrence R Deyton, « Understanding the Tobacco Control Act: Efforts by the US Food and Drug Administration to Make Tobacco-Related Morbidity and Mortality Part of the USA's Past, Not Its Future » (2013) 381 : 9877 Lancet 1570 aux pp 1572–73.

106 *Family Smoking Act*, *supra* note 17, § 910 (c) (2).

La loi canadienne, bien qu'elle ne traduise pas une telle logique proactive dans sa posture actuelle, comporte néanmoins une disposition depuis 2009 qui ouvre la porte à cette façon de réglementer les additifs :

> 7.1 (1) Le gouverneur en conseil peut, par décret, modifier l'annexe 1 par adjonction, modification ou suppression :
>
> a) du nom ou de la description d'un additif ou d'un produit du tabac ;
>
> b) d'une *mention générale visant tous les produits du tabac, avec ou sans exception*.
>
> (2) L'additif ou le produit du tabac peut être décrit par renvoi à un document produit par un organisme ou une personne autre que le ministre, soit dans sa version à une date donnée, soit avec ses modifications successives [nos italiques][107].

Ainsi, le gouvernement fédéral a le pouvoir d'interdire tout additif d'un certain type dans tout produit du tabac, actuel ou éventuel, à l'image de ce qui a été fait ailleurs dans le monde, mais également à l'image de ce qu'a fait le législateur québécois. C'est presque dix années après l'inclusion de cette disposition dans la loi que le gouvernement s'en est prévalue, eu égard au menthol et au clou de girofle[108].

IV. LA LOI QUÉBÉCOISE : UNE APPROCHE PLUS AUDACIEUSE

Dans le Décret de 2015 modifiant l'annexe de la *Loi sur le tabac*, le gouvernement fédéral indique que plusieurs provinces ont un pouvoir de réglementation leur permettant d'interdire ou de limiter l'utilisation d'additifs dans les produits du tabac et qu'ainsi, « [l]e Décret imposera des mesures de restriction minimales sur des types précis de cigares aromatisés qui sont offerts sur le marché canadien »[109]. Ce passage illustre bien le partage des compétences qui prévaut en matière de lutte contre le tabagisme au Canada[110], de même que la possibilité pour les provinces de compléter les

---

107 *Loi sur le tabac*, *supra* note 14, art 7.1.

108 Voir *ibid*, Annexe 1, items 1.2, 9.1.

109 *Décret* 2015, *supra* note 13.

110 Voir Barbara von Tigerstrom, « Canada », dans Tania Voon, Andrew D Mitchell

mesures fédérales et renforcer le contrôle des additifs. Le législateur de la Nouvelle-Écosse, par exemple, est la première autorité compétente dans le monde à avoir interdit le menthol dans les produits du tabac[111]. Tout comme cette province et quatre autres d'entre elles[112], le Québec s'est doté d'une mesure législative qui illustre le rôle important que peut jouer ce palier de gouvernement.

A. La portée de la loi

En 2015, le législateur québécois a adopté une mesure législative en matière d'arômes et de saveurs contenus dans les produits du tabac, qui est entrée en vigueur le 26 mai 2016. Selon cette mesure :

> 29.2 Il est interdit de vendre, d'offrir en vente ou de distribuer *un produit du tabac comportant une saveur ou un arôme autre que ceux du tabac, notamment* ceux liés au menthol, à un fruit, au chocolat, à la vanille, au miel, aux bonbons

---

et Jonathan Liberman, dir, *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues*, New York, Routledge, 2014, 212 aux pp 220–21.

111 Marc Montgomery, « World First: All Flavoured Tobaccos Banned in Nova Scotia », *Radio Canada International* (1 juin 2015), en ligne : <www.rcinet.ca/en/2015/06/01/world-first-all-flavoured-tobaccos-banned-in-nova-scotia/>.

112 En Ontario, la *Loi favorisant un Ontario sans fumée*, *supra* note 24, interdit depuis 2010 la vente, la mise en vente, la distribution, et l'offre de distribution des cigarillos aromatisés et des produits du tabac aromatisés au détail ou en vue d'une vente au détail, sauf si de tels cigarillos ou produits du tabac ont été prescrits (voir aussi Règl de l'Ont 48/06, art 11.1). Au Nouveau-Brunswick, la *Loi sur les ventes de tabac et de cigarettes électroniques*, *supra* note 24, art 2.1, interdit depuis 2015 de « vendre ou de permettre la vente de tabac ou bien qui est présenté comme étant aromatisé, entre autres par son emballage, dans la publicité ou autrement, ou bien qui contient un agent aromatisé, dont le menthol ». À l'Île-du-Prince-Édouard, le *Tobacco and Electronic Smoking Device Sales and Access Act*, *supra* note 24, art 3.1 prévoit depuis 2015 que « No person shall sell or offer to sell tobacco that contains a prescribed flavouring agent ». En Nouvelle-Écosse, le *Tobacco Access Act*, *supra* note 24, art 7(c)(d), interdit depuis 2015 la vente du tabac aromatisé et du papier à cigarettes aromatisé, mais prévoit certaines exemptions réglementaires (voir aussi *Tobacco Access Regulations*, NS Reg 9/96, art 8). En Alberta, le *Tobacco and Smoking Reduction Act*, *supra* note 24, art 7.4(2), interdit depuis 2013 de vendre ou d'offrir de vendre des produits du tabac aromatisés (voir aussi *Tobacco Reduction Regulation*, Alta Reg 240/2007, art 10.2(2)).

> ou au cacao, ou dont l'emballage laisse croire qu'il s'agit d'un tel produit [nos italiques][113].

Désormais, la loi québécoise est donc plus restrictive que la loi fédérale en matière de produits du tabac aromatisés, car contrairement à la loi canadienne qui prohibe l'utilisation de *certains* arômes et saveurs dans certains produits du tabac (incluant des exceptions), la nouvelle disposition québécoise vise quant à elle *tout* arôme et saveur sans exception, dans *tout* produit du tabac sans distinction. Dès lors, le Québec a choisi d'interdire la vente de certains produits sur son territoire alors qu'ils sont ou étaient encore permis au niveau fédéral, notamment tout produit mentholé et tout type de cigare aromatisé, visant ainsi le renforcement de la lutte contre le tabagisme.

Toutefois, la nouvelle interdiction québécoise ne s'applique pas aux cigarettes électroniques (avec ou sans nicotine) ni aux produits du tabac fabriqués au Québec et destinés exclusivement à l'exportation[114]. L'exception concernant la cigarette électronique peut surprendre à première vue, considérant que la *Loi visant le renforcement de la lutte contre le tabagisme* de 2015 « étend par ailleurs le champ d'application de la Loi sur le tabac à la cigarette électronique en assimilant cette dernière au tabac »[115]. Les interdictions visant les produits du tabac et relatives à l'usage (lieux interdits), à la vente (aux mineurs notamment), à l'affichage, à l'étalage, à la publicité et à la promotion s'appliquent donc à la cigarette électronique. À cet égard, les effets de ce produit sur la santé sont encore peu connus[116] ; surtout, la

---

113 *Loi concernant la lutte contre le tabagisme*, *supra* note 23, art 29.2.

114 *Ibid*, art 29.3. Outre des considérations relatives aux compétences provinciales, cela paraît logique dans la mesure où l'objectif du nouvel article 29.2 de la loi est de limiter l'accès à ce type de produits sur le territoire de la province.

115 PL 44, *Loi visant le renforcement de la lutte contre le tabagisme*, 1e sess, 41e lég, Québec, 2015, Notes explicatives (sanctionné le 26 novembre 2015), LQ 2015, c 28. Il s'agit de la loi qui a modifié la *Loi sur le tabac* en 2015, laquelle s'intitule maintenant *Loi concernant la lutte contre le tabagisme*. Depuis l'adoption de la *Loi visant à renforcer la lutte contre le tabagisme*, la cigarette électronique (avec ou sans nicotine) est assujettie aux mêmes règles que celles visant les produits du tabac, à quelques exceptions près. Voir *Loi concernant la lutte contre le tabagisme*, *supra* note 24, art 20.3.2 (lequel prévoit une possibilité d'exemption pour les cigarettes électroniques en matière d'étalage).

116 Voir INSPQ, *Mémoire*, *supra* note 34 à la p 6. Selon l'INSPQ :

> [u]n consensus se dégage de plus en plus parmi les experts à l'effet que la cigarette électronique serait beaucoup moins dom-

cigarette électronique pourrait constituer un instrument de « passerelle » et de « renormalisation » du tabagisme, minant du coup les efforts consentis jusqu'ici pour le dénormaliser[117]. D'ailleurs, une étude de l'INSPQ réalisée entre 2012 et 2013 révèle que 34 % des élèves du secondaire ont déclaré avoir déjà fait usage de la cigarette électronique[118] ; puis, selon une enquête canadienne, la proportion d'élèves ayant déjà utilisé une cigarette électronique était de 20 % en 2014-2015 et a augmenté à 23 % en 2016-2017[119]. De plus, il est estimé qu'entre 2014 et 2030, les ventes de cigarettes électroniques au niveau mondial se seront multipliées par 17[120]. Ainsi, pour éviter le phénomène de renormalisation du tabagisme, il est interdit au Québec, depuis 2015, de vapoter dans les lieux où il n'est pas permis de fumer et de vendre des cigarettes électroniques aux mineurs (avec ou sans nicotine).

En revanche, la cigarette électronique se présente comme un instrument incitatif de cessation tabagique qui serait moins nocif que la cigarette con-

---

> mageable pour la santé des fumeurs que la cigarette conventionnelle. (…) Les effets sur la santé de l'exposition à long terme à l'aérosol des cigarettes électroniques sont toutefois mal connus, tant pour les utilisateurs que pour les personnes exposées.

Voir aussi Institut national de santé publique du Québec, *La cigarette électronique : État de situation*, par Hélène Poirier, Gouvernement du Québec, 2013, en ligne : <www.inspq.qc.ca/pdf/publications/1691_CigarElectro_EtatSituation.pdf> [INSPQ, *État de situation*].

117 Organisation Mondiale de la Santé, Convention-cadre de l'OMS pour la lutte antitabac, *Inhalateurs électroniques de nicotine : Rapport de l'OMS*, (21 juillet 2014) OMS Doc FCTC/COP/6/10 aux pp 10–14, en ligne : <apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-fr.pdf> [OMS, *Inhalateurs électroniques*].

118 Institut national de santé publique du Québec, *L'usage de la cigarette électronique chez les élèves québécois du secondaire : 2012-2013*, par Benoit Lasnier et Annie Montreuil, Numéro 11, Gouvernement du Québec, 2014 à la p 1, en ligne : <www.inspq.qc.ca/pdf/publications/1917_Cigarette_Electronique_Eleves_Secondaire.pdf>.

119 Voir Santé Canada, *Résumé des résultats de l'Enquête canadienne sur le tabac, l'alcool et les drogues chez les élèves (ECTADE) 2016-2017*, Ottawa, Santé Canada, 2018, en ligne : <www.canada.ca/fr/sante-canada/services/enquete-canadienne-tabac-alcool-et-drogues-eleves/sommaire-2016-2017.html> [Santé Canada, *Résumé des résultats 2016-2017*].

120 OMS, *Inhalateurs électroniques*, *supra* note 117 à la p 2.

ventionnelle[121]. À ce titre, donnant foi aux représentations faites notamment par les pneumologues, les parlementaires ont convenu de permettre la vente de cigarettes électroniques aromatisées, en l'occurrence aux *adultes*, dans l'optique que les fumeurs actuels de cigarettes traditionnelles aromatisées se tournent vers ce nouveau produit considéré comme moins nocif, à défaut de cesser leur consommation[122]. Ainsi, l'exception concernant les cigarettes électroniques aromatisées traduit un choix législatif important par les parlementaires québécois, qui ont fait une place à l'approche de réduction des méfaits en matière de tabagisme. Toutefois, si l'on en venait à constater que les cigarettes électroniques aromatisées minent les efforts de santé publique et contribuent notamment à la hausse du tabagisme dans la population, le gouvernement pourra, par voie réglementaire, assujettir ces dernières à la nouvelle interdiction relative aux saveurs et aux arômes, prévue pour les produits du tabac[123]. Enfin, il est intéressant de noter que le Comité permanent de la Santé de la Chambre des communes du Canada s'est penché en 2015 sur un éventuel cadre réglementaire fédéral sur les cigarettes électroniques[124]. Il recommandait d'interdire la vente de ce produit aux mineurs et d'autoriser les cigarettes électroniques aromatisées dans une optique de réduction des méfaits, tout comme au Québec. Cependant, il recommandait aussi d'« interdire le recours à des arômes de liquides de cigarettes électroniques conçus spécifiquement pour plaire aux jeunes comme les saveurs de bonbons »[125], une avenue que n'a pas choisie le législateur québécois.

---

121 Voir *ibid* aux pp 7–9 ; INSPQ, *État de situation*, *supra* note 116 aux pp 25–27.

122 Voir Québec, Assemblée nationale, *Journal des débats de la Commission permanente de la santé et des services sociaux*, 41e lég, 1re sess, vol 44, n° 131 (24 novembre 2015) à la p 8057 ; Québec, Assemblée nationale, *Journal des débats de la Commission permanente de la santé et des services sociaux*, 41e lég, 1re sess, vol 44, n° 87 (12 novembre 2015) à la p 29 [*Journal des débats*, 12 novembre 2015].

123 Voir *Loi visant à renforcer la lutte contre le tabagisme*, *supra* note 115, art 32(2). Voir aussi *Journal des débats*, 12 novembre 2015, *supra* note 122, à la p 7.

124 Comité permanent de la Santé de la Chambre des Communes du Canada, *Vapotage : vers l'établissement d'un cadre réglementaire sur les cigarettes électroniques*, 41e légis, 2e sess (mars 2015), en ligne : <publications.gc.ca/collections/collection_2015/parl/xc62-1/XC62-1-1-412-9-fra.pdf>.

125 *Ibid* à la p 28. PL S-5, *Loi modifiant la Loi sur le tabac, la Loi sur la santé des non-fumeurs et d'autres lois en conséquence*, 1re sess, 42e parl, 2016 (sanctionné le 23 mai 2018), LC 2018, c 9 vise notamment l'encadrement des produits

Il reste que la loi québécoise ne s'attarde actuellement qu'aux arômes et aux saveurs[126], alors que la loi canadienne s'attarde aussi aux colorants, à certains additifs qui peuvent laisser croire que les produits du tabac sont bénéfiques pour santé, comme les vitamines et les acides gras essentiels, ainsi qu'à certains additifs associés à l'énergie et la vitalité, soit la caféine et la taurine. Le Québec a donc voulu combler les lacunes de la loi canadienne relativement aux produits du tabac *aromatisés*, réduisant du même coup la marge de manœuvre dont pouvait bénéficier l'industrie au niveau fédéral. Mais trouvant toujours application au Québec, la loi canadienne empêche qu'y soient vendus certains produits du tabac contenant d'autres types d'additifs.

Malgré leur complémentarité, les deux lois ne réglementent pas tout en matière d'additifs. En effet, ces deux lois s'attardent aux additifs de type attractif, ne réglementant pas ceux qui rendent les produits du tabac plus addictifs, comme l'ammoniaque, ou ceux qui augmentent la toxicité globale des produits du tabac comme le goudron. Rappelons que les directives relatives aux articles 9 et 10 de la *CCLAT* sont encore inachevées à cet égard. Or, tout comme au niveau fédéral, la portée de la loi québécoise pourrait être élargie dans l'avenir pour s'étendre à d'autres types d'additifs. En effet,

---

de vapotage. Les arômes sont autorisés dans les produits de vapotage, mais la promotion de produits de vapotage attrayants pour les jeunes est interdite, par exemple les produits ayant des arômes de bonbon (art 30.48, Annexe 3). De plus, sauf exception (i.e. substances de vapotage sur ordonnance, ou fabriquées ou vendues en vue de leur exportation), la loi interdit la fabrication et la vente des produits de vapotage contenant les catégories d'ingrédients suivantes : acides aminés, caféine, agents colorants, acides gras essentiels, glocuronolactone, probiotiques, taurine, vitamines, minéraux nutritifs (arts 7.21, 7.22, Annexe 2).

126 La *Loi concernant la lutte contre le tabagisme* ne définit pas les termes « arôme » et « saveur », mais en donne quelques exemples (*supra* note 24, art 29.2). À titre informatif, le Grand dictionnaire terminologique de l'Office québécois de la langue française définit « arôme » comme suit : « Propriété organoleptique perceptible par l'organe olfactif, par voie rétro-nasale lors de la dégustation. Note : S'utilise souvent comme synonyme d'odeur agréable et caractéristique d'un aliment ou d'une boisson… ». Quant au terme « saveur », il est défini comme suit : « Qualité spécifique de la sensation gustative. Note : Désigne les quatre sensations fondamentales (acidité, amertume, salinité, sucrosité) et leur mélange, issues de la stimulation des récepteurs gustatifs de la langue, ainsi que la propriété des corps purs ou des mélanges qui les stimulent… » (Office québécois de la langue française, *Grand dictionnaire terminologique*, *sub verbo* « arome », « saveur »).

depuis son adoption en 1998, la loi provinciale accorde au gouvernement le pouvoir réglementaire suivant :

> Le gouvernement peut déterminer, *par règlement*, des normes relatives à la *composition et aux caractéristiques* des produits du tabac fabriqués au Québec pour être vendus au Québec.
> *Ces normes peuvent exiger, prohiber ou restreindre l'utilisation de certaines substances* ou de certains procédés *et varier selon les différents produits du tabac*.
> Un distributeur de produits du tabac ne peut vendre au Québec un produit du tabac qui n'est pas conforme aux normes prévues au règlement visé au premier alinéa [nos italiques][127].

Telle que libellée, cette disposition confère une large portée au pouvoir réglementaire de la province en matière d'additifs. D'une part, le terme « substance » n'étant pas défini dans la loi, cela porte à croire qu'il peut s'interpréter largement et permettre au gouvernement de réglementer tout additif augmentant la toxicité, le pouvoir attractif ou le pouvoir addictif des produits du tabac. D'autre part, il n'est pas limitatif quant aux produits du tabac pouvant faire l'objet de certaines exigences réglementaires. Bien que la loi ne définisse pas l'expression « produit du tabac », son premier article énonce que :

> La présente loi s'applique au tabac récolté, qu'il soit traité ou non et quelles que soient sa forme et sa présentation. Est assimilé à du tabac, tout produit qui contient du tabac, la cigarette électronique et tout autre dispositif de cette nature que l'on porte à la bouche pour inhaler toute substance contenant ou non de la nicotine, y compris leurs composantes et leurs accessoires, ainsi que tout autre produit ou catégorie de produit qui, au terme d'un règlement du gouvernement, y est assimilé[128].

---

127 *Loi concernant la lutte contre le tabagisme*, *supra* note 24, art 29.

128 *Ibid*, art 1. La Loi définit également le terme « tabac » comme suit : « comprend également les accessoires suivants: les tubes, papiers et filtres à cigarette, les pipes, y compris leurs composantes, et les fume-cigarettes » (*ibid*, art 1.1). Voir aussi *Règlement d'application de la Loi concernant la lutte contre le tabagisme*, RLRQ 2015, c L-6.2, r 1 (le règlement indique que : « [a]ux fins de la Loi concernant la lutte contre le tabagisme (chapitre L-6.2), est assimilé à du tabac, tout produit qui ne contient pas de tabac et qui est destiné à être fumé »). La Loi définit le terme « fumer » comme suit : « vise également l'usage d'une

Force est de constater que cet article accorde au gouvernement du Québec un pouvoir aussi large que celui du gouvernement fédéral eu égard au choix d'additifs et de produits du tabac pouvant faire l'objet de restrictions. Dans un tel contexte de compétence partagée, la province pourrait donc adopter des normes complémentaires et plus restrictives que celles prévues dans la loi fédérale. Le gouvernement québécois n'a cependant jamais exercé son pouvoir réglementaire à ce jour, ce qui pourrait s'expliquer soit par l'existence de normes fédérales suffisantes à ses yeux, soit par un enjeu d'harmonisation entre les normes fédérales et québécoises, ou encore par un manque de volonté politique[129].

B. L'approche québécoise

L'examen des travaux parlementaires entourant l'adoption de la *Loi visant à renforcer la lutte contre le tabagisme* en 2015 révèle que, tout comme au niveau fédéral, la protection des jeunes contre le tabagisme est à l'origine de la nouvelle interdiction concernant les produits du tabac aromatisés[130]. Notamment, l'interdiction du menthol dans les produits du tabac

---

cigarette électronique ou de tout autre dispositif de cette nature » (*Loi concernant la lutte contre le tabagisme*, *supra* note 24, art 1.1.).

129 Voir Québec, Assemblée nationale, *Journal des débats de la Commission permanente de la santé et des services sociaux*, 41e lég, 1re sess, vol 44, n° 85 (10 novembre 2015) aux pp 24–28 [Journal des débats, 10 novembre 2015]. Lors de son adoption en 1998, l'article 29 de la *Loi sur le tabac* (maintenant intitulée *Loi concernant la lutte contre le tabagisme*, *supra* note 24) comportait une exigence selon laquelle le gouvernement québécois devait harmoniser ses normes avec celles adoptées en vertu de la loi canadienne sur le tabac. Lors de la modification de la loi québécoise en 2015, l'article 29 a été modifié pour supprimer cette exigence. À ce sujet, la ministre déléguée à la Protection de la Jeunesse, à la Santé publique et aux Saines habitudes de vie a expliqué que l'article 29 avait été jusqu'à maintenant difficile à utiliser en raison de l'exigence d'harmonisation des normes québécoises avec les normes fédérales, mais que le retrait de celle-ci permettrait désormais de recourir plus facilement à cet article de la loi, que celui-ci prendrait plus de force et permettrait au Québec d'être plus sévère que le gouvernement fédéral, s'il le souhaite. Réagissant à ces propos, un député de l'opposition a rétorqué que l'article 29 n'avait pas été utilisé à cause du manque de volonté d'investir en la matière et de l'absence de suivi des composantes contenues dans les produits du tabac.

130 Voir Québec, Assemblée nationale, *Journal des débats de la Commission permanente de la santé et des services sociaux*, 41e lég, 1re sess, vol 44, n° 90 (18 novembre 2015) ; Québec, Assemblée nationale, *Journal des débats de la*

contribuerait à faire disparaître les cigarettes ultraminces, lesquelles sont souvent mentholées et très attrayantes pour les jeunes filles[131]. Cependant, il appert que la province n'a pas retenu la même approche qu'au niveau fédéral pour remplir cet objectif.

D'une part, la loi québécoise ne semble pas sous-tendre la recherche d'un compromis entre la protection des jeunes et la liberté de choix des adultes. Le législateur n'a pas invoqué cette liberté pour permettre certains arômes ou saveurs dans certains produits du tabac. Ainsi est évacué tout besoin de distinguer les produits ou additifs attrayants pour les jeunes de ceux qui ne le sont pas et l'industrie ne pourrait pas profiter de cette dichotomie. Si l'on peut poser l'hypothèse que le Parlement canadien a agi autrement pour ne pas risquer d'enfreindre la *Charte*, force est de constater que la province du Québec ne semble pas s'être arrêtée à cette possibilité. La situation du Québec est toutefois incertaine, alors que l'industrie conteste sans surprise la validité de la *Loi concernant la lutte contre le tabagisme* devant les tribunaux, entre autres en ce qui a trait aux mesures visant les additifs[132] ; c'est également le cas dans d'autres provinces ayant adopté des mesures similaires[133].

Commission permanente de la santé et des services sociaux, 41e lég, 1re sess, vol 44, n° 132 (25 novembre 2015) (la ministre québécoise déléguée à la Santé publique a indiqué que le nouvel article 29.2 de la loi était adopté pour les jeunes).

131 Voir *Journal des débats*, 12 novembre 2015, *supra* note 122 à la p 16 (notons que le Parti québécois, à l'opposition, proposait tout simplement d'interdire les cigarettes ultraminces).

132 Voir Ariane Lacoursière, « Imperial Tobacco conteste la nouvelle Loi sur le tabac », *La Presse [de Montréal]* (1 mars 2016), en ligne : <www.lapresse.ca/actualites/justice-et-affaires-criminelles/actualites-judiciaires/201603/01/01-4956115-imperial-tobacco-conteste-la-nouvelle-loi-sur-le-tabac.php>. Imperial Tobacco prétend que la loi porte une atteinte injustifiée à ses droits constitutionnels en tant qu'entreprise légale. L'entreprise mentionne notamment que l'interdiction des produits du tabac aromatisés, y compris les cigarettes mentholées, aura sans doute pour résultat la croissance du marché déjà important des cigarettes illégales au Québec.

133 Voir Suzanne Lapointe, « Imperial Tobacco, 2 Smoke Shops Launch Suit Against Province », *CBC News* (30 mars 2016), en ligne : <www.cbc.ca/news/canada/new-brunswick/tobacco-menthol-ban-imperial-1.3511069>. Au Nouveau-Brunswick, Imperial Tobacco Canada et deux commerces contestent la validité des mesures législatives interdisant la vente de produits mentholés, alléguant que la province outrepasse ses compétences puisque cet additif est

D'autre part, la nouvelle interdiction québécoise traduit une approche proactive, plutôt que réactive, face aux pratiques de l'industrie en matière d'additifs aromatisés. Contrairement au gouvernement fédéral, qui préconise une surveillance des nouvelles tendances de l'industrie avant d'agir, la province a adopté une disposition largement restrictive couvrant de fait tout nouvel arôme ou saveur qui serait utilisé par l'industrie, ainsi que tout nouveau produit du tabac dans lequel il pourrait se retrouver. En ce sens, l'approche qui se dégage de la loi québécoise rappelle celle de la résolution brésilienne.

Dans le même ordre d'idées, il est intéressant de mentionner que, dans le cadre des travaux parlementaires entourant l'adoption de la nouvelle loi québécoise en 2015, le Parti québécois, parti de l'opposition, proposait un amendement qualifié de « moratoire ». Celui-ci visait à interdire l'introduction de tout nouveau produit du tabac sur le marché québécois sans l'approbation du gouvernement – incluant ceux contenant de nouvelles substances. Le moratoire proposé aurait permis d'aller au-delà de l'interdiction d'une catégorie d'additifs en particulier, par exemple les arômes et les saveurs. Cette proposition n'est pas sans évoquer le pouvoir d'évaluation préalable à la mise en marché accordé à la FDA aux États-Unis. La ministre québécoise déléguée à la Santé publique et aux Saines habitudes de vie s'est toutefois montrée en désaccord avec cet amendement proposé – d'ailleurs rejeté – argumentant entre autres que le pouvoir réglementaire prévu à l'article 29 de la loi permet de parvenir au même résultat[134]. Or, si ce pouvoir[135] est effectivement exercé un jour par le gouvernement, il n'est pas certain qu'il le sera selon une logique proactive. Le gouvernement pourrait très bien adopter des normes réglementaires concernant certains additifs ou catégories d'additifs en réaction aux effets néfastes constatés après leur mise en marché.

---

autorisé par la loi canadienne. Notons que l'adoption du décret fédéral supprimant l'exemption pour le menthol pourrait changer le cours de cette poursuite. Voir « Imperial Tobacco Launches Legal Challenge to Nova Scotia Ban on Menthol Tobacco », *Huffington Post* (28 mai 2015), en ligne: <www.huffingtonpost.ca/2015/05/28/imperial-tobacco-launches_n_7464696.html>.

134 Voir *Journal des débats*, 10 novembre 2015, *supra* note 129.

135 Voir pp 27–29, ci-dessus.

CONCLUSION

Entre 1998 et 2013, l'âge moyen d'initiation au tabac a augmenté au Canada[136], et le taux de tabagisme chez les jeunes a connu une baisse constante depuis les dernières années. En 2012-2013, 4 % des élèves de la 6e à la 12e année étaient des fumeurs actuels[137] ; ce taux est descendu à 3 % en 2016-2017[138]. Cette baisse s'est également observée pour les produits du tabac aromatisés (8 % en 2012-2013[139] et 7 % 2016-2017[140]). Néanmoins, les efforts pour lutter contre le tabagisme et, plus particulièrement, prévenir le tabagisme chez les jeunes, demeurent cruciaux[141]. Malgré l'intensification et la diversification des mesures de lutte contre le tabagisme, ce dernier entraîne toujours des conséquences sanitaires et économiques considérables au niveau mondial, et continue d'attirer de nouveaux consommateurs. Au Québec, par exemple, 35 % des jeunes de 15 à 19 ans avaient déclaré avoir déjà fumé un cigarillo en 2013[142].

---

136 Voir Québec, Ministère de la santé et des services sociaux, *La santé de la population : Portrait d'une richesse collective*, Rapport du directeur national de santé publique, Québec, MSSS, 2016 à la p 19 [*Richesse collective*]. Compte tenu que la *Loi sur le tabac* fédérale a été adoptée en 1997 et que l'annexe prévoyant la réglementation de certains additifs dans certains produits du tabac a été adopté en 2009, ces statistiques tendent à montrer l'impact positif de ces mesures.

137 Santé Canada, *Résumé des résultats de l'Enquête sur le tabagisme chez les jeunes 2012-2013*, Ottawa, Santé Canada, 2014, en ligne : <www.canada.ca/fr/sante-canada/services/publications/vie-saine/resume-resultats-enquete-tabagisme-chez-jeunes-2012-2013.html> [Santé Canada, *Résumé des résultats 2012-2013*]. L'enquête couvre les élèves de la 6e à la 12e année (de la 6e année au secondaire V au Québec). Les fumeurs « actuels » correspondent à la somme des fumeurs quotidiens et des fumeurs occasionnels).

138 Santé Canada, *Résumé des résultats 2016-2017*, *supra* note 119. L'enquête couvre les élèves de la 7e à la 12e année (de la 1re à la 5e année du secondaire au Québec). Le Nouveau-Brunswick n'a pas participé à l'enquête.

139 Santé Canada, *Résumé des résultats 2012-2013*, *supra* note 137.

140 Santé Canada, *Résumé des résultats 2016-2017*, *supra* note 119.

141 Voir *Richesse collective*, *supra* note 136 à la p 19.

142 *Ibid*. Peu après l'adoption, en 2009, de l'annexe de la *Loi sur le tabac* fédérale réglementant l'utilisation d'additifs dans certains produits du tabac, l'industrie a mis sur le marché des petits cigares (cigarillos) échappant aux interdictions fédérales en matière d'additifs et contenant des arômes très attirants pour les

La réglementation de la composition des produits du tabac est une avenue prometteuse de plus en plus exploitée dans le monde pour faire face au fléau du tabagisme, et il ne fait pas de doute que l'industrie du tabac perd de la latitude dans la manipulation de ses produits. Le Canada, en tant que membre du groupe de travail chargé de l'élaboration des *Directives partielles* de la *CCLAT* en matière de réglementation des produits du tabac, se doit donc d'être une source d'inspiration pour les autres pays. Selon l'analyse précédente, la loi canadienne n'est pas complètement exemplaire en matière de réglementation des additifs dans les produits du tabac. Sa portée est plus large que celle d'autres réglementations dans le monde, qui visent par exemple uniquement la cigarette et le tabac à rouler, ou encore seulement les additifs *aromatisants* et non les additifs associés à l'énergie et la vitalité. Cependant, sa portée n'est pas aussi large que le recommandent les normes internationales, puisque la loi canadienne permet encore que certains produits du tabac contiennent certains arômes et saveurs, alors que les normes internationales ne prévoient aucune exception.

De plus, la loi canadienne obéit à une logique réactive face aux pratiques de l'industrie et, en cela, elle laisse à cette dernière une marge de manœuvre qui pourrait menacer notamment l'objectif de protection des jeunes. Intervenir seulement une fois que l'on constate qu'un nouveau produit du tabac séduit effectivement les jeunes, plutôt qu'empêcher à l'avance les pratiques innovantes de l'industrie pour attirer les jeunes est un choix législatif lourd de conséquences pour la santé publique. La loi fédérale se distingue sur ce point d'autres réglementations au niveau international, qui traduisent une logique plus proactive face aux pratiques de l'industrie et laissent ainsi très peu, voire aucune, marge de manœuvre à celle-ci. Ces règlementations audacieuses laissent ainsi penser que la protection de la santé publique, en particulier la santé des jeunes, n'a pas à subir de compromis. Au contraire, au sein de la loi canadienne transparaît la recherche d'un compromis entre la protection de la santé publique et la protection des droits individuels, le spectre de la *Charte* se dégageant notamment des explications du gouvernement canadien eu égard à ses choix législatifs en matière d'additifs. Un tel compromis est-il encore de mise, alors que les astuces de l'industrie du tabac quant à la composition de ses produits sont de plus en plus connus et que les conséquences dévastatrices des produits du tabac ne sont plus à démontrer ? Le Québec semble résolu à renoncer au compromis, ayant adopté

---

jeunes. Ces statistiques québécoises tendent à montrer l'impact négatif de cette pratique de l'industrie. Ce n'est qu'en 2015 qu'un décret du gouvernement fédéral a permis d'apporter des ajustements à l'annexe de la loi canadienne pour interdire ces nouveaux cigarillos aromatisés.

une mesure interdisant *tout* arôme et saveur dans *tout* produit du tabac. Il illustre le rôle important que peuvent jouer les provinces pour contrebalancer les faiblesses de la loi canadienne et contribuer à maintenir la réputation de chef de file du Canada.

Néanmoins, la loi canadienne joue un rôle primordial dans le contexte normatif entourant la réglementation du tabagisme au pays. Elle est un exercice de la compétence du Parlement fédéral en matière criminelle visant à protéger l'ensemble des Canadiens des dangers que posent les produits du tabac[143]. En ce sens, elle établit des mesures de protection des Canadiens, que les provinces ne peuvent pas entraver[144]. Ainsi faudrait-il que ces mesures soient elles-mêmes exemplaires, laissant ainsi aux provinces le rôle d'innover, plutôt que celui de compenser les faiblesses de la loi canadienne? Dans l'état actuel, il nous apparaît essentiel de repenser la logique sur laquelle se fonde cette loi fédérale phare, afin qu'elle remplisse pleinement sa visée de protection de la santé publique. Pour ce faire, certains pouvoirs déjà existants pourraient être exploités davantage alors qu'ils semblent encore sous-utilisés ; par exemple, celui dont bénéficie le gouverneur en conseil de modifier l'annexe 1 de la loi pour prévoir une mention générale visant *tous* les produits du tabac relativement à l'utilisation d'additifs[145]. Ce ne sont pas forcément les pouvoirs prévus à la loi canadienne qui minent son exemplarité, mais la manière dont ils sont exploités et se manifestent, en l'occurrence à travers les décrets gouvernementaux qui se sont succédés pour façonnés l'annexe 1 de la loi.

---

143 Voir *RJR-MacDonald*, *supra* note 28 au para 32.

144 Voir *Rothmans*, *supra* note 30.

145 Voir *Loi sur le tabac*, *supra* note 14, art 7.1

ANNEXE

(Extrait de la *Loi sur le tabac*, LC 1997, c 13)

ANNEXE 1

(articles 5.1, 5.2, 7.1 et 23.1)

Additifs interdits

Article	Colonne 1 Additif	Colonne 2 Produit du tabac
1	Additif qui a des propriétés aromatisantes ou qui rehausse l'arôme (autres que ceux énumérés dans la colonne 1 de l'article 1.2), notamment : – tout additif qualifié d'aromatisant par le Comité mixte FAO/OMS d'experts des additifs alimentaires dans ses évaluations publiées dans la version à jour de la Série de rapports techniques de l'OMS – tout additif qualifié de substance aromatisante généralement reconnue comme inoffensive (« GRAS ») par le comité d'experts de l'association appelée Flavor and Extract Manufacturers Association (FEMA) dans ses listes de substances « GRAS » intitulées « GRAS 3 » à « GRAS 24 », ou dans ses listes de substances « GRAS » publiées subséquemment, s'il y en a Ne sont toutefois pas visés les additifs suivants : – acide benzoïque (CAS 65-85-0) et ses sels – hydroxytoluène butylé (CAS 128-37-0) – carboxyméthylcellulose (CAS 9000-11-7) – acide citrique (CAS 77-92-9) et ses sels – éthanol (CAS 64-17-5) – monolaurate de polyoxyéthylène de sorbitane (CAS 9005-64-5) – acide fumarique (CAS 110-17-8) – glycérol (CAS 56-81-5) – gomme de guar (CAS 9000-30-0) – acétate de n-propyle (CAS 109-60-4) – cire de paraffine (CAS 8002-74-2) – propylène glycol (CAS 57-55-6) – esters glycériques de résine de bois (CAS 8050-31-5) – acétate de sodium anhydre (CAS 127-09-3) – alginate de sodium (CAS 9005-38-3) – acide sorbique (CAS 110-44-1) et ses sels – triacétine (CAS 102-76-1) – acétylcitrate de tributyle (CAS 77-90-7)	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les cigares qui sont munis d'une cape non apposée en hélice, les cigares avec papier de manchette et les petits cigares **(3)** les feuilles d'enveloppe
1.1	Additifs interdits visés à l'article 1, sauf s'ils confèrent un arôme communément attribué au porto, au vin, au rhum ou au whisky	Les cigares qui sont munis d'une cape apposée en hélice et pèsent plus de 1,4 g mais au plus 6 g, sans le poids des embouts, sauf ceux visés à l'article 1 et ceux fabriqués ou vendus en vue de leur exportation
1.2	Menthol, y compris le l-menthol, et menthone, y compris la l-menthone	Les produits du tabac, sauf ceux fabriqués ou vendus en vue de leur exportation
2	Acides aminés	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe

Article	Colonne 1 Additif	Colonne 2 Produit du tabac
3	Caféine	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe
4	Agents colorants, sauf ceux utilisés pour blanchir le papier ou le filtre ou pour donner au papier de manchette l'aspect du liège	Les cigarettes, sauf celles fabriquées ou vendues en vue de leur exportation
4.1	Agents colorants	Les feuilles d'enveloppe, sauf celles fabriquées ou vendues en vue de leur exportation
4.2	Agents colorants, sauf ceux utilisés pour blanchir ou bronzer l'embout	Les cigares, sauf les suivants : **(1)** les petits cigares **(2)** les cigares avec papier de manchette **(3)** les cigares qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les cigares qui sont fabriqués ou vendus en vue de leur exportation
4.3	Agents colorants, sauf ceux utilisés pour blanchir le papier de gainage, pour brunir ou bronzer le papier de manchette, pour donner à ce dernier l'aspect du liège ou pour blanchir ou bronzer l'embout	Les petits cigares, sauf ceux fabriqués ou vendus en vue de leur exportation
4.4	Agents colorants, sauf ceux utilisés pour brunir ou bronzer le papier de manchette ou pour blanchir ou bronzer l'embout	Les cigares avec papier de manchette, sauf ceux fabriqués ou vendus en vue de leur exportation et les petits cigares
5	Acides gras essentiels	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe
6	Fruits, légumes et tout produit obtenu par leur transformation, sauf le charbon activé et l'amidon	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe

Article	Colonne 1 Additif	Colonne 2 Produit du tabac
12	Vitamines	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe
13	Minéraux nutritifs, sauf ceux qui sont nécessaires à la fabrication du produit du tabac	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe

Note 1 : Dans la colonne 1, ***FAO*** renvoie à l'Organisation des Nations Unies pour l'alimentation et l'agriculture, ***OMS*** à l'Organisation mondiale de la Santé et ***CAS*** se rapporte au numéro du service des résumés analytiques de chimie (Chemical Abstracts Service).

Note 2 : Dans la colonne 2, ***cape apposée en hélice*** s'entend de la cape d'un cigare qui est apposée avec un angle aigu d'au moins 30 degrés par rapport à l'axe longitudinal du cigare.

2009, ch. 27, art. 17; DORS/2015-126, art. 1 à 7; 2017, ch. 26, art. 20(F); DORS/2017-45; 2018, ch. 9, art. 68.

Article	Colonne 1 Additif	Colonne 2 Produit du tabac
12	Vitamines	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe
13	Minéraux nutritifs, sauf ceux qui sont nécessaires à la fabrication du produit du tabac	Sauf s'ils sont fabriqués ou vendus en vue de leur exportation : **(1)** les cigarettes **(2)** les petits cigares **(3)** tous les autres cigares, sauf ceux qui pèsent plus de 6 g, sans le poids des embouts, sont munis d'une cape apposée en hélice et n'ont pas de papier de manchette **(4)** les feuilles d'enveloppe

Note 1 : Dans la colonne 1, ***FAO*** renvoie à l'Organisation des Nations Unies pour l'alimentation et l'agriculture, ***OMS*** à l'Organisation mondiale de la Santé et ***CAS*** se rapporte au numéro du service des résumés analytiques de chimie (Chemical Abstracts Service).

Note 2 : Dans la colonne 2, ***cape apposée en hélice*** s'entend de la cape d'un cigare qui est apposée avec un angle aigu d'au moins 30 degrés par rapport à l'axe longitudinal du cigare.

2009, ch. 27, art. 17; DORS/2015-126, art. 1 à 7; 2017, ch. 26, art. 20(F); DORS/2017-45; 2018, ch. 9, art. 68.

The *McGill Journal of Law and Health* wishes to acknowledge the support of the following individuals and organizations:

La *Revue de droit et santé de McGill* tient à remercier les individus et les organisations suivants pour leur soutien :

Law Students' Association, McGill University
Association des étudiant-e-s en droit, Université McGill

Post-Graduate Students' Society, McGill University
Association étudiante des cycles supérieurs, Université McGill

Work Study Program, McGill University
Programme Travail-études, Université McGill

Faculty of Law, McGill University
Faculté de droit, Université McGill