

**2021 CBA Essay Contest Winner: Health Law Section**

Towards an equity-driven regulatory framework for germline editing: considerations for amending the *Assisted Human Reproduction Act*

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*5740 words*

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The future is already here — it's just not very evenly distributed.

WILLIAM GIBSON

## **Contents**

<b>Introduction</b>	<b>3</b>
<b>Part 1: The World of CRISPR/Cas9</b>	<b>8</b>
1.1 Life-saving possibilities	8
1.2 The bright line: improvement vs enhancement	10
1.3 Canada’s international human rights obligations	11
<b>Part 2: Canada’s current framework</b>	<b>12</b>
2.1 The insufficiency of the AHRA re: biotechnology innovation	12
2.2 The wrong tool for the job: criminal sanctions in the AHRA	13
<b>Part 3: CRISPR/Cas-9 considerations with respect to vulnerable people</b>	<b>14</b>
3.1 Concerns re: Eugenics	15
3.2 Longitudinal health risks to children	18
3.3 Professional self-regulation of scientists	18
3.4 Possible “chilling effect” on scientific research	20
3.5 Lacking minority data in genomic research	21
<b>Conclusion</b>	<b>22</b>
<b>Bibliography</b>	<b>24</b>

## I. Introduction

In the 1997 dystopian film *Gattaca*, filmmakers depict a bleak genetic caste society in which the quality of their DNA determines citizens' prospects. In this future, those individuals whose genes are engineered (deemed "Valid") qualify for prestigious jobs and opportunities in society. In contrast, those individuals whose genes are *not* engineered (deemed "Invalid") are condemned to menial, low-paying work. Invalids suffer systemic discrimination and social isolation, unable to compete against genetic perfection. Vincent Freeman, invalid and the story's forlorn protagonist, remarks, "I'll never understand what possessed my mother to put her faith in God's hands, rather than her local geneticist."<sup>1</sup>

The film is a prophetic introduction to themes that characterize the modern debate surrounding genetic engineering in Canada. Genome editing is a scientific technique used to precisely modify DNA within a cell or organism, including plants, bacteria, animals, and humans.<sup>2</sup> Modifications are made to either somatic cells—wherein the change is limited to the individual whose DNA was modified—or to germ cells, wherein the change is passed on to future offspring.<sup>3</sup> The latter refers to *germline editing*, which ultimately affects "not only the targeted cells but also future generations and the genetic heritage of the human species as a whole."<sup>4</sup>

Enacted in 2004, section 5(1)(f) of the *Assisted Human Reproduction Act*<sup>5</sup> ("AHRA") criminalizes human germline editing in Canada: "no person shall knowingly alter the genome of

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<sup>1</sup> *Gattaca*. 1997. [film] Directed by A. Niccol. California, United States: Columbia Pictures.

<sup>2</sup> Erika Kleiderman & Ian Norris Kellner Stedman. "Human germline genome editing is illegal in Canada, but could it be desirable for some members of the rare disease community?" (2019) 11 *Journal of Community Genetics*

<sup>3</sup> Guishan Zhang, Junjiu Huang & Wenbin Ma "Genome modification by CRISPR/Cas9." (2014) 281 *FEBS Journal* at 5186.

<sup>4</sup> Jocelyn Maclure and David Hughes, "[The creation in China of genetically modified "CRISPR" babies should give Canadian policymakers pause. A Quebec commission has new recommendations](#)" (25 April 2019) online: *Policy Options*.

<sup>5</sup> *Assisted Human Reproduction Act*, SC 2004, c 2.

a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants." Contravention of this provision may result in criminal charges, including a fine of up to \$500,000 and/or imprisonment for up to 10 years.<sup>6</sup>

The ethical implications of conducting genetic research remain controversial. Canada is right to be cautious in its approach to regulating germline editing; as the global scientific community grapples with how best to balance privacy and scientific advancement, there continues to be no authoritative guidelines.<sup>7</sup> In 2018, in response to growing concerns from the scientific community that the AHRA provisions barring technologies like CRISPR/Cas9 were stifling genetic innovation in Canada, the *Commission de l'éthique en science et en technologie*<sup>8</sup> published a report exploring the ethical issues of germline modification. Missing from this report, and largely absent from public discourse around germline editing more broadly, is lucid, nuanced direction on how we might craft a regulatory framework that balances the right to engage in scientific exploration with the need to protect the inviolability of human genetic material, particularly as it relates to historically disenfranchised racial and ethnic minorities.

Since the enactment of the AHRA, the biotechnology landscape has progressed dramatically. One technology in particular—*clustered regularly-interspaced short palindromic repeats* or CRISPR<sup>9</sup>—has made germline editing less expensive, more accurate, and ultimately, more accessible than ever before.<sup>10</sup> When paired with a protein known as Cas9, CRISPR “works

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<sup>6</sup> *Supra* note 5, s. 60.

<sup>7</sup> Sarah Zhang ["Scientists Are Just as Confused About the Ethics of Big-Data Research as You"](#) Wired (May 20, 2016).

<sup>8</sup> Quebec, Commission de l'éthique en science et en technologie, [Genetically Modified Babies: Ethical Issues Raised by the Genetic Modification of Germ Cells and Embryos](#). (Gouvernement du Québec, 2018) at 8.

<sup>9</sup> Addison V. Wright, James K. Nunez & Jennifer A. Doudna. “Biology and applications of CRISPR systems: harnessing nature’s toolbox for genome engineering.” (2016) 164:(1-2) Cell

<sup>10</sup> Jennifer Doudna & Rodolphe Barrangou. “Applications of CRISPR technologies in research and beyond.” (2016) 34 Nat. Biotechnol 933-941.

like a pair of molecular scissors.”<sup>11</sup> Scientists can direct CRISPR/Cas9 to a specific region of a person's DNA, cut out parts of the genetic sequence, and make therapeutically relevant changes.<sup>12</sup> Particularly compelling was the discovery that CRISPR/Cas9 can be applied to eradicate heritable neurocognitive diseases like Alzheimer's, Parkinson's, and Huntington's, all of which have variations caused by genetic mutations.<sup>13</sup>

Colloquially speaking, legislators have effectively thrown the baby out with the bathwater by criminalizing human germline editing in the AHRA. Health Canada's rationalization for the ban centered around three key themes: “commodification concerns, social consensus, and the protection of the health and safety of Canadians.”<sup>14</sup> They did so out of well-founded fears of a Gattaca-like future in which genetic hierarchies emerge, barring marginalized people from reaping the benefits of gene therapy. However, by responding with a wholesale, criminal ban of germline editing, legislators overlooked the possibility of developing a regulatory framework that may not only protect Canadians from potentially deleterious effects of the technology but could also have considerable positive therapeutic benefits for Canadians suffering from genetic conditions.

As scholars and bioethicists have remarked, imposing severe criminal sanctions on scientific discovery hinders scientific progress and stifles public debate, preventing the scientific community from engaging with emergent technology.<sup>15</sup> As attorney and founder of the Health Sciences Law Group Robyn Shapiro noted, “Even beyond the lives that may be affected by the

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<sup>11</sup> Andrea Ramirez, "[Editing the Book of Life with Molecular Scissors](#)," (2013) Nat'l Hum. Genome Research Institute.

<sup>12</sup> Alexandra L. Foulkes, Takahiro Soda, Martilias Farrell, Paola Giusti-Rodríguez & Gabriel Lázaro-Muñoz. "Legal and Ethical Implications of CRISPR Applications in Psychiatry." (2019) 97:5 North Carol Law Rev. 1359-1398

<sup>13</sup> *Ibid.*

<sup>14</sup> Timothy Caulfield and Tania Bubela "[Why a Criminal Ban? Analyzing the Arguments Against Somatic Cell Nuclear Transfer in the Canadian Parliamentary Debate](#)," (2007) 7:2 The Am J of Bioethics 1, online: *PubMed*.

<sup>15</sup> Timothy Caulfield "[Bill C-13 The Assisted Human Reproduction Act: examining the arguments against a regulatory approach](#)" (2002) 11:1 Health Law Rev 20.

legislative resolution of the embryonic stem cell research debate, lawmakers should be keenly aware that their action will more generally help to shape the law governing research and the freedom of scientific inquiry.”<sup>16</sup> In 2017, the Centre of Genomics and Policy of McGill University convened a group of legal and ethics experts published an editorial urging the government to allow gene editing for research purposes, including pre-clinical research on germ cells prior to implantation.<sup>17</sup> Health Canada purports to be working on an update to the AHRA, with no word on whether this will include changes to the germline editing provisions.

Hansard of the parliamentary debates that informed the enactment of the AHRA provisions that criminalized germline editing in 2004 featured unsophisticated, incendiary arguments about the need to prevent “designer babies” in Canada, as well as highly politicized posturing around the moral status of the embryo. Two themes were notably absent from the parliamentary debate surrounding the enactment of the provisions banning germline editing in Canada: i) consideration of the range of therapeutic possibilities made available by germline editing, particularly for racialized Canadians who experience inequality in the health care system; and ii) whether a criminal ban was an appropriate regulatory instrument to govern scientific inquiry. Though just an introduction to the topic of germline editing in Canada, this work aims to address the two themes missing from that parliamentary debate. Part 1 offers an overview of the possibilities of germline editing and the therapeutic applications of CRISPR/Cas9 around the world, as well as Canada’s international obligations concerning human rights and scientific exploration. Part 2 explores how criminal sanctions are an inappropriate limit to scientific exploration and suggests that a regulatory approach may better balance the protection of bodily autonomy and the sanctity

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<sup>16</sup> Robyn S Shapiro, "Legislative Research Bans on Human Cloning" (2003) 12:4 Cambridge Q Healthcare Ethics 393.

<sup>17</sup> Patrick Bedford et. al., “[Human gene editing: revisiting Canadian Policy](#)” Editorial (2017) 2:3 Regenerative Medicine 1, online: *NPJ*.

of human genetic material with the right to engage in scientific exploration. Part 3 considers how vulnerable people experience inequities in the Canadian health care system and how those experiences should inform the development of a regulatory framework for germline editing that safeguards the rights and promotes the interests of vulnerable persons.

## **Part 1: The World of CRISPR/Cas9**

### **1.1 Life-saving possibilities**

In June 2014, a bouncy 7-pound, 10-ounce baby named Layla was born in a hospital in London, England.<sup>18</sup> When Layla refused to feed and was crying more than usual, her parents sought medical attention, learning that Layla had acute lymphoblastic leukaemia that required aggressive treatment. Layla endured weeks of chemotherapy and a full bone marrow transplant, but none of the treatments were successful. Doctors told her parents that Layla was out of options. By happenstance, Dr. Waseem Qasim, an immunologist working a few doors down from the leukemia ward where Layla was being treated, heard about her case. Dr. Qasim had been developing a treatment for leukaemia: using CRISPR/Cas9, Dr. Qasim could instruct the white blood cells from a donor to attack cancer cells in the body and then inject the edited donor cells into the patient. Until that point, however, Dr. Qasim's patients had only been mice. After acquiring emergency approval from the ethics board, Dr. Qasim injected Layla with 1 ml of the CRISPR-edited white blood cells, making her the first human to receive a vial of gene-edited cells. The treatment worked, and baby Layla made a full recovery.

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<sup>18</sup> Ian Sample, "[Baby girl is first in the world to be treated with 'designer immune cells'](#)" (5 November 2015) online: *The Guardian*.



Layla's story is just one example of the tremendous power of the CRISPR/Cas9 technology. CRISPR/Cas9 shows significant possibilities in disabling or correcting problematic genes associated with a broad range of diseases, from blood disorders to hereditary blindness. In addition to the discovery that CRISPR/Cas9 can eradicate heritable variations of neurocognitive diseases like Alzheimer's, Parkinson's, and Huntington's, CRISPR/Cas9 has many therapeutic applications that could significantly improve quality of life and health outcomes. In 2019, American biochemist Jennifer Doudna remarked on the impact of CRISPR, which "became a democratizing tool that allowed labs to do experiments that in the past had been prohibitive for various reasons, whether due to expense or just technical difficulty."<sup>19</sup> In 2020, Doudna and French microbiologist Emmanuelle Charpentier were awarded the Nobel prize in chemistry for "the development of a method for genome editing."<sup>20</sup>

In 2019, the global market of CRISPR/Cas9 gene editing was valued at 846.2 million USD and is expected to reach 10,825.1 million USD by 2030.<sup>21</sup> Start-ups worldwide have emerged to explore the endless possibilities of highly-targeted biotechnology that allows scientists to cut and potentially alter DNA at precise locations in a genome. Beam Therapeutics, a biotechnology company that uses CRISPR to develop precision genetic medicines for serious diseases, was valued at 843 million USD at the time of its initial public offering.<sup>22</sup> Mammoth Biosciences uses CRISPR-Cas technology to improve disease detection and has raised over 69.5 million USD.<sup>23</sup>

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<sup>19</sup> Maywa Montenegro de Wit, "[Democratizing CRISPR? Stories, practices, and politics of science and governance on the agricultural gene editing frontier](#)," (2020) 8:1 Elem Sci Anth, 9.

<sup>20</sup> The Royal Swedish Academy of Sciences, Press Release, "[The Nobel Prize in Chemistry 2020](#)" (7 October 2020).

<sup>21</sup> Research and Markets, "[Outlook on the CRISPR Gene Editing Global Market to 2030 - Analysis and Forecasts](#)" (8 February 2021).

<sup>22</sup> Crunchbase, "[Beam Therapeutics](#)."

<sup>23</sup> Crunchbase, "[Mammoth Biosciences](#)."

## 1.2 The bright line: improvement vs. enhancement

At the heart of the conversation around genetic intervention is where to draw the bright line between *improvements* and *enhancements*. When they enacted the AHRA, legislators intoned the fear that scientists would use germline editing to “improve” the human race, privileging some physical characteristics over others and bringing about the kind of *Gattaca-esque* society where eugenics broaden the chasms of social hierarchy.

One ethical factor that the international scientific community generally agrees upon is that a distinction exists between *therapeutic* applications of the technology to improve serious, otherwise untreatable conditions and non-therapeutic, proscribed interventions designed to *enhance* human qualities. However, without a considered, exhaustive legal framework to hold them to account, scientists worldwide have been unable to agree on where to draw that line. As a result, some scientists have used CRISPR/Cas9 indiscriminately—with considerable backlash from regulators and ethicists alike. In 2018, Chinese biophysicist Dr. He Jianku announced that the first two “CRISPR babies” were born.<sup>24</sup> Dr. He and his colleagues claimed to have disabled the *CCR5* gene in a set of twins—a gene that encodes a protein that allows HIV to enter cells—effectively protecting the babies from contracting HIV. Jiankui was subsequently convicted of illegal medical practice in 2019 and sentenced to three years in prison and a fine of \$450,000.

Meanwhile, Russian biologist Denis Rebrikov began research to repair the *GJB2* gene in human eggs, a gene responsible for hearing impairments that require their hosts to wear hearing aids or cochlear implants. Rebrikov sought permission from the local review board to conduct his research, emphasizing that he will not transfer an edited embryo without permission from the Ministry of Health of the Russian Federation. Some critics challenged the experiment because

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<sup>24</sup> David Cyranoski, "[The CRISPR-baby scandal: what's next for human gene editing](#)" (26 February 2019).

hearing loss is not a fatal condition—including CRISPR pioneer Jennifer Doudna, who described the project as “recklessly opportunistic, clearly unethical and damages the credibility of a technology that is intended to help, not harm.”<sup>25</sup>

### **1.3 Canada’s international human rights obligations**

The right to engage in scientific exploration is a long-protected right protected by two key international law instruments to which Canada is a party. The first is Article 27(1) of the *Universal Declaration of Human Rights*<sup>26</sup> (“UDHR”), which protects every person’s “right freely to participate in” and “share in scientific advancement and its benefits.” This right was later enshrined in Article 15 of the *International Covenant on Economic, Social and Cultural Rights*<sup>27</sup> (“ICESCR”), which recognizes “the right of everyone ... (b) To enjoy the benefits of scientific progress and its applications.” Article 15 further states that in becoming parties to the Covenant, states undertake an obligation to take steps “1. [...] necessary for the conservation, the development and the diffusion of science and culture [...],” “2. [...] to respect the freedom indispensable for scientific research [...],” and “3. [...] recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields [...].” As a State Party to the ICESCR, Canada has a duty to implement its treaty obligations and report this progress to the UN Committee on Economic, Social, and Cultural Rights every five years. The blanket prohibition of germline editing, which could play a significant role in improving health outcomes for people suffering from otherwise untreatable

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<sup>25</sup> David Cyranoski, "[Russian ‘CRISPR-baby’ scientist has started editing genes in human eggs with goal of altering deaf gene](#)" (18 October 2019).

<sup>26</sup> *Universal Declaration of Human Rights*, GA Res 217A (III), UNGAOR, 3rd Sess, Supp No 13, UN Doc A/810 (1948) 71 at art 27.

<sup>27</sup> *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 UNTS 3, Can TS 1976, art 15 (accession by Canada on 19 May 1976, entered into force on 19 August 1976).

genetic conditions. Canada's lack of meaningful consideration of germline editing is in stark contrast with other parties to both the UDHR and the ICESCR.

## **Part 2: Canada's current framework**

### **2.1 The insufficiency of the AHRA re: biotechnology innovation**

Section 5(1)(f) of the *AHRA*<sup>28</sup> reads, "no person shall knowingly alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants." Some scientists contend that "the intent of the germline prohibition was not to *stop gene alteration altogether* because it can *theoretically* be transmitted to descendants, but that the *genetic modification must not be transmitted to descendants.*"<sup>29</sup> [emphasis added] The effect of the legislation, however, was to criminalize both therapeutic and non-therapeutic applications of technology like CRISPR/Cas9. In doing so, legislators effectively blocked any possibility for biotechnological innovation using CRISPR/Cas9.

### **2.2 The wrong tool for the job: criminal sanctions in the AHRA**

There is no question that germline editing presents a complex web of social, moral, cultural, and ethical concerns. True to the positivist tradition, the sovereign granted legislators the authority to enact penal sanctions barring activities at their discretion. While positivism claims to be value-neutral, the human rights arguments which legislators use to justify criminal sanctions in the AHRA are driven by moral principles; the Hansard reveals an approach to germline editing that

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<sup>28</sup> *Assisted Human Reproduction Act*, SC 2004, c 2.

<sup>29</sup> Zubin Master and Patrick Bedford "[CRISPR Gene Editing Should Be Allowed in Canada, But Under What Circumstances?](#)" (2018) 40:2 J Obstet & Gynaecology Can at 226-226.

is deeply rooted in natural law—restricting biotech on *moral grounds* rather than adopting a more nuanced, deferential stance that considers the expert perspectives.

In 1982, the Law Reform Commission of Canada noted that criminal law should act as 'an instrument of last resort' used exclusively for "conduct which is culpable, seriously harmful, and generally conceived of as deserving of punishment."<sup>30</sup> Criminal law is, *prima facie*, an ineffective policy tool for regulating scientific research. Indeed, applying criminal sanctions not only hinders the scientific community's ability to respond to evolving scientific practices like CRISPR/Cas9—but it also drives public debate of the issues underground.<sup>31</sup> That debate is crucial to driving political support for biotechnology and is crucial to increasing public literacy around DNA and the rights associated with genetic data.

The language of Section 5(1)(f), “no person shall *knowingly* alter the genome of a cell of a human being or *in vitro* embryo...” where *knowingly* implies *mens rea* or criminal intent. From this language, we can infer that legislators intended to deter germline editing and punish those who intended to do harm by carrying out the prohibited conduct. This singular view discounts therapeutic possibilities of germline editing—including the possibility of significant public good—and effectively prejudices genetic engineering in the public discourse.

The concerns around ‘designer babies’ are, of course, salient. However, CRISPR/Cas9 also presents vast potential for social good. It falls upon legislators to work with bioethicists, scientists, anthropologists, and medical professionals to establish the bright ethical line, adopting therapeutic applications of CRISPR/Cas9 and developing meticulous protocols around informed

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<sup>30</sup> Canada, Law Reform Commission of Canada, [\*The Criminal Law in Canadian Society\*](#) (Ottawa: Criminal Law Review, 1982) at 4.

<sup>31</sup> Timothy Caufield, "Bill C-13 The Assisted Human Reproduction Act: examining the arguments against a regulatory approach," (2002) 11:1 Health Law Rev at 20.

consent, the use and storage of human tissue, data collection, privacy and confidentiality—every bioethical dimension.

The criminal prohibition of germline editing in Canada has created a hostile environment where biotechnology tools like CRISPR/Cas9 cannot develop. As one researcher remarked, “A criminal ban is a suboptimal policy tool for science as it is inflexible, stifles public debate, and hinders responsiveness to the evolving nature of science and societal attitudes.”<sup>32</sup> The issue of germline editing is complex and requires a correspondingly nuanced regulatory approach that carefully considers the potential deleterious and salutary effects of the technology.

### **Part 3: CRISPR/Cas-9 considerations with respect to vulnerable people**

Access to health care is a form of social justice. When effectively regulated, biotechnology tools like CRISPR/Cas9 have the potential to reduce health disparities, particularly among vulnerable populations who experience systemic discrimination in the Canadian health care system; because of the relative accessibility of CRISPR/Cas9, the technology could be especially effective in targeting genetic diseases that are specific certain minority groups. For example, CRISPR/Cas9 has shown promise in eradicating sickle-cell anaemia, an inherited blood disorder that disproportionately affects Black populations.<sup>33</sup> Approximately 5000 Canadians live with chronic pain due to sickle cell disorder and have a life expectancy of 25 to 30 years less than those without the disorder.

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<sup>32</sup> *Supra* note 29.

<sup>33</sup> Sickle Cell Disease Associations of Canada. [Bill S-211: Recognizing June 19 as the Canadian Sickle Cell Awareness Day](#) (Toronto). Sickle cell trait occurs in 300 million people worldwide, with the highest prevalence of approximately 30% to 40% in sub-Saharan Africa.

Ethical concerns around CRISPR/Cas9 editing fall into four broad categories: concerns around eugenics, longitudinal health risks to children with edited genes, professional self-regulation of scientists conducting gene editing, and concerns that germline editing will have a “chilling effect” on scientific research.<sup>34</sup> Each of these concerns poses a higher risk to vulnerable populations who already experience inequities in accessing health care. A fifth risk has arisen concerning the lack of baseline genomic data from individuals of non-European ancestry, which must be addressed if Canadian regulators are to ensure equitable access to the therapeutic benefits of germline editing.

### **3.1 Concerns re: Eugenics**

In Canada, visible minorities, Indigenous populations, immigrants, refugees, and those who speak neither official Canadian languages already experience indirect, systemic discrimination when navigating the health care system.<sup>35</sup> It is reasonable to be concerned that—if authorized—this discrimination will extend to germline editing. Indeed, while scientists can edit genes for both therapeutic and non-therapeutic purposes (i.e., genetic enhancement), Hansard reveals that it is the latter category with which legislators appear to take issue. According to parliamentarians who enacted the legislation, section 5(1)(f) stands for the proposition that Canadians “cannot create custom made human beings. We cannot say, ‘I want a girl with blue eyes and I want all her descendants to have blue eyes.’”<sup>36</sup> The Gattaca-esque inference is that legislators feared that

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<sup>34</sup> Bartha Maria Knoppers & Erika Kleiderman, ““[CRISPR babies](#)”: What does this mean for science and Canada?” (2019) 191:4 CMAJ at E91-E92.

<sup>35</sup> Sana Halwani, “[Racial inequality in access to health care services](#)” (December 2004), Ontario Human Rights Commission.

<sup>36</sup> Canada, Parliament, *House of Commons Debates*, 37<sup>th</sup> Parl, 2<sup>nd</sup> Sess, Vol 138, No 030 (22 November 2002) at 1220 (Mr. Réal Ménard).

allowing germline editing will promote the possibility of parents using the technology to prefer certain physical characteristics over others.

Researchers have described eugenics as a kind of leitmotif in conversations surrounding germline editing, harkening back to Gattaca as a disturbing cautionary tale of the risks inherent with genetic intervention. Concerns around eugenics are, of course, inherently valid. However, regulators are encouraged to remember that a bright line can be drawn between genetic *improvements* and *enhancements*. Through extensive consultation with the medical community and diverse ethical stakeholders, regulators may draw clear boundaries between conditions and diseases scientists should treat using germline editing technology. Moreover, there are opportunities to focus research efforts on conditions that disproportionately affect vulnerable persons, presenting a unique opportunity to address systemic inequality that is pervasive in the health care system.

Such bright lines have already been drawn in other areas of Canadian health law. In 2017, recognizing the increased prevalence of genetic testing and its potentially transformative impact on the healthcare system, the Canadian government passed the *Genetic Non-Discrimination Act*<sup>37</sup> (“*GND Act*”). The *GND Act* serves to “prohibit and prevent genetic discrimination,” barring any person from ordering a mandatory genetic screening as a condition for (a) providing goods or services to an individual, (b) entering into or continuing a contract or agreement with an individual, or (c) offering or continuing specific terms or conditions in a contract or agreement with an individual.<sup>38</sup> The *Act* also barred persons from requiring the disclosure of genetic test results as a pre-condition of any of those activities. The *GND Act* was a lucid step in protecting against discrimination that could occur as a result of biotechnology and a strong example of the

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<sup>37</sup> *Genetic Non-Discrimination Act*, SC 2017, c 3.

<sup>38</sup> *Ibid*, at s. 3(1).



kind of nuance that should be present in the AHRA concerning the regulation of germline editing.

Another theme concerning eugenics is the idea of inadvertently discriminating against persons with genetic differences such as Down syndrome. When prospective parents screen positive for the condition using non-invasive prenatal testing (“NIPT”), the vast majority choose to terminate the pregnancy, even though Down syndrome is characterized as a “genetic difference that is consistent with living a good life.”<sup>39</sup> As many jurisdictions grapple with the idea of public health screening for Down syndrome using NIPT, Down syndrome advocates argue that public funding “would strongly imply that the government, as a representative of the public, has adopted the goal of eliminating people with Down syndrome.”<sup>40</sup> Likewise, advocates are concerned that germline editing could be used to permanently eradicate Down syndrome, sending a strongly discriminatory message that may fly in the face of sections 7 and 15 of the *Canadian Charter of Rights and Freedoms*.<sup>41</sup> Regulators should be cautious in crafting a regulatory framework that protects the constitutional rights of those individuals with genetic differences like Down’s Syndrome.

### **3.2 Longitudinal health risks to children**

In the first two “CRISPR babies” born in 2018, Dr. He and colleagues claimed to have disabled the CCR5 gene,<sup>42</sup> which encodes a protein that allows HIV to enter cells, effectively protecting the babies from contracting HIV. The CCR5 gene is also considered helpful in fighting off other

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<sup>39</sup> Chris Kaposy, “[The ethical line for Down Syndrome testing](#)” (22 April 2019).

<sup>40</sup> *Ibid.*

<sup>41</sup> *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (UK)*, 1982, c 11 [“Charter”].

<sup>42</sup> David Cyranoski, “[The CRISPR-baby scandal: what's next for human gene editing](#)” (26 February 2019).

viruses like West Nile. However, disabling the CCR<sub>5</sub> could theoretically cause mutations in other parts of the genome, which could have unpredictable health consequences for the twins later in life. Though Dr. He and his team claim that they did not find such mutations, it points to an important concern around germline editing: it could be a challenge to enact legislation without longitudinal data about the consequences of editing germline cells. Therein lies the catch-22 that often characterizes innovation: we need longitudinal data to give us peace of mind that the technology works, but to acquire that data, we need disciplined means of testing the technology. As such, regulation of germline editing needs to carefully authorize Canadian scientists to engage in genetic engineering research so that they can closely monitor any consequences of the technology and collect longitudinal data.

### **3.3 Professional self-regulation of scientists**

Another concern is that the self-regulatory nature of the scientific community is insufficient for addressing the ethical complexity of germline editing. When Dr. He announced the birth of the “CRISPR babies,” broad assumptions were made about the lack of mechanisms in place to regulate germline modification of embryos in China. Some countries, like China, allow germline modification of embryos before 14 days *if not implanted*—Dr. He and his colleagues were in contravention of those laws.<sup>43</sup> When regulating germline editing, Canadian regulators should thus consider the feasibility, implementation, and system-wide impacts that germline editing would have on the sector itself, in consultation with a broad cross-section of stakeholders. Both Belgium<sup>44</sup> and England have introduced licensing schemes to manage the ethical concerns

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<sup>43</sup> *Supra* note 40 at E92.

<sup>44</sup> Guido Pennings et al., “Human Embryo Research in Belgium: An Overview,” (2017) 96:1 *Fertility & Sterility* at 108.

associated with genetic engineering. A federal licensing scheme would allow government oversight of genomic research, ethical protocols, and ongoing evaluation.

Consultation with vulnerable populations is especially critical, especially as it relates to informed consent. In the 1990s, researchers at Arizona State University collected blood samples from Havasupai Indians.<sup>45</sup> The tribe suffered extraordinarily high levels of Type 2 diabetes and was eager to work with scientists to curtail the disease. In another Indigenous population, researchers discovered a link between a genetic variant and high rates of diabetes; the Havasupai were eager to understand if they too shared a genetic trait that explained the high incidence rate of diabetes among their people. However, members of the Havasupai council discovered that their DNA was used for dozens of other research projects without their consent on topics ranging from schizophrenia to inbreeding.<sup>46</sup> As one group of researchers described:

Unethical behavior, lack of clear communication, disrespect of cultural and spiritual beliefs, and a failure to address the interests and priorities of particular Indigenous communities and their membership have created an environment of mistrust between researchers and Indigenous communities.<sup>47</sup>

To prevent exploitation of Indigenous communities, persons whose first language is not English, or simply those of us who are not sufficiently literate in medical science, legislators must consider rigorous and precise regulations around informed consent for scientists conducting genomic research. DNA presents its own *sui generis* privacy challenges; the data cannot be anonymized by its very nature. As such, regulators must design unique frameworks to safeguard genetic data and prevent the exploitation of vulnerable persons.

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<sup>45</sup> Amy Harmon, "[Indian Tribe Wins Fight to Limit Research of its DNA](#)" (21 April 2010).

<sup>46</sup> *Ibid.*

<sup>47</sup> Nanibaa' A. Garrison et. al, "[Genomic Research Through an Indigenous Lens: Understanding the Expectations](#)" (2019) 20:1 Annu. Rev of Genom. Hum. Genet. at 496.

In addition to consultation, a diverse range of voices in the scientific community is also an essential component of designing a robust biotechnology sector in Canada. Dr. Frank Dukepoo, a geneticist from the Hopi community in Arizona, eloquently articulated his peoples' view of DNA:

To us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it is part of a person, it is sacred, with deep religious significance. It is part of the essence of a person."<sup>48</sup>

Human genes are highly intimate, and the regulatory scheme must include a strict informed consent-based approach to germline editing research, one that considered the complex, intersecting cultural, social, and spiritual dimensions. One way to achieve this is to develop the regulatory framework with intersectional oversight and leadership, bringing together a broad cross-section of stakeholders to develop culturally competent ethical guidelines and review procedures.

### **3.4 Possible “chilling effect” on scientific research**

After Dr. He announced the birth of the world's first “CRISPR babies” in 2018, the international scientific community opined the researchers' ethical recklessness; after all, HIV is a highly manageable condition that physicians can treat with far less risky, onerous interventions than genetic engineering. As such, there is a rising concern that experiments like that of Dr. He and his colleagues could work against the interests of biotech innovation. According to Dr. Francis Collins, Director of the National Institutes of Health in the US,<sup>49</sup> “[s]hould such epic scientific misadventures proceed, a technology with enormous promise for prevention and treatment of disease will be overshadowed by justifiable public outrage, fear and disgust.”

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<sup>48</sup> *Ibid* at 498.

<sup>49</sup> Gina Kolata & Pam Belluck, "[Why are scientists so upset about the first CRISPR babies?](#)" (5 December 2018).

There are also some equality concerns concerning a possible chilling effect. Even if CRISPR/Cas9 can completely eradicate the genes associated with certain heritable conditions, there is concern that research efforts to support those already living with the condition may be stilted if research projects and clinical trials upon which they rely are defunded as a result of prioritizing genomic research. The priority for any public health regulatory framework in Canada should be to promote the health of all Canadians, and legislators should build safeguards to protect existing therapeutic research programs.

### **3.5 Lacking minority data in genomic research**

Research demonstrates that Indigenous peoples around the world experience poorer health and social outcomes than non-Indigenous populations.<sup>50</sup> Using human genomics, scientists can reconstruct population history and identify which genes are associated with specific diseases. Scientists then use that data matrix to identify whether a person may be susceptible to certain diseases due to their genes. One critical ethical concern ensuring equity in genomic research is achieving minority representation in the data.

A lack of diversity in genomic sequencing studies results in a lack of baseline data from minority groups, and thus, an inability to recognize pathologic variants. Because “the population frequency of variants detected in sequencing is not known for Indigenous populations,”<sup>51</sup> the diagnostic results for Indigenous populations are potentially less precise than those of populations that are well-represented in the data. As some scientists remarked, “Unequal access to genomic technologies, negative socioeconomic determinants, and lack of relevant population

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<sup>50</sup> Ian Anderson et. al, “[Indigenous and tribal peoples’ health \(The Lancet–Lowitja Institute Global Collaboration\): a population study](#),” (2016) *Lancet*, at 1. Data collected from 28 populations across 23 countries (including Canada) provide evidence of poorer health and social outcomes for Indigenous peoples than for non-Indigenous peoples.

<sup>51</sup> *Supra* note 45.

genetic variation data all contribute to the limited relevance and reduced effectiveness of genetic and genomic research for Indigenous peoples.” An analysis<sup>52</sup> published in March 2019 revealed that just 22% of people in genome-wide association studies were of non-European descent and that together, indigenous people and those of African and Latin American descent represented less than 4% of participants as of 2018. Quite reasonably, both women and minority groups often have a deep mistrust of the health care system. A report published by the British Columbia Women's Health Foundation in partnership with the Pacific Blue Cross found that 51% of BC women felt that a physician had diminished or overlooked their symptoms. A startling 83% of Indigenous women aged 16-24 reported challenges accessing necessary medical services.<sup>53</sup> A regulatory scheme concerning germline editing must be drafted in collaboration with community partners to build trust and effectively communicate informed consent.

## **Conclusion**

In the interest of biotech democracy, human rights, and reducing health disparities in Canada, legislators ought to reconsider the criminal prohibition of germline editing in Canada. Genetic information represents the most intimate, cogent features of human beings. Written into each sequence is a story of who a person is and how that person came to be. Canada’s approach to germline editing must honour the unique fragility and integrity of the human genome whilst ensuring that every individual has access to the benefits of scientific advancement. As the practice of somatic gene editing develops, the need for an informed, meticulous policy approach to germline editing—one that protects vulnerable populations promote their health interests, and allows Canadian scientists to participate meaningfully in this emergent technology—is crucial to

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<sup>52</sup> Giorgia Guglielmi, “[Facing up to injustice in genome science](#),” *Nature News* (16 April 2019).

<sup>53</sup> B.C. Womens Foundation, [In Her Words: Womens' experience with the healthcare system in BC](#), November 2019.

distributing its therapeutic benefits. Crafting a responsible, human rights-driven regulatory framework that allows germline editing technology to thrive while safeguarding the rights of vulnerable people is a means of achieving modern social justice, one that could dramatically reduce inequities in the healthcare sector and improve outcomes for vulnerable people.

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