Canadian Journal of Law and Technology

Volume 19 | Number 1 Article 8

1-30-2023

CRISPR, Like any Other Technology: Shedding Determinism & Reviving Athens

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Abstract

This article examines current narratives surrounding CRISPR (clustered regularly interspaced short palindromic repeats) and the current Canadian treatment of this novel biotechnology. It argues that Canada's current approach to genetic research and CRISPR appear to have succumbed to the false narrative of technological determinism. It argues that Canada must buck the narrative and alter the current status quo in two principal ways: Canada should pursue more somatic CRISPR clinical trials in humans and permit pre-clinical germline editing. To design a regulatory regime for clinical germline editing and better guidance on somatic CRISPR clinical trials, Canada should engage Deliberative Polling to ensure Canadians' views are represented in future legislation and regulations.

> A technology is not merely a system of machines with certain functions; rather, it is an expression of the social world. Electricity, the telephone, radio, television, the computer, and the Internet are not implacable forces moving through history, but social processes that vary from one period to another and from one culture to another. These technologies were not "things" that came from outside society and had an "impact"; rather, each was an internal development shaped by its social context. No technology exists in isolation. Each is an open-ended set of problems and possibilities. Each technology is an extension of human lives: someone makes it, someone owns it, some oppose it, many use it, and all interpret it. Because of the multiplicity of users, the meanings of technology are diverse.[1]

I lost a best friend in 2016. If I left one message about him, it would say this: "No treatment helped Mr. Russell escape death—lost short, courageous, painful battle to cancer; left behind a new grandson, loving family, and lifelong friends. The world was better when he was here."

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[1] David E Nye, *Technology Matters: Questions to Live With*, (MIT Press: Cambridge, 2006) at 47.

If Mr. Russell was still alive, would you not want him to participate in shaping a new technology that could revolutionize cancer treatment like the opening quote invites? CRISPR, a tool that scientists can use to alter DNA sequences and modify gene function, is such a biotechnology. It is not an implacable force.[2] It can, like any other technology, be shaped. Its evolution is unpredictable. Like any technology, it will have upsides and downsides. But it does not contain a deterministic code; its problems and possibilities are open-ended.

Despite these facts, CRISPR's current narrative reeks of technological determinism— the idea technology is the key force in society's evolution that independently determines its economic and societal impacts. The Canadian federal government's current approach to CRISPR appears to have succumbed to this narrative. Canada is failing to foster an open-ended set of possibilities.[3] This paper's thesis is simple: Canada must abandon deterministic approaches and interpret CRISPR's open-ended potential through the eyes of Mr. Russell and anyone who suffers from fatal conditions. These eyes suggest two paths forward: pursue more somatic CRISPR clinical trials and permit pre-clinical germline editing (Path 1); and, engage Deliberative Polling to design a regulatory regime for clinical germline editing and better guidance for somatic CRISPR clinical trials (Path 2). I explain my thesis in three parts:

- *Part 1* explains how rhetoric surrounding CRISPR invokes technologically deterministic views, why these views are false and potentially harmful, and why Canada should avoid such views.
- *Part 2* describes Path 1. Frustrating scientific efforts to help thousands of Canadians who suffer and die from conditions that CRISPR could treat is illogical and immoral. To avoid these fates, Canada should quickly provide better guidance on somatic CRISPR clinical trials and permit pre-clinical germline editing.
- *Part 3* describes Path 2. Canada should revive Athens's approach to deliberative democracy by availing Deliberative Polling to design a comprehensive regulatory regime for clinical germline editing.

1. CRISPER DISCUSSIONS ABOUT CRISPR

How CRISPR is viewed and discussed is imperative. Flawed discourse or metaphors may lead to flawed regulation, flawed public discourse, and flawed research.[4] Closely examining the current discourse and metaphors surrounding CRISPR demonstrates that CRISPR, like many technologies before it,[5] has

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[2] Many CRISPR narratives imbue the technology with god-like status (see *e.g.* Eric Lander et al, "Adopt a moratorium on heritable genome editing", *Nature* 567 (14 March 2019) 165, DOI: < 10.1038/d41586-019-00726-5 >) versus another medical tool, like vaccination (see *e.g.* Erika Check Hayden, "Should you edit your children's genes?" *Nature* 530:7591 (25 February 2016) 402, DOI: < 10.1038/530402a >).

[3] Please note that throughout this paper "Canada" refers to the Canadian federal government.

acquired the stench of technological determinism. This idea espouses that technology is the key force in society's evolution that independently determines its economic and societal impacts.[6] CRISPR's popular discourse includes that idea. Instead of a subservient technology that society shapes, CRISPR is portrayed as an autonomous technological agent.[7]

But this idea is wrong. As O'Keefe et al argue, the discourse on CRISPR's ethical complexity, how CRISPR works, and what is known and unknown about CRISPR needs renovation.[8] This discourse is currently inhibiting the prospect of responsibly using CRISPR,[9] including in Canada.

(a) Ethical Complexity: CRISPR Lives in Society's World

This article does not broadly review the rhetoric scientists use to describe biotechnology.[10] Rather, it focusses on two pivotal moments in genetic research where scientists called for the voluntary deferral of the use of certain genetic biotechnologies.

This focussed analysis suggests scientists talk differently about CRISPR than they did about previous biotechnology. Instead of CRISPR being a tool we control, scientists' current rhetoric anthropomorphizes CRISPR and treats it like an autonomous agent.[11] Ceccarelli puts it best: "recent texts suggest a technological determinism in our current thinking [about CRISPR] that makes it hard for scientists to conceive of an active role for themselves in fostering

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4 See Meaghan O'Keefe et al, "'Editing' Genes: A Case Study About How Language Matters in Bioethics" (2015) 15:12 American J Bioethics 3 at 3, DOI: <10.1080/15265161.2015.1103804>.

5 See *e.g.* Arun Sundararajan, "Invest in Technology with Social Benefits", *New York Times* (4 October 2016), online: <www.nytimes.com/roomfordebate/2016/10/04/easing-the-pain-of-automation/invest-in-technology-with-social-benefits>.

6 See *ibid.* See also Merritt Roe Smith, "Technological Determinism in American Culture" in Merritt Roe Smith & Leo Marx, eds, *Does Technology Drive History? The Dilemma of Technological Determinism* (Cambridge: MIT Press, 1994) 1 at 2; Alan Hook, *Technology and Culture: Technological Determinism,* Lecture for Media and Cultural Theories module in the MSc and MA in Creative Technology and Creative Games (Salford School of Arts, Media and Creative Technology University of Salford, 2009), online: <www.slideshare.net/Alan_Hook/technological-determinism>.

7 See Leah Ceccarelli, "CRISPR as agent: a metaphor that rhetorically inhibits the prospects for responsible research" (2018) 14:24 Life Sciences, Society & Policy 1 at 3, 7, DOI: <10.1186/s40504-018-0088-8> [Ceccarelli, "CRISPR as agent"].

8 See O'Keefe et al, *supra* note 4 at 4.

9 See Ceccarelli, "CRISPR as agent", *supra* note 7.

10 For an interesting discussion on the language pop culture, in particular cinema, uses to discuss genetics and genetic engineering, see David A Kirby, "The New Eugenics in Cinema: Genetic Determinism and Gene Therapy in '*GATTACA*'" (2000) 27:2 Science Fiction Studies 193.

11 See Ceccarelli, "CRISPR as agent", *supra* note 7 at 7.

ethical constraints on biomedical research."[12] Put simply, scientists are now using language that suggests they are no longer in charge, biotechnology is.

Ceccarelli demonstrates this point by comparing the linguistic and narrative differences between two *Science* publications:[13] the 1974 Berg letter (calling for voluntarily deferring particular recombinant DNA experimentation)[14] and the 2015 Doudna letter (calling for an open discourse on CRISPR's use and steps to discourage germline modification).[15] Her analysis also examines two other documents: the 1975 Asilomar Conference on Recombinant DNA Molecules summary statement[16] (it responded to the Berg letter) and the 2015 International Summit on Human Gene Editing summary statement (it responded to the 2015 Doudna letter).[17]

These documents share many similarities.[18] But a close rhetorical examination reveals the shift that occurred over the last 40 years.[19] The 1974 letter employs language that portrays biotechnology as something scientists choose to use. Biotechnology is not an independent agent; scientists are the agents who choose to use the biotechnology.[20] In contrast, the language in the

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[12] Leah Ceccarelli, "Conceiving of technologies as autonomous agents takes responsibility away from the people who are using them" (20 November 2018), online (blog): *BMC* < http://blogs.biomedcentral.com/on-society/2018/11/20/conceiving-technologies-autonomous-agents-takes-responsibility-away-people-using/ > .

[13] See Ceccarelli, "CRISPR as agent", *supra* note 7 at 2.

[14] See Paul Berg et al, "Potential biohazards of recombinant DNA molecules" (1974) 185:4148 Science 303, DOI: < 10.1126/science.185.4148.303 > . A point about 1974 moratorium is noteworthy. Henry Millar argues the Asilomar experience was not a success: "It exaggerated the potential risks of recombinant DNA technology, modern biotechnology's core technique; gave rise to a years-long research moratorium; and induced NIH to draft and promulgate 'biosafety' guidelines. Those process-based guidelines, which were focused on the use of a single technique instead of on the risks of experiments, have plagued genetic engineering research ever since." Henry I Miller, "Germline gene therapy: We're ready" (2015) 348:6241 Science 1325 at 1325, DOI: < 10.1126/science.348.6241.1325-a > .

[15] See David Baltimore et al, "A prudent path forward for genomic engineering and germline gene modification" (2015) 348:6230 Science 36, DOI: < 10.1126/science.aab1028 > .

[16] Paul Berg et al, "Asilomar conference on recombinant DNA molecules" (1975) 188:4192 Science 991, DOI: < 10.1126/science.1056638 > .

[17] See Organizing Committee for the International Summit on Human Gene Editing, News Release, "On Human Gene Editing: International Summit Statement" (3 December 2015), online: < www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID = 12032015a > . See also Ceccarelli, "CRISPR as agent", *supra* note 7 at 6-9.

[18] Leah Ceccarelli, "Bioscience as Change Agent: Rhetorics of Restraint and Inevitability in Response to Advances in Genetic Technologies" in Jenny Rice, Chelsea Graham & Eric Detweiler, eds, *Rhetorics Change/ Rhetoric's Change*, (Parlor Press: South Carolina, 2018) 210, online (pdf): < https://parlorpress.com/products/rhetorics-change?_pos = 1&_sid = 550ae255e&_ss = r > .

[19] For detailed analysis, see *ibid.*

[20] See Ceccarelli, "CRISPR as agent", *supra* note 7 at 6.

2015 letter imbues CRISPR with autonomous, godlike power to reshape our biosphere.[21] It is an independent agent that is "not invented, or even discovered, by scientists; instead, it emerges, and carries with it imminent prospects, as if it were a newly evolved species or organism with an ominous destiny."[22]

To be clear, scientists' fear of biotechnologies' role in genetic science and the view of genetic determinism is not new.[23] The 1974 Berg letter, 1975 Asilomar Conference summary statement, and the twenty-fifth anniversary Asilomar Conference in 2000 clearly show that scientists were concerned about human genome research and genetic biotechnologies. [24] But those documents lack the deterministic rhetoric that Ceccarelli highlighted—rhetoric that "encourages passivity and acquiescence . . . [and] discourages meaningful public involvement . . .."[25]

Unfortunately, scientists are not the only ones making deterministic statements. A 2015 *Science* article even named CRISPR "Breakthrough of the Year" and stated that "we all now live in CRISPR's world."[26] Such language suggests that "[s]cientists are powerless in CRISPR's world, carried along for the ride by a family of technologies that are revolutionizing biomedicine."[27]

For Canada to have meaningful public involvement and more robust scientific and regulatory discussions, deterministic rhetoric must be challenged and abandoned. CRISPR must be represented like any other technology—a tool that societies use and choose how to use.

(b) How CRISPR Actually Works: Re-focusing the Conversation

A conceptual point about how CRISPR can be used is important. Like other genetic biotechnologies, CRISPR can be used for somatic or germline modifications. This infographic captures the technical differences of somatic (left) and germline (right) modifications:[28]

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21 *Ibid*. at 7.

22 *Ibid*.

23 See Michael J Zerbe, "Toward A Rhetoric of DNA: The Advent of CRISPR" (2019) 14:2 Project Rhetoric Inquiry 1, DOI: <10.13008/2151-2957.1276> (for a fantastic discussion of how the rhetoric of DNA).

24 See Charles Weiner, "Drawing the Line in Genetic Engineering: Self-Regulation and Public Participation" (2001) 44:2 Perspectives in Biology and Medicine 208 at 216 (for more on the 25th anniversary Asilomar conference in 2000 and the concerns articulated).

25 *Ibid*. at 217.

26 John Travis, "Making the cut: CRISPR genome-editing technology shows its power" *Science* 350:6267 (18 December 2015) 1456 at 1457, online (pdf): <www.sciencemag.org/news/2015/12/and-science-s-2015-breakthrough-year>.

27 Ceccarelli, "CRISPR as agent", *supra* note 7 at 9.

28 Mary Todd Bergman, "Perspectives on gene editing" *The Harvard Gazette* (9 January 2019), online: <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/> (graphic by Judy Blomquist/Harvard Staff).

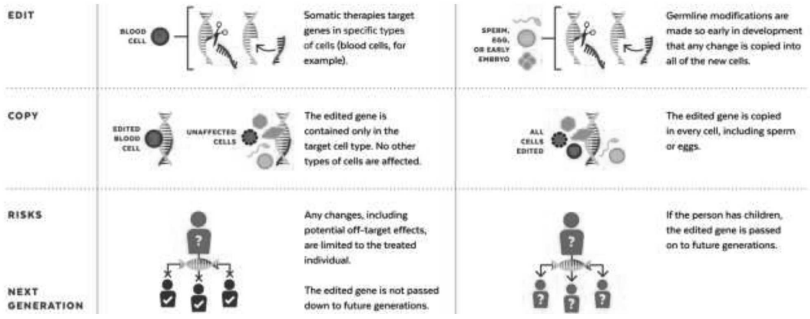

Figure A: Differences between somatic and germline editing [+]

Most buzz around CRISPR's power relates to germline "editing" versus somatic "editing".[29] This buzz makes sense: germline editing modifies gametes and creates heritable changes.[30] Canada's *Assisted Human Reproduction Act* (*AHRA*) criminalizes such changes.[31] But somatic editing only modifies somatic cells and does not create heritable changes.[32] The *AHRA* does not preclude somatic editing,[33] and Canada has no regulations or guidelines that specifically apply to modifying somatic cells for therapeutic purposes. Somatic gene therapies are generally considered biological drugs. They fall under Canada's *Food and Drug Regulations*[34] and require research ethics board approval.[35] Those

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[+] Mary Tod Bergman, Perspectives on gene editing (9 January 2019) The Harvard Gazette, online: <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/> [graphic by Judy Blomquist/Harvard Staff].

[29] As I note in further along in this paper, "editing" is a crude term that needs to be approached with caution.

[30] See *e.g.* Anthony JF Griffiths et al, *An Introduction to Genetic Analysis,* 7th ed (New York: WH Freeman, 2000), online: <www.ncbi.nlm.nih.gov/books/NBK21894/>; Bartha Maria Knoppers et al, "Human Genome Editing: Ethical and Policy Considerations" (Montréal: Centre of Genomics and Policy, McGill University and Génome Québec Innovation Centre, 2018) at 3, online (pdf): <www.genomequebec.com/DATA/PUBLICATION/34_en˜v˜Human_Genome_Editing_-_Policy_-Brief.pdf>; Jacqueline Detwiler-George, "Legal vs. Illegal Gene Editing: Here's What's Banned, and Why" *Popular Mechanics* (4 December 2018), online: <www.popularmechanics.com/science/health/a25385071/gene-editing-crispr-cas9-legal/>.

[31] *Assisted Human Reproduction Act*, S.C. 2004, c. 2, s. 5(1).

[32] See Griffiths et al, *supra* note 30; Knoppers et al, *supra* note 30 at 3.

[33] Knoppers et al, *supra* note 30 at 1. Some people may misunderstand this nuance. See *e.g.* Rick Giercazk, "CRISPR-Cas9 technology and personalized medicine: What about Canada?" (17 September 2018), online (blog): *Science Borealis* <https://blog.scienceborealis.ca/crispr-cas9-technology-and-personalized-medicine-what-about-canada/> (Giercazk states that the Act is "so broadly written that Canadian scientists are prohibited from using the CRISPR-Cas9 technology on even somatic cells.")

[34] *Food and Drug Act,* R.S.C., 1985, c. F-27, *Food and Drug Regulations,* C.R.C., c. 870.

[35] Knoppers et al, *supra* note 30 at 1.

regulations are likely appropriate for regulating general somatic research. But as we see the number of somatic gene therapy clinical trials increase (for CRISPR or other genetic therapies), additional guidance on safety, traceability, and quality is likely necessary.[36]

Unfortunately, much like the deterministic rhetoric we just discussed, the current buzz around CRISPR often does not adequately capture the scientific differences between somatic and germline modifications. For example, when scholars and the media discuss CRISPR generally, somatic genome "editing", or somatic CRISPR clinical trials, the focus often shifts to how CRISPR could be used for germline editing and things like designer babies (recall the 1997 blockbuster, *Gattaca*).[37] This shift is unsurprising: "Genetic engineering represents our fondest hopes and aspirations as well as our darkest fears and misgivings."[38] But this skewed narrative is problematic. It can comprise public understanding about the important differences between germline and somatic

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[36] See Council of Canadian Academies, *From Research to Reality: The Expert Panel on the Approval and Use of Somatic Gene Therapies in Canada* (Ottawa: Council of Canadian Academies, 2020), online (pdf): < https://cca-reports.ca/wp-content/uploads/2019/08/Report-From-Research-to-Reality-EN.pdf > [CCA, *From Research to Reality*].

[37] See "Gattaca", online: *IMDB* < www.imdb.com/title/tt0119177/ > . See *e.g.* Lander, *supra* note 2 (which is a recent moratorium call that neither mentions these diseases nor stresses the importance of pursuing somatic therapy. All it says on this topic is that their proposed moratorium does not apply to "genome editing in human somatic (non-reproductive) cells to treat diseases, for which patients can provide informed consent and the DNA modifications are not heritable" (*ibid.* at 166); Katrine S Bosley et al, "CRISPR germline engineering—the community speaks" (2015) 33:5 Nature biotechnology 478 DOI: < 10.1038/nbt.3227 > (though they do note the difference, they hardly discuss somatic uses); Jon Fingas, "CRISPR gene editing has been used on humans in the US" (16 April 2019) online (blog): *Engadget* < www.engadget.com/2019/04/16/human-crispr-gene-editing-trial-begins-in-us/ > (he discusses somatic therapy and then proceeds to tacitly lumps it with germline editing). For a more balanced narrative, see David Baltimore & Paul Berg, "Let's Hit 'Pause" Before Altering Humankind" *Wall Street Journal* (8 April 2015), online: < www.wsj.com/articles/lets-hit-pause-before-altering-humankind-1428536400 > ("it is important to make a distinction between somatic cells and germ-line cells. Somatic cells are the run-of-the-mill cells of our bodies: muscles, nerves, skin and the like. Germ-line cells are the egg and sperm cells that, when joined, give rise to offspring. Making gene changes in somatic cells can have dramatic effects, but they are not transmitted to the next generation and therefore fall comfortably into the category of pure therapeutics and generate minimal controversy."); Letter from Burt Adelman et al to the Honourable Alex Azar II, Secretary of the U.S. Department of Health and Human Services (24 April 2019), online (pdf): *American Society of Gene + Cell Therapy* < www.asgct.org/global/documents/clinical-germline-gene-editing-letter.pdf > (More than 60 American scientists, CEOs, and bioethicists signed this letter. Their letter clearly calls for a global moratorium on germline modifications. But the signatories are clear that their call does not apply to somatic therapies, and they spend considerable space pleading for the support and advancement of somatic therapies).

[38] Jeremy Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World* (New York: Jeremy P. Tarcher/Putnam, 1999) at xii.

modifications, and it can hype of fears of germline uses to the detriment of somatic uses.

The current buzz around CRISPR also uses many inappropriate, science-fiction-like metaphors to describe CRISPR and what it might be able to do.[39] These metaphors include "blueprint/construction", "code", "map", "origami', "war/battle/fight", "editing", "cut and paste", and "target."[40] The term "editing" showcases the problem of such metaphors. Even though it sounds positive, its association with the human embryo is negative. As O'Keefe et al note, "'editing' implies a vision, a set of changes designed to improve text. However, the idea of 'improving' or 'editing' embryos seems to be associated with eugenics."[41] These words also portray a dangerous and false sense of control that feeds into misinformation about what we know and do not know about DNA: "the idea that we can 'edit', or . . . 'proofread' DNA . . . in the same way that we correct a typo or run-on sentence is, at least at present, fundamentally flawed..."[42]

This issue is not just a terminological one. Such metaphors have some clear negative connotations. They likely can even "undermine informed public discussion by pushing public concern toward the potential for misuse, a potential that needs to be addressed but not at the expense of problems that demand attention now."[43] This "expense" has probably already occurred in many venues.[44] The current public narrative already focusses more on misuse than the problems that somatic therapy might address. Indeed, the current narrative about how CRISPR works focuses on designer babies instead of somatic therapy's application to cancer, Parkinson's, sickle cell anemia, cystic fibrosis, and a host of other potential applications for somatic therapy. Put plainly, germline editing and fears about it monopolize conversations about CRISPR.[45]

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[39] See Bosley et al, *supra* note 37 at 478-480 ("[t]he main current societal risk is the backlash from an exaggerated but potentially pervasive view that gene-editing technologies will lead to science-fiction scenarios in which humans are bred upon design leading to a whole array of unanticipated effects . . .. Even if these are unrealistic scenarios, they may generate fear, distrust [of] scientists and over-caution on the use of the current technologies, which may inhibit their full exploitation for less problematic and more fruitful applications in somatic gene therapy, biotech and biomedical research" at 481).

[40] O'Keefe et al, *supra* note 4 at 6-7.

[41] *Ibid*, at 7. See also Zerbe, *supra* note 23 at 4, 15-16.

[42] Zerbe, *supra* note 23 at 16.

[43] O'Keefe et al, *supra* note 4 at 7 (emphasis added).

[44] As I discuss below, scientists are clear on the difference between somatic and germline uses. But media coverage and scientific reporting is not always so clear. That said, scientists use rhetoric that promotes negative conations, misunderstanding, and perhaps even "genohype."

[45] See *e.g*. Lander, *supra* note 2; Bosley, *supra* note 37; Fingas, *supra* note 37; Baltimore & Berg, *supra* note 37; Adelman et al , *supra* note 37.

An interplay likely exists between exaggerated scientific claims (aka "genohype"),[46] pop-culture films[47] and scientific journalism[48] on dystopic/utopic ideas about genetic therapy and engineered humans, and how we view the ethics of genetics research and biotechnologies.[49] Conversations about genetic therapies must be rooted in reality, not false assumptions or unrealistic representations of reality. Otherwise, abstract concerns about exaggerated benefits or potentially hyped risks could delay the actual research and use of CRISPR or other similar genetic therapies. Caulfield aptly summarizes this risk:

> [Genohype claims have many] adverse social consequences, including misleading the public and hurting the long-term legitimacy of the field. It may also be contributing to less-than-ideal funding decisions, the premature implementation of technologies, an erosion of public trust, and perhaps, the harm of patients.[50]

While high research standards are needed, genetics researchers already face many hurdles.[51] New medical technologies and research strategies—for example, large scale machine learning genetics research—will raise new challenges and implementation barriers, including tough ethical, legal, and social conversations. But false or unrealistic representations about genetic biotechnology can compromise such conversations and unnecessarily delay developing lifesaving biotechnologies.[52]

In short, the current buzz surrounding CRISPR compromises the future of genetic biotechnology research. It promotes deterministic fears, such as a fear of slippery slopes where "nothing can stop this development."[53] To avoid such a slope, we must create more suitable metaphors or no metaphors at all, find more

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[46] See Neil A Holtzman, "Are genetic tests adequately regulated?" (1999) 286:5439 Science 409, DOI: < 10.1126/science.286.5439.409 > .

[47] See *e.g.* Kirby, *supra* note 10.

[48] See *e.g.* Ferris Jabr, "Are We Too Close to Making Gattaca a Reality?" (28 October 2013), online (blog): *Scientific American* < https://blogs.scientificamerican.com/brain-waves/are-we-too-close-to-making-gattaca-a-reality/ > .

[49] See *e.g.* Kirby, *supra* note 10.

[50] Timothy Caulfield, "Ethics hype?" (2016) 46(4) Hastings Center Report 13 at 13, DOI: < 10.1102/has.612 > .

[51] See *e.g.* Ontario Genomics, "Call for an Ontario Health Data Ecosystem" (2015) at 1, online (pdf): < www.ontariogenomics.ca/wp-content/uploads/sites/1/2016/10/Call-for-an-Ontario-Health-Data-Ecosystem.pdf > ; Council of Canadian Academics, *Accessing Health and Health Related Data in Canada: The Expert Panel on Timely Access to Health and Social Data for Health Research and Health System Innovation,* (Ottawa: Council of Canadian Academies, 2015) online (pdf): < https://cca-reports.ca/wp-content/uploads/2018/10/healthdatafullreporten.pdf > [CCA, *Accessing Health*].

[52] See generally, Caulfield, *supra* note 50.

[53] Cameron Shelley, "CRISPR will give us wings!" (12 August 2016), online (blog): *University of Waterloo Centre for Society, Technology and Values* < https://uwaterloo.-ca/centre-for-society-technology-values/blog/post/crispr-will-give-us-wings > .

suitable narratives that are grounded in reality versus genohype, and finally, focus more on lifesaving therapeutic applications versus designer baby enhancement conversations.[54]

(c) The Future is Unknown: Uncertainty About Technology is Normal and Fine

Predicting the future of any technology, including CRISPR, or its social effects is impossible.[55] Culture and society determine technology's future—not the other way around.[56] Technology is neither predetermined nor predictable.[57] Trying to forecast potential best- and worst-case scenarios is futile. No one predicted that the technologies that are ubiquitous today would become ubiquitous. The telegraph, telephone, phonograph, and personal computer, "surely four of the most important inventions in the history of communications, were initially understood as curiosities."[58] Cultural and social pressures have repeatedly caused such technologies to morph into unexpected terrain.[59] History provides many such examples:

> [D]evelopers did not imagine things such as Amazon.com, pornography on the net, downloading digitized music to a personal computer, or most of the other things people today use the Internet for. In short, when we review the history of the phonograph, the radio, the refrigerator, and the Internet, technologies conceived for one clearly defined use have acquired other, unexpected uses over time.[60]

History also clearly demonstrates that biotechnologies often fail or that deterministic fears about the biotechnology were wrong.[61] For example, "[i]n

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[54] See O'Keefe et al suggest that "a multidisciplinary approach is critically needed to understand the impact that metaphors can have for bioethics" O'Keefe et al, *supra* note 4 at 3.

[55] See Nye, *supra* note 1 at 46-53.

[56] See Langdon Winner, "Do Artifacts Have Politics?" (1980) 109:1 Daedalus 121 at 122; Allan Dafoe, "On Technological Determinism: A Typology, Scope Conditions, and a Mechanism" (2015) 40 Science, Technology, & Human Values 1047 at 1050, 1060, DOI: < 10.1177/01622439 > ; Thomas P Hughes, "The Evolution of Large Technological Systems" in Wiebe E Bijker, Thomas P Hughes, & Trevor Pinch, eds, *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (Cambridge: MIT Press, 1987) 45 at 51-54; Nye, *supra* note 1 at 21, 51, 67.

[57] See Nye, *supra* note 1 at 33, 46, 67.

[58] *Ibid.* at 41.

[59] See *ibid.* at 21-22.

[60] *Ibid.* at 45. The computer was "once feared as the physical embodiment of rationalization and standardization, gradually came to be seen as an engine of diversity" (*ibid.* at 77).

[61] No technology is inevitable. Some do not even get approved, and many other applications simply fail. See *e.g.* Jacob S Sherkow, "Controlling CRISPR Through Law: Legal Regimes as Precautionary Principles" (2019) 2:5 CRISPR J 299 at 300, DOI: < 10.1089/crispr.2019.0029 > .

1972, the British magazine Nova ran a cover story saying test tube babies were 'the biggest threat since the atom bomb.'"[62] Similarly, in 2019, Werner commented: "CRISPR offers tremendous opportunities . . . [but it is] potentially more dangerous than nuclear weapons because of its ease of development and precision of applicability."[63] One should wonder why the media and scholars make such deterministic predictions: are they trying to will them into existence?

These philosophical and historical views about technology and technological determinism provide a clear view about what is known and unknown about CRISPR. This view is the one Canadians should subscribe to when we discuss CRISPR:

- Known: CRISPR is like any other technology—humans created it. Humans are the agents over it. This reality must not be forgotten. Some might argue that CRISPR allows humans to play god. A response to that point is easy. Medicine facilitates playing god, so does vaccination, and we do not call for a moratorium over either.
- Unknown: Governments, scientists, and so-called futurists will never have enough information to be certain about CRISPR's future. Only time will tell. Many other things are arguably more harmful to the world—plastic, fossil fuels, even procreation—yet some governments allow them without so much as a second thought.

2. "BREAK A RIB; SAVE A LIFE"

CPR training's adage still rings true. Having an alive patient with broken ribs is far better than a dead patient with unblemished ribs. The same is true for people who are dying and participating in experimental clinical trials. You are going to die, so why not consider any available, ethical, treatment, including experimental CRISPR trials.

Yet "many scientists argue that [CRISPR] experiments in humans are premature: The risks and uncertainties around CRISPR modification are extremely high."[64] This statement does not discriminate between germline and somatic experiments, and the view is not uncommon in the scientific community. For example, notwithstanding ethical approval,[65] at least one United States

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[62] "Canadian scientists fear blowback over CRISPR babies could undermine their work" *CBC Radio* (8 December 2018), online: < www.cbc.ca/radio/day6/episode-419-pot-jobs-in-alberta-p-is-for-pterodactyl-the-impeach-o-meter-crispr-for-good-and-more-1.4934721/canadian-scientists-fear-blowback-over-crispr-babies-could-undermine-their-work-1.4934732 > .

[63] Eric Werner, "The Coming CRISPR Wars: Or why genome editing can be more dangerous than nuclear weapons" (2019) at 7 [unpublished, archived at ResearchGate], DOI: < 10.13140/RG.2.2.17533.00485 > .

[64] Brad Plumer et al, "A simple guide to CRISPR, one of the biggest science stories of the decade", *Vox* (27 December 2018), online: < www.vox.com/2018/7/23/17594864/crispr-cas9-gene-editing > .

somatic CRISPR trial on humans is being criticized as unethical.[66] Yet in the one of most recent moratorium calls,[67] which occurred after the now famous Chinese "CRISPR twins" were born (twins with CRISPR germline edited DNA),[68] Lander and his team's moratorium focussed on germline modifications. They argued that "[c]linical application [of germline editing] should be considered only if there is a sufficiently compelling reason."[69] But Lander and his team were clear. Pre-clinical germline editing and somatic applications can proceed:

> [O]ur proposed moratorium does not apply to germline editing for research uses, provided that these studies do not involve the transfer of an embryo to a person's uterus. It also does not apply to genome editing in human somatic (non-reproductive) cells to treat diseases, for which patients can provide informed consent and the DNA modifications are not heritable.[70]

Canada's current approach largely does not align with this statement from leaders in the field or similar statements.[71] It needs a new path forward.

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65 See "A Safety and Efficacy Study Evaluating CTX001 in Subjects with Transfusion-Dependent ß-Thalassemia", Study Record Detail, (US National Library of Medicine, first posted 31 August 2018, last updated 16 February, 2021), online: < https://clinicaltrials.gov/ct2/show/NCT03655678 > [Transfusion-Dependent ß-Thalassemia Study].

66 See *e.g.* Françoise Baylis & Marcus McLeod, "First-in-human Phase 1 CRISPR Gene Editing Cancer Trials: Are We Ready?" (2017) 17:4 Current Gene Therapy 309, DOI: < 10.2174/1566523217666171121165935 > .

67 See Julia Belluz, "After China's gene-edited baby debacle, CRISPR scientists want a moratorium" *Vox* (13 March 2019), online: < www.vox.com/science-and-health/2019/3/13/18261888/crispr-gene-editing-china-babies > (for a summary of the controversy).

68 See *e.g.* David Cyranoski & Heidi Ledford, "International outcry over genome-edited baby claim", *Nature* 563 (29 November 2018) 607, DOI: < 10.1038/d41586-018-07545-0 > ; Haoyi Wang et al, "CRISPR twins: a condemnation from Chinese academic societies", *Nature* 564:345 (19 December 2018),DOI: < 10.1038/d41586-018-07777-0 > (for a summary of the condemnation).

69 Lander, *supra* note 2 at 166.

70 *Ibid.* (emphasis added).

71 See Organizing Committee for the International Summit on Human Gene Editing, *supra* note 17. *Contra* G Owen Schaefer, "Why treat gene editing differently in two types of cells" *The Conversation* (7 December 2015), online: < https://theconversation.com/amp/why-treat-gene-editing-differently-in-two-types-of-human-cells-51843 > (as a bioethicist, she argues that the dichotomy between somatic and germline is tenuous: both involve genetic engineering and "the long-term risks of inheritability unique to germline modification are much less certain and actually more manageable than the short-term risks of harmful modifications shared by somatic therapies").

(a) Canada's Current Approach to CRISPR Falls Well Below an Acceptable Mark

Canada's current approach is flawed in two principal ways: the approach to somatic trials lacks sufficient guidance, which will likely cause inefficiency and potentially harm, and the criminalization of germline editing is too restrictive.

First, as Part 1 suggested, Canada's current approach to CRISPR somatic trials will likely soon be inefficient. Experts agree that CRISPR "somatic applications require additional, explicit guidance."[72] Yet, as previously discussed, Canada has none.[73] Canada should soon fill this gap. While Canada has not yet birthed Canadian somatic CRISPR clinical trials,[74] somatic genome medications are slowly making its way into Canadian hospitals in multi-site/multi-country clinical trials (for example, CRISPR sickle-cell and beta thalassemia somatic clinical trials have Canadian sites).[75]

Second, as Part 1 noted, germline editing for all purposes—including research (or pre-clinical) purposes—is criminalized. Canada is one of the few countries with such a restrictive approach that altogether criminalizes pre-clinical editing.[76] Despite urging,[77] Canada is not revisiting the prohibition in its current

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[72] Knoppers et al, *supra* note 30 at 4.

[73] See CCA, *From Research to Reality, supra* note 44 (for guidance on what changes could be made).

[74] As of March 2021, I have been unable to locate any clinical somatic human CRISPR trials that originate in Canada. But as noted, clinical somatic human CRISPR trials are occurring in Canada as part of multi-site trials.

[75] See "A Safety and Efficacy Study Evaluating CTX001 in Subjects with Severe Sickle Cell Disease", Study Record Detail (US National Library of Medicine, first posted 19 November 2018, updated 22 January 22 2021), online: < https://clinicaltrials.gov/ct2/show/NCT03745287?term = crispr&draw = 2 > ; Transfusion-Dependent ß-Thalassemia Study, *supra* note 65.

[76] See Tom Blackwell, "End Canada's criminal ban on contentious CRISPR gene-editing research, major science group urges", *The National Post* (8 November 2017), online: < https://nationalpost.com/health/end-canadas-criminal-ban-on-contentious-crispr-gene-editing-research-major-science-group-urges > ; Zubin Master & Patrick Bedford, "CRISPR Gene Editing Should Be Allowed in Canada, But Under What Circumstances?" (2018) 40:2 J Obstetrics & Gynaecology 224 at 225, DOI: < 10.1016/j.jogc.2017.08.028 > . At least 29 countries preclude clinical germline editing (see Motoko Araki & Tetsuya Ishii, "International regulatory landscape and integration of corrective genome editing into in vitro fertilization" (2014) 12:108 Reproductive Biology & Endocrinology 1 at 8; Francoise Baylis et al, "Human Germline and Heritable Genome Editing: The Global Policy Landscape" (2020) 3:5 CRISPR J 365 at 366, DOI: < 10.1089/crispr.2020.0082 >).

[77] See Knoppers et al, *supra* note 30 at 2; Bartha Maria Knoppers et al, "Human gene editing: revisiting Canadian policy" (2017) 2:3 Regenerative Medicine 1 at 1; Ben Schaub, "Human Gene Editing Could Change the World — What are the Laws Governing it in Canada?" *CBC* (*The Nature of Things*), online: < www.cbc.ca/natureofthings/m_features/gene-editing-in-canada > ; Tania Bubela et al, "Canada's *Assisted Human Reproduction Act:* Pragmatic Reforms in Support of Research" (2019) 6:157 Frontier Medicine 1, DOI: < 10.338/fmed.201900157 > .

AHRA reforms.[78] Canada should. In the words of leading Canadian researchers, "Canada's *Assisted Human Reproduction Act* is long overdue for Parliamentary review."[79] That said, Health Canada did recently develop and enact regulations to the *AHRA* that were long overdue.[80] While Health Canada should have developed these regulations far earlier (the *AHRA* was enacted in 2004), these regulations do demonstrate Health Canada's willingness to consider the *AHRA*'s shortcomings.

Leaving aside the issue of germline editing for clinical purposes[81] (a point that Part 3 briefly discusses), conducting pre-clinical germline research is likely necessary for adequate somatic therapy.[82] "[R]esearchers still have a long way to go to understand the genes involved" in certain diseases (like Huntington's, Duchenne muscle dystrophy, HPV, HBV, cystic fibrosis, cancer, etc.) that involve several genetic mutations.[83] Researchers also need to improve CRISPR's efficiency and specificity while reducing off-target and knock-on effects: "the development of an effective, safe and cell-specific CRISPR/Cas9 delivery system remains a major challenge."[84] Put plainly:

> Germline editing in a dish can help researchers figure out what the health benefits could be, and how to reduce risks. Those include targeting the wrong gene; off-target impacts, in which editing a gene might fix one problem but cause another; and mosaicism, in which only some copies of the gene are altered.[85]

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[78] "Toward a strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals", (11 July 2017) online: *Government of Canada* <www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction/document.html>. Notably, some researchers argue that the *AHRA* does not preclude such testing and suggest it conforms with the *AHRA* (see Master & Bedford, *supra* note 76 at 224). Their view, however, appears to be a minority position when you consider the calls to reform the *AHRA*.

[79] Bubela et al, *supra* note 77 at 8.

[80] See *e.g.* Alison Motluk, "Long-awaited regulations bring clarity to assisted reproduction act" (2019) 191:32 CMAJ E902, DOI: <10.1503/cmaj.109-5791>.

[81] Some argue that "there is no legitimate ethical argument about whether gene editing should be used, either to treat people living with the condition now or to spare their children from it. 'Anyone who has to actually face the reality of one of these diseases is not going to have a remote compunction about thinking that there is any moral issue at all.'" Hayden, *supra* note 2 at 403.

[82] See Blackwell, *supra* note 76 ("basic, pre-clinical science is important for increasing knowledge and understanding of how genetic disease and embryos develop").

[83] Hayden, *supra* note 2 at 405. See also Alessio Biagioni et al, "Delivery systems of CRISPR/Cas9-based cancer gene therapy" (2018) 12:33 J Biological Engineering 1 at 23, DOI: <10.1186/s13036-018-0127-2>.

[84] Marta Martinez-Lage et al, "CRISPR/Cas9 for Cancer Therapy: Hopes and Challenges" (2018) 6:4(105) Biomedicines 1 at 3, DOI: <10.3390/biomedicines6040105>. See also *ibid.* at 6-7.

[85] Bergman, *supra* note 28.

Surely pre-clinical germline research would help develop robust somatic therapies.[86] Yet instead of pursuing all avenues to resolve these challenges, Canada is not removing its prohibition on pre-clinical germline editing.

This unfortunate state of affairs remains the case despite cancer being the leading cause of death in Canadians and the second leading cause of death in the world, which imposes an incredible economic and social burden.[87] The facts are clear: cancer kills about twenty-five per cent of Canadians. Nearly one in two Canadians will be diagnosed with cancer in their lifetime. In 2017 alone, 206,200 Canadians were diagnosed with cancer, and 80,800 people died from cancer. Canada has made strides, but it is losing its overall battle to cancer. By 2030, cancer diagnoses are projected to be eighty per cent higher than in 2005.[88] Canada simply does not have time to wait. Unsurprisingly, other areas of the world agree. China, the United States, and Europe are already conducting somatic CRISPR clinical trials for humans with cancer.

More pre-clinical germline editing research and somatic clinical cancer trials are urgently needed.[89] Why Canada is waiting to join this global movement of improving health is unknown. Perhaps government officials do not comprehend what is at stake and what is possible. Perhaps they subscribe to fears about germline editing. Whatever the reason, three reasons demonstrate why Canada's inaction is unacceptable. And these reasons justify my Path 1 recommendation: Canada should pursue more somatic CRISPR clinical trials and permit pre-clinical germline editing.

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[86] See *ibid.* (''[d]eveloping safe, effective ways to use gene editing to treat people with serious diseases with no known cures has so much potential to relieve suffering that it is hard to see how anyone could be against it'' at 26)

[87] Martinez-Lage et al, *supra* note 84 at 1.

[88] Canadian Cancer Statistics Advisory Committee, *Canadian Cancer Statistics 2018* (Toronto: Canadian Cancer Society, 2018) at 6, 42, online (pdf): < www.cancer.ca/~/media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2018-EN.pdf?la = en > .

[89] See Katherine Wright, ''CRISPR gene-editing trial tests new way to treat cancer'' (4 February 2017) online: *Canadian Cancer Society* < https://web.archive.org/web/20180405123600/https://www.cancer.ca/fr-ca/research-horizons/f/e/9/crispr-gene-editing-trial-tests-new-way-to-treat-cancer/ > . See also Antonio Regalado, ''CRISPR has been used to treat US cancer patients for the first time'', *MIT Technology Review* (17 April 2019), online: < www.technologyreview.com/the-download/613321/crispr-has-been-used-to-treat-us-cancer-patients-for-the-first-time/ > ; ''CRISPR Therapeutics and Vertex Announce FDA Has Lifted the Clinical Hold on the Investigational New Drug Application for CTX001 for the Treatment of Sickle Cell Disease'', *Global News Wire* (10 October 2018), online: < www.globenewswire.com/news-release/2018/10/10/1619581/0/en/CRISPR-Therapeutics-and-Vertex-Announce-FDA-Has-Lifted-the-Clinical-Hold-on-the-Investigational-New-Drug-Application-for-CTX001-for-the-Treatment-of-Sickle-Cell-Disease.html > .

(a) Path 1: Three Justifications

Three justifications for Path 1 are that the potential gains outweigh the potential harms, aversion bias influences current policy, and germline editing in humans will likely happen in other countries and Canadian scientists should participate.

First, the potential harms of Path 1 do not outweigh the expected valuable gains. People are already dying, so should not Canada find ways to facilitate[90] more somatic CRISPR clinical trials that might save them?[91] Such facilitation should clearly include permitting pre-clinical germline testing. Canada could examine "right to try" legislation, like the United States' *Right to Try Act of 2017*.[92] But American experts criticize that legislation. In some ways, it is redundant because special access regimes already exist (while the two regimes are different, the FDA authorizes more than ninety-nine per cent of Expanded Access requests).[93] Canada also has a Special Access Programme that enables

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[90] In most cases, Canada does not involve itself in clinical trial research. Rather, it focuses on regulating and importing non-approved drugs for use in human clinical trials. In other cases, however, Canada is involved in clinical trials, and individuals must apply to Health Canada's Research Ethics Board for ethical approval to proceed (see "Clinical Trial Regulations", online: *Government of Canada* <www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/policy-procedures/clinical-trial-regulations-policies-procedures.html>). My point is that Canada should create research environments that foster this kind of research.

[91] These ethical issues have been addressed in other contexts—*e.g.*, experimental HIV/AIDS research or "desperation oncology." Nothing is exceptionally unique about CRISPR somatic research in a way that prevents Canada from pursuing and facilitating developing such somatic trials.

[92] See *e.g.* Benjamin A Cohen-Kurzrock, Philip R Cohen & Razelle Kurzrock, "The right to try is embodied in the right to die" (2016) 13:7 Nature Rev Clinical Oncology 399; Udo Schüklenk, "Should dying patients have the right to access experimental treatments?" *The Conversation* (11 November 2014), online: <https://theconversation.com/should-dying-patients-have-the-right-to-access-experimental-treatments-33884>; Gina Kolata, "'Desperation Oncology': When Patients Are Dying, Some Cancer Doctors Turn to Immunotherapy", *The New York Times* (26 April 2018), online: <www.nytimes.com/2018/04/26/health/doctors-cancer-immunotherapy.html>; Nick Boisvert, "Terminally-ill patients demand better access to experimental treatments", *CBC News* (22 November 2016), online: <www.cbc.ca/news/canada/toronto/terminally-ill-experimental-treatments-1.3861638>. *Contra* Yoram Unguru, "'Right to Try' laws are compassionate, but misguided" *The Conversation* (20 October 2014), online: <https://theconversation.com/right-to-try-laws-are-compassionate-but-misguided-33440>.

[93] See Alison Bateman-House et al, "Right-to-try laws: Hope, Hype, and Unintended Consequences" (2015) 163:10 Annals of internal medicine 796, DOI: <10.7326/m15-0148> ("right-to-try laws do nothing to significantly change patient access to investigational medical products. Worse, these laws may result in unintended negative consequences for patients and society" at 796); Kelly Folkers, Carolyn Chapman & Barbara Redman, "Federal Right to Try: Where Is It Going?" (2019) 49:2 Hastings Center Report 26, DOI: <10.1002/hast.990> ("[t]he federal right-to-try pathway, ostensibly a route by which patients can gain access to drugs that are still under investigation, has probably done little to change pharmaceutical companies' practices.

emergency access to drugs that cannot otherwise be sold or distributed in Canada.[94] So right to try legislation may be of little benefit, and harms may outweigh benefits.

Second, Canada's current status quo approach shows an apparent loss aversion bias:[95] "the retention of the status quo is an option in many decision problems. . . . loss aversion induces a bias that favours the retention of the status quo over other options."[96] The certain and future loss of life due to cancer versus the uncertain loss of not allowing pre-clinical germline research and actively pursuing and facilitating CRISPR somatic trials is clear. Waiting to see what happens before deciding to change the law is a decision. Indeed, deciding not to decide is a decision,[97] and it is the wrong one.

Third, actual germline editing in humans is likely inevitable in the world.[98] As noted, it has already happened. But scientists still have much to understand and many technical and biological barriers to solve.[99] Should not Canadian scientists be allowed to help, especially since it is what they want.[100] At the very least, Canada should quickly remove the prohibition on pre-clinical germline research. The slope of permitting it is not slippery. As Ravitsky eloquently notes:

However, it may have undermined the government's role in monitoring the safety and efficacy of drugs, and it may even have created a loophole by which companies can sell unapproved drugs to the public" at 26); Holly Fernandez Lynch, Patricia J Zettler & Ameet Sarpatwari, "Promoting Patient Interests in Implementing the Federal Right to Try Act" (2018) 320:9 JAMA 869, DOI: < 10.1001/jama.2018.9880 > .

94 See "Health Canada's special access programs: Request a drug" (2020), online: *Government of Canada* < www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html > .

95 See Amos Tversky & Daniel Kahneman, "Loss Aversion in Riskless Choice: A Reference-Dependent Model" (1991) 106:4 QJ Economics 1039 ("the basic intuition concerning loss aversion is that loses (outcomes below the reference state) loom larger than corresponding gains (outcomes above the reference state). Because a shift of reference can turn gains into losses and vice versa, it can give rise to reversal of preference" at 1047).

96 *Ibid.* at 1042.

97 See *e.g.* Itiel E Dror & Glenn Langenburg, "Cannot Decide': The Fine Line Between Appropriate Inconclusive Determinations Versus Unjustifiably Deciding Not To Decide" (2018) 64:1 J Forensic Science 10, DOI: < 10.1111/1556-4029.13854 > ; Sebastian Gluth, J—rg Rieskamp & Christian Büchel, "Deciding Not to Decide: Computational and Neural Evidence for Hidden Behavior in Sequential Choice" (2013) 9:10 PLOS Computational Biology 1, DOI: < 10.1371/journal.pcbi.1003309 > .

98 See Bosley, *supra* note 37 at 478-479.

99 See *ibid.* at 479-480.

100 Kristen V Brown, "This Outdated Law makes CRISPR Illegal in Canada—and that's Hurting Science" (20 November 2017), online: *Gizmodo* < https://gizmodo.com/this-outdated-law-makes-crispr-illegal-in-canada-and-th-1820612582 > (as Ravitsky notes, "Scientists here feel left behind. . . . They have the technical capacity to do this research and they have these good research questions. The only reason they're not doing it is legal.")

> If you allow us to genetically alter an embryo for research, what's next . . .. embryos don't fall by chance into a uterus. By banning research you are banning research that is not just about making babies. This research can promote our understanding of reproductive development, of the development of diseases. It makes no sense to say no to research.[101]

(b) Canada's Silence

Canadian public political discourse on CRISPR is almost non-existent despite all the potential somatic uses and calls to change the *AHRA*.[102] So the Canadian government has not overtly perpetuated the three issues we discussed in Part 1. But much like its decision to do nothing, its decision to say nothing is equally problematic. It is missing a chance to impact the narrative and to develop a Canadian narrative about CRISPR. Shockingly, CRISPR has only been discussed eleven times in committee and debate.[103] The most interesting

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[101] Vardit Ravitsky as quoted in Brown, *ibid.* (emphasis added).

[102] For completeness, I searched debates and committee work by availing two sources: openparliament.ca and ourcommons.ca.

[103] CRISPR has only been discussed 11 times in committee and debate, and it has not been discussed since 2019:

- The Standing Committee on Agriculture and Agri-Food has been the main discussion venue. It discussed CRISPR six times. Discussions between members and industry centred on keeping regulatory pace with the United States. See House of Commons, Standing Committee on Agriculture and Agri-Food, 42-1, No 22 (4 October 2016) at 900 (Dennis Prouse); Standing Committee on Agriculture and Agri-Food, 42-1, No 77 (7 November 2017) at 1555 (Ian Affleck), 1555 (Dennis Prouse), 1605 (Francis Drouin); Standing Committee on Agriculture and Agri-Food, 42-1, No 98 (30 April 2018) at 1550 (Lloyd Longfield), 1535 (Krista Thomas), 1550 (Krista Thomas); House of Commons, *Toward a Resilient Canadian Agriculture and Agri-Food System: Adapting to Climate Change: Report of the Standing Committee on Agriculture and Agri-Food* (May 2018) (Chair: Pat Finnigan) at 35-36; House of Commons, Standing Committee on Agriculture and Agri-Food, 42-1, No 105 Number 105 (20 September 2018) at 0940 (Earl Dreeshen); House of Commons, Standing Committee on Agriculture and Agri-Food, 42-1, No 135 (4 April 2019) at 1145 (Lloyd Longfield).
- The Standing Committee on International Trade discussed CRISPR twice. Discussions between industry related to being unable to understand CRISPR and between private citizens related to Monsanto and CRISPR. See House of Commons, Standing Committee on International Trade, 42-1, No 13 (21 April 2016) at 0930 (Cam Dahl); House of Commons, Standing Committee on International Trade, 42-1, No 035 (29 September 2016) at 1200 (Martha Asseer).
- The Standing Committee on Finance discussed CRISPR once. Discussions between members and industry centred on keeping regulatory pace with the United States. See House of Commons, Standing Committee on Finance, 42-1, No 105 (25 September 2017) at 1750 (Dennis Prouse).
- The Standing Committee on Industry, Science and Technology discussed CRISPR once. Discussions again centred on keeping up with the fast pace of innovation. See House of Commons, Standing Committee on Industry, Science, and Technology, 42-1, No 149 (19 February 2019) at 1015 (Dane Lloyd), 1020 (Dave Carey).
- An MP raised it in terms of Canada's health system and a motion for federally funded health research and noted that CRISPR was a "marvellous genius" idea: it is "what we are working for and striving for, to support the empowerment of our brilliant innovators and scientists who will change the landscape of medicine and public health" (House of Commons Debates, 42-1, Vol 148 No 228 (2 November 2017) at 1810 (Eva Nassif).

comment came from a member of the Standing Committee on Agriculture and Agri-Food:

> We have all of this new technology. We have blockchain technology, which we haven't talked about. We have CRISPR technology, which is associated with it. How do we get ahead of that, to make sure the messages we have are going to get through to the general public?[104]

This comment and the other ten interactions reveal two things. First, Canada is paying a paucity of attention to CRISPR, and the limited attention it has paid has focused on agriculture versus medicine. And even those conversations are more like comments in passing versus actual robust debates. Second, these comments suggest that some people really misunderstand CRISPR (and blockchain technology).[105]

3. REVIVING ATHENS—DELIBERATIVE DEMOCRACY AND "DELIBERATIVE POLLING"

Technology's history suggests the market is an apt selector of technology. For example, "[h]ad congress trusted in the free market and avoided subsidies, more cities would have built or maintained mass transit, fewer power companies would have built nuclear reactors, and the United States would consume far less energy."[106] Market selection makes sense: it is often consumers versus scientists or developers that determine technologies' place in society.[107] Market selection also makes sense in the CRISPR context because individuals have to choose whether to avail somatic or future germline modifications. But history is also clear that laws are sometimes the best mechanism to curb technological follies.[108]

From time to time, however, neither the market nor regulation alone can deal with the deeply political and moral questions that some technologies invite.[109] CRISPR is likely one such technology. Canadians' views are paramount. Much like colonists demanded a voice in tax policy,[110] Canadians deserve a voice in CRISPR regulation. But Canada is doing little, if anything, to gather Canadian's views. It simply lacks "empirical data, qualitative or quantitative, assessing public perceptions and attitudes towards either somatic

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[104] House of Commons, Standing Committee on Agriculture and Agri-Food, 42-1, No 105 (20 September 2018) at 0940 (Earl Dreeshen).

[105] See House of Commons, Standing Committee on International Trade, 42-1, No 13 (21 April 2016) at 0930 (Cam Dahl) (the President of Cereals Canada noted that he could not "talk about things like CRISPR-Cas, the new gene editing technique. My brain is not capable of understanding it . . . Farmers, using precision agriculture, can place a seed within centimetres of where it was intended to go.")

[106] *Nye*, *supra* note 1 at 142.

[107] See *ibid.* at 39.

[108] See *ibid.* at 143.

[109] See *ibid.* at 147.

[110] See *ibid.* at 146.

or germline human genome editing."[111] This issue is also broader than just CRISPR. We already have other human genome editing therapies (for example, zinc fingers and TALENs). So Canada should resolve this data deficit about Canadians' public perception on human genome editing as soon as possible.

How, then, should Canada involve Canadians? "Deliberative Polling" presents a possible excellent mechanism.[112] Canada could use it to engage Canadians and provide them valuable information while simultaneously educating itself on their views. It has been used over one hundred times in twenty-eight countries, including the United Kingdom, Japan, China, the United States, and the European Union to name just a few.[113] Scholars have even used it to address healthcare related issues,[114] including in Canada.[115]

Fishkin coined the phrase "Deliberative Polling" and has created a framework that Canada could deploy with minimal modifications, a point we will shortly discuss. Deliberative Polling is unlike normal modern polling because it strives for deliberation. Depending on how polls are struck, researchers or governments could also attempt to resolve the typical self-selection bias and weighting issues that plague most traditional polls, surveys, and epidemiological studies.[116]

Typical poll and survey respondents answer questions off the "top-of-their-heads" without deliberating; they give opinions that could be called "nonattitudes."[117] Deliberative Polling's aims are different. It seeks to raise the level of deliberation while maintaining political equality. It seeks to foster better democracy, a more deliberative democracy[118] where citizens are actively involved in decision-making:

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[111] Knoppers et al, *supra* note 30 at 1.

[112] See Nye, *supra* note 1 at 158.

[113] See "What is Deliberative Polling?" online: *Centre for Deliberative Democracy, Stanford University* < https://cdd.stanford.edu/what-is-deliberative-polling/ > ; James Fishkin et al, "Deliberative Democracy in an Unlikely Place: Deliberate Polling in China" (2010) 40:2 British J Political Science 435 at 436, DOI: < 10.1017/S0007123409990330 > ; "Deliberative Polling by the People" online: *Centre for Deliberative Democracy, Stanford University* < https://cdd.stanford.edu/2018/deliberative-polling-by-the-people/ > .

[114] See *ibid*; "Health" online: *Centre for Deliberative Democracy, Stanford University* < https://cdd.stanford.edu/dp-topics/health/ > .

[115] See Julia Abelson et al, "Does the Community Want Devolved Authority? Results of deliberative polling in Ontario" (1995) 153:4 CMAJ 403.

[116] See *e.g.* Claire Keeble et al, "Choosing a Method to Reduce Selection Bias: A Tool for Researchers" (2015) 5:3 Open J Epidemiology 155.

[117] James S Fishkin & Robert C Luskin, "Experimenting with a Democratic Ideal: Deliberative Polling and Public Opinion" (2005) 40:3 Acta Politica 284 at 287, DOI: < 10.1057/palgrave.ap.5500121 > .

[118] See *e.g.* James S Fishkin & Jane Mansbridge, "Introduction" (2017) 146:3 Daedelus 6, DOI: < 10.1162/DAED_x_00442 > (for a brief discussion of deliberative democracy).

> by exposing random samples to balanced information, encouraging them to weigh opposing arguments in discussions with heterogenous interlocutors, and then harvesting their more considered opinions. It is a way, at least in miniature, of serving both deliberation and equality. The deliberation lies in the learning, thinking, and talking that distinguishes Deliberative Polls from conventional ones. The political equality stems from random sampling. In theory, every citizen has an equal chance of being chosen to participate, and on average, over infinitely repeated sampling from the same population, the sample would resemble the population exactly.[119]

In short, Deliberative Polling emulates Athenian democracy.[120] It seeks to promote the space and time that Athens provided for public debates where "[c]itizens were expected to be active in the administration of the city, to articulate themselves publicly, and to vote in decisions affecting them.[121] As Hadfield argues, "[t]he genius of the Athenian democracy was its almost fanatical attention to achieving common knowledge."[122]

The genius of Deliberative Polling is that it rejects traditional, elitist, top-down regulatory approaches and classic political posturing.[123] It promotes the goals of democratic reform (deliberation and political equality),[124] and it is well-suited to helping regulate CRISPR's use.[125] Indeed, scholars continue to stress the need for collective approaches and inclusivity versus elitism in discussing and addressing the issues CRISPR may raise.[126]

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[119] *Ibid.* at 287.

[120] See Fishkin & Luskin, *supra* note 117 at 287; Nye, *supra* note 1 at 158.

[121] Genevieve Fuji Johnson, *Democratic Illusion: Deliberative Democracy in Canadian Public Policy* (Toronto: University of Toronto Press, 2015) at 8.

[122] Gillian Hadfield, *Rules for Flat World: Why Humans Invented Law and How to Reinvent it for Complex Global Economy* (Oxford: Oxford University Press, 2017) at 307.

[123] For example, on issues such as germline applications in humans, Canada needs to hear from those most impacted—*e.g.*, the rare disease community who may desire human genome editing (see Erika Kleiderman & Ian Norris Kelner Stedman, "Human germline genome editing is illegal in Canada, but could it be desirable for some members of the rare disease community?" (2020) 11:2 J Community Genetics 129.

[124] See Fishkin & Luskin, *supra* note 117 at 287.

[125] See Guilia Cavaliere, Katrien Devolder & Alberto Giubilini, "Regulating Genome Editing: For an Enlightened Democratic Governance" (2019) 28:1 Cambridge Q Healthcare Ethics 76 at 84-85, DOI: < 10.1017/S0963180118000403 > .

[126] See Christopher Thomas Scott & Cynthia Selin, "What to Expect When Expecting CRISPR Baby Number Four" (2019) 19:3 American J Bioethics 7 at 8, DOI: < 10.1080/15265161.2018.1562793 > ; Bartosz Bartkowski & Chad M Baum, "Dealing With Rejection: An Application of the Exit—Voice Framework to Genome-Edited Food" (2019) 7:57 Frontiers Bioegineering Biotechnology 1 at 12, DOI: < 10.3389/fbioe.2019.00057 > ; Sheila Jasanoff, J Benjamin Hurlbut & Krishanu Saha, "CRISPR Democracy Gene Editing and the Need for Inclusive Deliberation" (2015) 32:1 Issues Science & Technology 25.

Before moving on to describe how Canada could use Deliberative Polling, I want to be clear. Deliberative Polling is not perfect. It is not some panacea solution without flaws. For example, Deliberative Polling is expensive and laborious (finding a balanced advisory committee who is willing to participate can prove difficult).[127] These reasons likely explain why Deliberative Polling is not more mainstream.[128] That said, we do not have to look far to see sieges upon democracy and low approval ratings of democratic institutions. Indeed, "[a]pproval ratings for democratic institutions in most countries around the world are at near-record lows."[129] Many countries are experiencing democratic recessions.[130] Deliberative polling will be expensive and laborious. We have no way around that reality. But the cost of democratic recession, increased polarization, and the near certain loss of life from various diseases that biotechnology (such as CRISPR) could treat or cure are far more costly and laborious.[131]

If Canada sought to deploy Deliberative Polling to engage Canadians in regulating CRISPR, it could follow Fishkin and Luskin's established framework,[132] and it could proceed through these seven steps:

1. Canada must create a random sample to ensure political equality, representativeness, and the ability to measure degrees of certainty (*i.e.*, confidence levels and intervals).
2. Once it selects a random, polling group, it then asks them questions about their views on CRISPR.

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[127] See Alice Siu, "Deliberative Polling", online: *PG Exchange (Archive)* <https://web.archive.org/web/20100630225856/http://www.pgexchange.org/index.php?option=com_content&view=article&id=132&Itemid=121>. Other downsides include finding participants (see *e.g.* James Fishkin, *The Voice of the People* (New Haven: Yale University Press, 1995). If participants are not conscripted or required to participate—like in traditional juries—the same self-selection bias issues that plague traditional polls or surveys will also arise.)

[128] One suggestion to address some flaws is using online deliberative polls, but such polls obviously lose the community that could be built during in-person interactions (see *e.g.* Riu Wang & Alice Siu, "Refined or Biased Opinions? Examining Self-Selected Participation in Deliberation and Post-survey in On-line Deliberative Polls" (Paper delivered at American Association for Public Opinion Research 64th Annual Conference, Florida, 16 May 2009), online (pdf): <http://www.asasrms.org/Proceedings/y2009/Files/400061.pdf>.

[129] Fishkin & Mansbridge, *supra* note 118 at 6.

[130] See Larry Diamond, "Facing Up to Democratic Recession" (2015) 26:1 J Democracy 141, DOI: <10.1353/jod.2015.0009>.

[131] Additionally, one might assume there are *Charter* or constitutional challenges against the *AHRA*'s restrictive regimes. Unsurprisingly, *Charter* and constitutional litigation is extremely expensive—for both plaintiff and the government (See *e.g.* Alan Young, *The Costs of Charter Litigation* (Ottawa: Government of Canada, 2016/2017), online (pdf): *Department of Justice* <www.justice.gc.ca/eng/rp-pr/jr/ccl-clc/ccl-clc.pdf>).

[132] See Fishkin & Luskin, *supra* note 117 at 288-289.

3. Then, it would send the polling group balanced briefing materials that include empirical premises and facts about CRISPR. A pre-determined advisory board of stakeholders would have vetted those materials for balance and accuracy.
4. The polling group would then attend a single site for weekend long deliberations. The format would include randomly assigned small groups where participants discuss the issues and plenary panel discussions with policy experts and policymakers. Trained moderators would lead the small groups. The moderators would maintain civility and respect, encourage diffident participants, restrain loquacious participants, and ensure that all major proposals and arguments for and against CRISPR are raised.[133]
5. Policy experts and policymakers in the plenary would respond to small group questions. Such questions would not be merely factual. Rather, they would be directed at policy alternatives and costs, trade-offs, etc. related to CRISPR. The same advisory board who vetted the briefing materials could also vet the panel composition.
6. After the deliberative weekend concludes, Canada would again ask participants questions about their views on CRISPR.
7. Canada could also use a control group—an independent sample that does not deliberate—to measure responses.

Such an approach would not be unfounded. Deliberative Polling's validity in Canada has been confirmed through actual experiences involving medical issues.[134] And scholars have advocated for its increased use (or similar deliberative processes, for example, citizen juries) in Canada,[135] including for bioethics issues.[136] They have also provided Canadian-centric views on designing

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[133] Moderators would also maintain the following parameters (see Fishkin & Luskin, *supra* note 117 at 285):

- Informed: Appropriate and reasonably accurate factual claims should support arguments;
- Balanced: Contrary views are welcome and must be present;
- Conscientious: Participants must talk and listen with civility and respect;
- Substantive: Participants must consider arguments on their merits versus how they are made or who makes them; and
- Comprehensive: Any view that significant portions of the population hold must receive attention.

[134] See Julia Abelson et al, "Does deliberation make a difference? Results from a citizens panel study of health goals priority setting?" (2003) 66:1 Health Policy 95 at 95, 102, 104, DOI: < 10.1016/S0168-8510(03)00048-4 > .

[135] See *How Can the Public Be Meaningfully Involved in Developing and Maintaining an Overall Vision for the Health System Consistent with Its Values and Principles?* Commission on the Future of Health Care in Canada, Discussion Paper No 33, (2002) at iv; *Public Participation and Citizen Governance in the Canadian Health System*, Commission on the Future of Health Care in Canada, Discussion Paper No 7, (2002) at iv; Devidas Menon & Tania Stakinski, "Engaging the public in priority-setting for health technology assessment: findings from a citizens jury" (2008) 11 Health Expectations 282 at 282, DOI: < 10.1111/j.1369-7625.2008.00501.x > .

[136] See Julia Abelson et al, "Public Deliberation in Health Policy and Bioethics: Mapping an emerging, interdisciplinary field" (2013) 9:1 J Public Deliberation at 12.

and using deliberative democracy tools in the healthcare context.[137] The Canadian government has even recognized the possibility of using Deliberative Polling (albeit in different circumstances).[138]

With such information, Canada could ascertain its citizens' views on CRISPR and regulating CRISPR. It could also gauge more appropriate ways to speak about CRISPR that do not succumb to inappropriate narratives or technological determinism. Such a process would further democracy's goals and reduce the increasing populistic fractures in Canada's democracy.[139]

4. CONCLUSION: THE WORLD WILL BE BETTER WHEN THEY'RE HERE TOO

Technological determinism is pervasive in healthcare. The cycle over overhyped benefits and risks repeats itself over and over. For example, in 2004, Ontario passed the *Personal Health Information Protection Act, 2004* (*PHIPA*).[140] *PHIPA*'s legislative history shows what legislatures sought to accomplish:

> Bill 31 is an important piece of this government's health care policy, one that's intent upon blowing up [the silos that exist in the healthcare system] . . . one that recognizes that technology is going to be a way for us to bring together hospitals, home care providers, people who are engaged in the administration of drugs and other health care providers.

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[137] See Julia Abelson et al, "Deliberations about deliberative methods: issues in the design and evaluation of public participation processes" (2003) 57:2 Social Science & Medicine 239 at 249.

[138] See House of Commons, *Strengthening Democracy in Canada: Principles, Process, and Public Engagement for Electoral Reform: Report of the Special Committee on Electoral Reform* (December 2016) (Chair: Francis Scarpaleggia) at 148-151; Political and Social Affairs Division (prepared by Claude Emery) "Public Opinion Polling in Canada" (1994) at N13, online: < http://publications.gc.ca/Collection-R/LoPBdP/BP/bp371-e.htm > .

[139] See *Prospects & Limits of Deliberative Democracy* (2017) 146:3 *Daedalus* (for a thorough discussion of these issues and the world's current crisis of confidence in democracy). For Canadian specific issues see *e.g.* Stephanie Levitz, "New Research suggests Rob Ford's Populist Appeal Could be Duplicated Across Canada", *The Globe and Mail* (4 February 2018), online: < www.theglobeandmail.com/news/national/new-research-suggests-rob-fords-populist-appeal-could-be-duplicated-across-canada/article37849081/ > ; Frank Graves & Macael Valpy, "Canada is a tinderbox for populism. The 2019 election could spark it", *Maclean's* (3 December 2018), online: < www.macleans.ca/politics/canada-is-a-tinderbox-for-populism-the-2019-election-could-spark-it/ > (Canada "isn't immune to the economic and demographic forces currently dividing the United States"). *Contra* Amanda Taub, "Canada's Secret to Resisting the West's Populist Wave" (27 June 2017) *New York Times*, online: < www.nytimes.com/2017/06/27/world/canada/canadas-secret-to-resisting-the-wests-populist-wave.html > ("[a]s right-wing populism has roiled elections and upended politics across the West, there is one country where populists have largely failed to break through: Canada.")

[140] S.O. 2004, c.3, Sched. A.

> If we can get rid of these silos, if we can use technology so that we work together and do not enter into this ridiculous situation where at times we're competing, I think we're going to see a movement forward in our health care system.[141]

Yet seventeen years later, researchers still do not have ready access to healthcare data, despite the incredible promise that big data, machine learning, and artificial intelligence offer Canadian healthcare.[142] The data is still siloed in a "complex maze of policy, privacy and security issues involving multiple stakeholders with differing interests and objectives."[143] These current long access processes are costly: they delay research, engender increased costs, and amount to *de facto* denials of access.[144] Put another way, they cause lives to be lost. A likely reason for these lost lives—as well as possible overhyped fears and benefits of big data and medicine—is again a fear of technological determinism. For example, despite breaches rarely, if ever, occurring in many health data regimes, many seem to fear researchers or individuals will inevitably exploit information in health data.[145]

To avoid this all-too-common narrative of repeating inevitable cycles, we must embrace technology for what it is: something humans make, own, use, and interpret.[146] We do not serve technology; it serves us.[147] Anytime deterministic narratives arise, we must remember the people who technology could help—the Mr. Russells of the world—and use technology to put them first.

We must also accept that we are not always going to get it right. The best narratives, the best metaphors, the best predictions, the best science, and the best Deliberative Polling will still be insufficient: CRISPR will have flaws. Things will not be perfect. But relying on Path 1 and Path 2 for CRISPR research will lead to outcomes where individuals may not have to face the same outcome as Mr. Russell. The world will be better when they are here too.

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[141] See *e.g.* Ontario, *Hansard*, 38-1, (5 April 2004) at 1640.

[142] See *e.g.* Marzyeh Ghassemi, "How Machine Learning Enhances Healthcare" (19 February 2021) online (video): *TedxTalks*, *YouTube* <www.youtube.com/watch?-v=zpcOjNtd-70>; Dianne Daniel, "Machine learning makes process in care at Ontario Hospitals", *Canadian Healthcare Technology* (29 October 2020), online: <www.can-health.com/2020/10/29/machine-learning-makes-progress-in-care-at-ontario-hospi-tals-2/>.

[143] See Ontario Genomics, supra note 51 at 1.

[144] CCA, *Accessing Health* supra note 51 at 46.

[145] See *e.g. Data Availability and Use: Productivity Commission and Inquiry Report Overview and Recommendations (No 82,31)* (Commonwealth of Australia, 2017) at 11, online (pdf): <www.pc.gov.au/inquiries/completed/data-access/report/data-access-over-view.pdf>; CCA, *Accessing Health*, *supra* note 51 at xix.

[146] Nye, *supra* note 2 at 47.

[147] See *e.g.* Gillian Hadfield, "Toronto can be a global leader in harnessing AI to serve rather than enslave is", *Toronto Star* (7 January 2020), online: <www.thestar.com/opinion/contributors/2020/01/07/toronto-can-be-a-global-leader-in-harnessing-ai-to-serve-ra-ther-than-enslave-us.html>.