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The Impact of Narratives on the Legal and Regulatory Discourse of Heritable Human Genome Editing

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Abstract

Since its discovery in 2012, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology in somatic and germline cells has rapidly advanced within a very short timeframe. Notably, Heritable Human Genome Editing (HHGE), which refers to the editing of germline cells for the purpose of reproduction, has significant potential for therapeutic application. This article argues that the framing and expression of ethical considerations as a narrative can guide the establishment of a legal and regulatory approach to HHGE. Its purpose is to demonstrate the role and value of narratives in the ethical and legal permissibility of a frontier technology: CRISPR technology. To achieve this purpose, the article applies narrative theory, specifically through a case study, to support an argument for the ethical and legal sanctioning of HHGE, *in certain circumstances*. This article has identified one instance in which HHGE ought to be legally permitted: to prevent Tay-Sachs Disease. The argument is framed through the lens of the four key principles of medical ethics: autonomy, non-maleficence, beneficence and justice. To progress as a society and change our circumstances, we must be open to editing the narrative of HHGE as a potential lifesaving treatment for fatal monogenic genetic disease/s. HHGE provides an opportunity to write an exciting new chapter. Although not unaccompanied by risks, our future global society may look back upon this time to learn about the importance of honest and accurate facts underpinning the CRISPR narrative.

Keywords: Heritable human genome editing; gene editing; narrative theory; regulation; technology law; ethics

1. Introduction

We are the stories we are told and we are the stories we tell ourselves. To change our circumstances, we need to change our story: edit it, modify it, or completely rewrite it.[1]

Harold R Johnson, an Indigenous Canadian lawyer and writer, aptly captured the power of narratives on social discourse. Although raised in a different context, these observations are relevant to a number of areas, including the development of frontier technologies. These technologies are perceived to be at the precipice of the bounds of knowledge, generating new ideas and expanding knowledge and understanding.[2] By their very nature, frontier technologies emerge within 'a diverse collection

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[1] Johnson, "Harold R. Johnson."
[2] Nuffield Council on Bioethics, Emerging Biotechnologies Report.

of research programmes [and] forms of knowledge and techniques'.[3] Narratives are the fundamental glue underpinning the interactions between science, law and regulation. Specifically, with respect to frontier technologies, their societal acceptance and regulation, often manifested through legal sanctioning, are reliant upon the dominant narrative espoused within a society. Consequently, over time, the role of narrative science has been explored, becoming a relevant contributor to knowledge generation and regulatory discourse.

This article demonstrates the role and value of narratives in the ethical and legal permissibility of a frontier technology: Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology. Narratives are perceived to be a 'technology of sense-making',[4] enabling the representation of knowledge and ideas to assist in navigating complex subject-matter. Therefore, this article applies narrative theory, specifically through a case study, to argue for the ethical and legal sanctioning of Heritable Human Genome Editing (HHGE), in *certain circumstances*. These circumstances are limited to prevent, treat or correct fatal monogenic genetic diseases. By applying the four principles of medical ethics[5] – autonomy, non-maleficence, beneficence and justice, this article argues an ethical imperative exists to pursue HHGE to prevent Tay-Sachs Disease (TSD) – a fatal monogenic genetic disease.[6]

Section 2 identifies the narrative of CRISPR technology as a means to contextualise the sources of its legal and ethical concerns. The dominant narrative associated with CRISPR technology is accompanied by fear and uncertainty, which has permeated to mainstream media and the global community. This raises the relevance of applying narrative theory as one means to explore the possibility of pursuing HHGE *in certain circumstances*. Section 3 focuses on narrative theory, specifically the adoption of a case study, to investigate the ethical and legal permissibility of HHGE for a therapeutic use: to prevent, treat or correct *fatal monogenic* genetic disease/s. For the purpose of this argument, its therapeutic use has been limited to fatal (or terminal) genetic diseases that are caused by a known single mutation.[7] Their known genetic cause and severity present compelling justifications to render them candidate diseases to target therapeutically. This also acknowledges the technology's current capability to edit one mutation precisely. Further, based on current research and previous experiences in the context of transitioning somatic genome editing to clinical trials, monogenic genetic diseases will be the likely candidates used in the first clinical trials for HHGE.[8] This offers a constructive transition to section 4, which presents the case study, formulating the basis of this article. TSD was selected as a therapeutic candidate because it is a fatal monogenic genetic disease. The aetiology of the disease provides necessary context and understanding about its genetic cause, inheritance and symptomatology. Following this background, a hypothetical scenario is proffered, in which prospective parents who may be unable to conceive a genetically related healthy child are confronted with a decision to pursue HHGE as a means to prevent TSD. The adoption of a case study approach enables the application of an ethical discourse to narrate the possibilities of pursuing HHGE in this scenario. This discourse is interrogated in section 5, in which the case study is narrated through the lens of the four principles of medical ethics. In section 6, the article concludes that there is a strong, ethically justified argument to pursue HHGE to prevent TSD. The use of narrative theory illustrates the power of reframing the narrative and rhetoric attached to CRISPR technology.

2. The CRISPR Narrative

Since its discovery in 2012, CRISPR technology in somatic and germline cells has rapidly advanced within a very short timeframe. Notably, HHGE has significant potential for therapeutic application, with insurmountable transformative potential. There are two cellular contexts in which CRISPR technology may be applied – in somatic and germline cells. Germline cells refer to human gametes or reproductive cells, such as the female egg and male sperm. Germline genome editing can be further sub-categorised into *HHGE* and *germline editing*. HHGE refers to the editing of germline cells using CRISPR technology for reproductive purposes.[9] This means once an edit is made, the edited embryo will be implanted to achieve a pregnancy. The union of germ cells create a zygote and subsequent genome modification of the zygote is heritable. In contrast, germline editing

[3] Nuffield Council on Bioethics, Emerging Biotechnologies Report, xvii.
[4] Morgan, "Narrative," 4.
[5] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report; Pandos, Heritable Human Genome Editing.
[6] Pandos, Heritable Human Genome Editing.
[7] The use of HHGE to prevent, treat or correct polygenic diseases (those caused by more than a single mutation) will not be explored, due to the complexity of the edit and current limitations in the technology's capability.
[8] National Academies of Sciences, Engineering and Medicine and The Royal Society, Heritable Human Genome Editing Report; van Rheenen, "Genetic Correlations."
[9] Baylis, "Human Germline and Heritable Genome Editing," 365; WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, WHO Framework, v; Lovell-Badge, Statement from the Organising Committee.

refers to the editing of germline cells not for reproduction.[10] This indicates that germline editing is undertaken for a research purpose. The sole focus of this article is HHGE for therapeutic applications.

In Australia, the current legal and regulatory framework is highly prohibitive.[11] This manifests as a legislative blanket prohibition and criminalisation of HHGE.[12] The underlying motivation for this prohibitive legal and regulatory position is attributed, in part, to a dominant narrative associated with HHGE: fear and uncertainty. This narrative was further compounded by the alleged birth of the first 'CRISPR babies' in 2018, which was the catalyst prompting an immediate informal global moratorium on HHGE. Described as a 'reckless ethical disaster', the experiment, undertaken by He Jiankui, was an affront to well-established ethical principles and practices in medical research.[13] The aim of the experiment was to genetically modify the *CCR5* gene, involved in HIV infection. If successful, the offspring containing the edited *CCR5* gene should be immune to HIV infection.[14] This reflects the potential therapeutic value of HHGE. However, in the absence of preclinical evidence pertaining to its safety and efficacy and ongoing societal debate with respect to its application, HHGE should not be undertaken.[15]

The CRISPR babies experiment is arguably a predominant source for the fear and uncertainty attached to HHGE. Further, it represents an inviolable red line that ought not to be crossed, especially in the absence of evidence to establish its safe and effective use. It is imperative to be cognisant of this dominant narrative, which is shaping the regulation of HHGE. Notably, the adoption of a moratorium is not indicative of an indefinite ban. Rather, it was enforced to enable time for responsible research and development of the technology in order to improve understanding and data collation. Therefore, it is timely to consider a pathway forward for the ethical and legal permissibility of HHGE. The application of narrative theory is one pathway lending support to this campaign.

3. Narratives, Stories and Discourse

This article advances the following argument: if applied in a therapeutic context, HHGE should only be undertaken to prevent, treat or correct *fatal monogenic* genetic disease/s.[16] These are diseases caused by a single mutation to a gene. Reliance upon narrative theory through the presentation of a case study on TSD will demonstrate its valuable role in shaping future legal and regulatory discourse. Importantly, it reinforces the power of narratives within ethical and societal deliberations of a frontier technology.

It is important to clarify the meaning of a narrative for the purpose of this article. Narrative theory is a flourishing research area and is vast in its literature. Generally, the term 'narrative' is synonymous with 'story'.[17] In simple terms, narratives provide a means to describe developments and changes over time or how different 'things' are made known.[18] From the perspective of a narratologist, a narrative is perceived as a 'dynamic relation' between a story (which communicates events) and discourse (the way in which these events are communicated).[19] This is particularly pertinent to HHGE, as the CRISPR babies experiment embodied the discourse that confronted the global community. The power of a narrative was subsequently observed in the immediate condemnation of this experiment and enforcement of the global moratorium, which continues today. However, as the technology inevitably matures, society ought to engage in a productive dialogue to consider whether HHGE should be ethically and legally permissible and, if so, under what circumstance/s.

This raises a key role of narrative theory: its ability to be used as a tool to navigate these societal dialogues and shape future legal and regulatory discourse. Professors Mary Morgan and M. Norton Wise usefully described the value of narrative theory and narrative knowing. Especially in complex cases, such as frontier technologies, the function of a narrative is clear – it provides a mechanism for coherence-making.[20] This mechanism refers to a narrative's capability to discern pieces of

[10] Baylis, "Human Germline and Heritable Genome Editing"; WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, WHO Framework.
[11] Pandos, "Traversing Uncharted Territory?"; Nicol, "Regulation of Human Germline Genome Modification," 565; Pandos, Heritable Human Genome Editing.
[12] Pandos, "Traversing Uncharted Territory?"; *Gene Technology Act 2000* (Cth); *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15, 20(3); *Research Involving Human Embryos Act 2002* (Cth).
[13] Greely, "CRISPR'd Babies," 113.
[14] Greely, "CRISPR'd Babies," 113–114.
[15] Lovell-Badge, Statement from the Organising Committee, 2.
[16] Pandos, "Navigating the Ethics."
[17] Hajek, "What is Narrative?" 31.
[18] Morgan, "Narrative Science," 2.
[19] Hajek, "What is Narrative?" 43–44.
[20] Morgan, "Narrative Science," 2.

information and reveal the ways in which these various pieces interrelate.[21] Importantly, the 'explanatory power' of a narrative is premised in its ability to 'chart a satisfactory path not just through contingencies, possibilities and alternatives, but to do so by making active use of those features.'[22] This was also reinforced by John Beatty, who noted that a 'narrative indicates or alludes to non-actualized possibilities, and their consequences, by treating events … not just as points along the way to the outcome, but as "turning points"'.[23] Therefore, narratives are an effective mechanism to explore a variety of complex subject-matter. This article relies on narrative theory to elucidate the ethical issues associated with HHGE, with a view to reconcile value pluralism, thus enabling its legal permissibility.

Narratives serve a specific utility in conveying complex subject-matter (the story) in a comprehensive way to provide solutions to a given problem (its subsequent discourse). In this way, a narrative may be perceived as a tool to solving complex puzzles. In the context of HHGE, this article adopts the definition and purpose of a narrative as noted above to determine whether it can be used to argue for the ethical and legal permissibility of certain applications. Importantly, in providing the following case study, it contains sufficient detail to identify alternative views and solutions to justify the outcome of a decision or pathway forward.[24]

4. A Case Study: Tay-Sachs Disease

This case study investigates whether HHGE ought to be ethically and legally permitted as a means to prevent Tay-Sachs Disease (TSD). The utility of a case study is clear: it provides a narrative of a hypothetical scenario and enables critical evaluation of various ethical arguments to determine permissible applications of HHGE. If an ethical outcome permitting the application of HHGE can be achieved, this provides a stronger grounding to argue for its legal sanctioning. It is imperative to reinforce the dominant narrative attached to HHGE. In light of the CRISPR babies experiment, there is apprehension regarding a repeat of this unethical experiment and unscrupulous applications involving genetic enhancement.[25] These fears manifest as two dominant protagonists influencing perceptions of HHGE, namely 'CRISPR babies' and 'superhumans'. These concerns are valid, and they ought to be considered when determining permissible applications of HHGE.

Importantly, this article reframes the dominant narrative for HHGE to a lifesaving therapeutic treatment. Further, it applies a discourse to guide discussion, specifically the application of the four key pillars of medical ethics: autonomy, non-maleficence, beneficence and justice. This discourse was selected as future proposed applications of HHGE will be deliberated within the realm of medicine and human medical research. These fundamental principles underpin research and regulatory decision-making. In order to support this reframing of narrative, the case study considers the application of HHGE solely within a therapeutic context. Further, it is presumed that the technology has become safe to consider human clinical trials, supported by preclinical evidence.

4.1 Disease Aetiology

TSD is a fatal progressive neurodegenerative, autosomal recessive monogenic genetic disease.[26] It is caused by a mutation to the hexosaminidase A (*HEXA*) gene,[27] which is responsible for the production of an enzyme that breaks down fatty substances in the brain.[28] This mutation causes neurones to stop producing this enzyme, leading to an accumulation of fatty substances in the brain and spinal cord.[29] This results in the damage and death of cells[30] and a progressive dysfunction of the central nervous system.[31]

Disease onset is early, within three to six months of birth, and death occurs between three and five years of age.[32] Symptoms of TSD include progressive muscle weakness, loss of motor skills (such as swallowing), spasticity, blindness, seizures,

[21] Morgan, "Narrative Science," 2.
[22] Morgan, "Narrative Science," 2.
[23] Beatty, "What are Narratives Good For?" 36; Crasnow, "Process Tracing," 10.
[24] Crasnow, "Process Tracing," 11.
[25] Please note that genetic enhancement is not explored in this article.
[26] Online Mendelian Inheritance in Man, "Tay-Sachs Disease (TSD)."
[27] Online Mendelian Inheritance in Man, "Tay-Sachs Disease (TSD)"; Victorian State Government Department of Health, "Tay-Sachs Disease."
[28] Victorian State Government Department of Health, "Tay-Sachs Disease."
[29] Victorian State Government Department of Health, "Tay-Sachs Disease."
[30] Victorian State Government Department of Health, "Tay-Sachs Disease."
[31] National Organization for Rare Disorders, "Tay Sachs Disease."
[32] National Health Service, "Tay-Sachs Disease"; National Organization for Rare Disorders, "Tay Sachs Disease."

paralysis, hearing loss and cognitive deficits (such as confusion, disorientation and intellectual disability).[33] Death is often a result of this progressive degeneration, such as respiratory failure caused by aspiration pneumonia.[34] Currently, there are no available treatments or cures for TSD.[35] Treatments are targeted to alleviate and manage symptoms as they arise and worsen.[36]

4.2 The Hypothetical Scenario

Consider the following scenario:

> *Prospective parents have undergone IVF treatment, which has only produced two viable embryos. This is their third and final attempt of IVF, due to financial and health constraints. Both parents are aware they are carriers of a pathogenic mutation to the hexosaminidase A (HEXA) gene, causing TSD. Due to their difficulty in producing a larger quantity of viable embryos, they are offered two options. First, they may risk the fate of the embryos by undertaking pre-implantation genetic testing (PGT), which will confirm whether the embryo will be affected by TSD. Second, they are informed of a preclinical treatment option, which is yet to be approved. It uses HHGE to modify and correct the DNA of the embryo, to prevent TSD. If successful, this treatment will restore the function of the gene, which means their future offspring*[37] *will no longer carry a risk of having TSD. This option has been raised to the prospective parents, along with the available information regarding the nature of the treatment, risks, benefits and costs, if it were to be approved.*
>
> *In obtaining further information from their treating team and genetic counsellors, they are informed that PGT requires the embryo to undergo a few cycles of cell division in order to genotype its DNA. If results show the embryo will be disease affected, it would be too late to pursue HHGE if it is made available in clinical trials. They are also advised about TSD's poor prognosis and health implications.*

Under these circumstances, should HHGE be permitted as a therapeutic treatment for TSD? This article advances a strong argument to support the lifting of Australia's blanket prohibition on HHGE to enable its use in this instance. Further, it will be shown an ethical imperative exists to pursue HHGE as a treatment for fatal monogenic genetic diseases similar to TSD. Therefore, this argument may apply to support the use of HHGE to treat a broader range of fatal monogenic genetic diseases, such as cystic fibrosis and Duchenne muscular dystrophy.

5. Ethical Discourse for Case Study Narration

In order to reframe the dominant narrative, the way this case study is articulated is important. As noted earlier, this article will show the influence of a narrative through a case study, which concentrates on 'the exploration of puzzles [various views] within a single case'.[38] To guide the exploration of these views, the case study will be narrated through the lens of the four principles of medical ethics. At the conclusion of the case study, this article will proffer an answer to the following question: Should HHGE be permitted as a therapeutic treatment for TSD, thereby supporting a lift of Australia's blanket prohibition?

5.1 Autonomy

The principle of autonomy broadly promotes self-governance in decision-making, enabling the exercise of free choice without interference, such as coercion.[39] Consequently, the two primary tenets of autonomy are agency (autonomous decision-making) and liberty (freedom from external influences).[40] This article argues that another fundamental principle accompanying autonomy is *respect*. The notion of respect is intricately related to respect for autonomy to make free choices regarding reproduction and respect for human dignity. Despite its philosophical origins,[41] dignity as a right is also reinforced in international conventions, including Article 1 of the United Nations Universal Declaration of Human Rights. Further, the

[33] National Organization for Rare Disorders, "Tay Sachs Disease"; National Health Service, "Tay-Sachs Disease"; Victorian State Government Department of Health, "Tay-Sachs Disease"; Online Mendelian Inheritance in Man, "Tay-Sachs Disease (TSD)."
[34] National Organization for Rare Disorders, "Tay Sachs Disease"; National Health Service, "Tay-Sachs Disease."
[35] Victorian State Government Department of Health, "Tay-Sachs Disease"; National Organization for Rare Disorders, "Tay Sachs Disease."
[36] National Organization for Rare Disorders, "Tay Sachs Disease."
[37] The term 'future offspring' is globally adopted by leading institutions, including the National Academies of Sciences, Engineering and Medicine and the Nuffield Council on Bioethics, featuring in authoritative reports on this topic: National Academies of Sciences, Engineering and Medicine and The Royal Society, Heritable Human Genome Editing Report; National Academies of Sciences, Engineering and Medicine, Science, Ethics and Governance Report; Nuffield Council on Bioethics, Genome Editing and Human Reproduction Report.
[38] Morgan, "Narrative Ordering and Explanation," 90.
[39] Beauchamp, Principles of Biomedical Ethics, 101.
[40] Beauchamp, Principles of Biomedical Ethics, 102.
[41] Grayling, The History of Philosophy, 256–268.

Oviedo Convention[42] recognises the importance of respecting human dignity, noting that its role represents 'the essential value to be upheld. It is at the basis of most of the values emphasised in the Convention'.[43] When referring to human dignity, this article considers the ways in which, in this scenario, HHGE could preserve the dignity of future offspring. This may be achieved by maximising welfare, by preventing the occurrence of a fatal monogenic genetic disease. In applying the principles of autonomy and respect, a strong argument exists to support an ethical imperative to pursue HHGE in this case.

As mentioned, TSD is a fatal monogenic genetic disease that causes premature death at the age of three to five years. In addition to this poor prognosis, the clinical features of the disease are severe, progressively deteriorating until death. The neurodegenerative symptoms significantly impact the quality of life of the child, which diminishes over time. Although medical interventions are available to alleviate and manage symptoms, this deterioration is inevitable and cannot be prevented. Therefore, any improvement to quality of life will be minor and short term. The severity of TSD presents a compelling argument to pursue HHGE, given the high mortality rate, significant clinical features and diminished quality of life.

First, in order to exercise autonomy, it is paramount that the prospective parents are harnessed with all relevant and necessary information to make an informed decision. This information must address many topics, including benefits, risks (including those to the embryo), economic considerations and long-term management. To exercise their agency and decision-making capacity, measures to enhance this ability must be provided to prospective parents. These measures may include guidance from genetic counsellors, communication tools, the presence of support persons and time to consider options in order to reach a decision. In this scenario, there is a strong possibility that the prospective parents are unable to have a genetically related child without TSD. Their personal cultural, ethical, religious and social values will influence their perception of parenthood and the priority attached to genetic parenthood. Therefore, it would be presumptuous to argue these parents can and should consider alternative pathways to parenthood, such as adoption and foster care. While these options should be communicated (if available), preserving autonomy means respect for decisions, regardless of their merit or motivation.

Second, if this scenario were viewed through the lens of respect for human dignity, an ethical imperative would exist to pursue HHGE to prevent this disease and reduce its prevalence within the population.[44] This argument also applies to the dignity of the prospective parents in terms of exercising their decision-making autonomy to undergo HHGE. Respect for dignity does not discriminate against the reason/s for a decision – whether it be to pursue HHGE to maximise the parents' opportunity to have a genetically related child, to ensure a future child does not inherit TSD or to avoid the grief and financial pressures associated with having a terminally ill child. Alternatively, this may be a decision to refuse HHGE due to religious or ethical opposition/s, an acceptance that they cannot have a genetically related child or to prevent future suffering of the child due to the unknown health impacts of HHGE. Regardless of the justification, respect for human dignity involves the preservation of individual choice. Therefore, the application of HHGE in this case promotes reproductive autonomy and safeguards human dignity. In this scenario, their lack of success in producing a large quantity of viable embryos compounds the complexity of their decision. A decision to undertake PGT carries its own risks and, notably, eliminates the possibility of pursuing HHGE if it were to proceed to clinical trials. Therefore, in a society that values individual choice, especially in the context of health and medicine, the decision to pursue HHGE, should it become available, ought to remain at the discretion of the prospective parents.

Human dignity also applies to the interests of future offspring. The prospective parents have an opportunity to ensure their future child does not have TSD. Further, HHGE introduces a unique prospect to remove TSD from their future genetic lineage, so no subsequent generation will be faced with a diagnosis or risk being a carrier. To refuse HHGE in this instance arguably violates the dignity of future offspring, who will endure suffering and inevitable premature death.

If there is recourse to avoid a fatal monogenic genetic disease, why not attempt HHGE? Where both outcomes are premature death (whether caused by TSD or a 'worst-case scenario' risk of HHGE), a decision to pursue HHGE is ethically justified. This justification is bolstered by a reliance upon the preservation of human dignity, the pursuit of a future in which pathogenic genes causing TSD are corrected, prevention of suffering and death and maximising the genetic health of future generations. While common ethical arguments continue to operate concerning naturalness and instrumentalization of an individual (by intervening in the genome), these are arguably flawed.[45] A plethora of ways exist in which naturalness may be compromised – such as through epigenetics, gene interactions, environmental exposures and social milieu. Further, the purpose of HHGE is to correct

[42] Its formal name is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.
[43] Council of Europe, Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 3.
[44] Pandos, Heritable Human Genome Editing.
[45] Birnbacher, "Prospects of Human Germline Modification."

and restore function of a disease-causing mutation, which aims to prevent future suffering, preserve the rights, interests and welfare of offspring and maximise the welfare of generations.[46] The means to achieve these goals – whether a naturally occurring phenomenon such as evolution or technological intervention – should be embraced.

Adherence to the principles of autonomy and respect provide a strong argument to support HHGE to prevent TSD. It promotes the dignity of the prospective parents and, importantly, dignity of risk – which recognises that an individual is entitled to make decisions that carry risk/s. If prospective parents exercise their choice to undertake HHGE, should it become available, understanding the risks (both known and unknown) ought to be respected. This highlights that each individual involved in this process brings their own ethical perspectives. To respect choice, provided it is informed and made voluntarily, without coercion or interference, upholds autonomy. Further, the dignity of future offspring is also preserved. This can be achieved by removing TSD for future generations, avoiding suffering and premature death, reducing and/or preventing terminations where TSD is diagnosed in an embryo via PGT and enabling a child to have an open future without the certainty of imminent death. To refrain from using HHGE in this context undermines society's commitment to upholding the fundamental right of autonomy.

5.2 Non-maleficence

This principle is often translated to 'above all do no harm'.[47] In the context of determining the permissibility of HHGE, this principle is mostly concerned with the technology's risk/s, including the known/unknown side-effects, toxicity, short- and long-term effects and uncertainty regarding data and knowledge deficits. Notably, the principle of non-maleficence carries greater narrative power, as it requires active consideration of risks associated with HHGE. This inevitably perpetuates the current narrative of HHGE in relation to fear and uncertainty. However, this narrative need not dominate and prevail. These considerations ought to shape future legal and regulatory approaches. The utility of a case study as a narrative provides a more holistic evaluation of a proposed application of HHGE. Therefore, it requires the narrator to identify various possibilities or arguments and importantly, offer a multifactorial analysis of them. This may involve balancing various considerations and prioritising arguments.

Sensibly, in practice, non-maleficence is of particular significance. In order to enforce this principle, HHGE for TSD must be safe and efficacious. With respect to regulatory decision-making, the universal evidentiary threshold states that the benefits of a proposed treatment must outweigh its risks.[48] This threshold attempts to mitigate premature approval of proposed treatments that carry risk/s to human health. Therefore, regulators are actively adhering to an ethical obligation to *do no harm* by intentionally making regulatory decisions that seek to avoid and/or manage risk/s and harm/s.[49] Furthermore, the overarching aim of a regulator is to foster a regulatory environment that is legitimate, responsive and proportionate. This enables responsible development and innovation of frontier technologies that pose a threat to human health.

5.2.1 Risks

Consistent with the purpose of a case study, the primary risks associated with HHGE for TSD should be identified. First, one must consider the context in which this technique would be administered. Heritable Human Genome Editing will likely be undertaken in conjunction with an Assisted Reproductive Technology ('ART') – which increases the risks to the affected embryo. Some risks associated with an ART include, but are not limited to, multiple gestations, birth defects, genetic abnormalities, possible damage due to the manipulation of oocytes and embryos, preterm birth, perinatal mortality rate, infection and bleeding.[50] Consequently, prospective parents must consider the cumulative risks of both an ART and HHGE.[51] This has implications for risk tolerance in discerning an acceptable threshold of risk for both the ART and HHGE. Second, it is important to note that PGT cannot be undertaken at this stage, as the zygote[52] has developed. This indicates that prospective parents must decide to refuse or pursue HHGE at an early stage, prior to genetic testing for known genetic diseases. Third, the delivery and nature of this treatment raises unique considerations. The treatment would be administered as a blind injection of the CRISPR system into all cells, which targets the mutated *HEXA* gene. The success of HHGE cannot be ascertained until the embryos are cultured and screened, akin to the process of PGT. While HHGE will restore function of the *HEXA* gene, this approach does not cater for *de novo* mutations. These are new mutations arising during development, which may confer disease or predisposition to disease. The likelihood of the occurrence of a *de novo* mutation is unknown. Fourth, the technical limitations

[46] Birnbacher, "Prospects of Human Germline Modification," 57–58.
[47] Beauchamp, Principles of Biomedical Ethics, 150.
[48] Therapeutic Goods Administration, "How the TGA Regulates"; Food and Drug Administration, "Benefit-Risk Assessment for New Drug and Biological Products"; European Medicines Agency, "ICH Guideline E2C (R2) on Periodic Benefit-Risk Evaluation Report (PBRER)."
[49] Beauchamp, Principles of Biomedical Ethics, 150–153.
[50] The American College of Obstetricians and Gynecologists, "Perinatal Risks"; Rebar, "What are the Risks?" 152.
[51] Drabiak, "Untangling the Promises," 999.
[52] A diploid cell formed by the complete fertilisation of a human egg and human sperm.

of the technology give rise to risks of on- and off-target events and mosaicism. These are changes to the DNA that are prompted by CRISPR technology. The severity, type, duration and probability of these events is unknown. In addition to these technical limitations, the short- and long-term health consequences of HHGE are unknown. The intergenerational impact cannot be foreseen or quantified prior to treatment. This is a risk uniquely associated with germline editing, as the genetic edit is heritable to subsequent generations. Consequently, this further compounds the fear and uncertainty attached to HHGE, as the future impact of those edits cannot be known prior to treatment. In light of its intergenerational impact, long-term follow-up to monitor individuals subject to HHGE will facilitate rigorous oversight and ongoing data collection relating to its safety and efficacy. It will also facilitate ongoing developments in research, which will provide much-needed understanding about the technique and its outcomes.

Finally, in this circumstance, the *patient* is yet to exist. As such, the onus is upon the prospective parents to make an informed decision regarding the fate of the potential patient. The risk tolerance of the prospective parents may be reduced, given that it is their final attempt at IVF to birth a genetically related child and only two viable embryos remain. It is a possibility that the fate of those embryos is death if they are disease-affected. In this vein, it may be that acceptance of unknown risks associated with HHGE is the 'lesser of two evils'. Importantly, where there is a foreseeable benefit of TSD prevention, this alone may be sufficient to justify the decision of the prospective parents. These are some of the primary risks associated with HHGE. This article may not capture all the possible risks. However, it has identified four risks that dominate the narrative of HHGE. It is clear there are uncertainties, many of which may result in harm to the future offspring – although, in the context of new therapeutics, the concept of 'zero risk' does not exist. These risks, however severe, minor or remote, must be balanced against the benefits of HHGE.

5.2.2 Benefits

Consistent with a decision-making process, one must consider the consequences of a decision. In the context of this scenario, prospective parents must weigh and balance the risks of HHGE against its benefits. As such, it is integral to consider some of the primary benefits of HHGE. First, the intended and foreseeable benefit of undertaking HHGE will result in a genetically related child who does not have TSD. This may be particularly pertinent to prospective parents who seek genetic parenthood. For some, genetic parenthood may not be possible. This treatment will enable this cohort of prospective parents to have a genetically related child. Second, the genetic cause of the disease is relevant. TSD is monogenic, which alleviates the technical difficulties of undertaking HHGE, as opposed to polygenic genetic diseases (caused by more than a single gene). Where a disease is caused by more than a single gene, this has implications on the complexity and efficacy of the technique. Third, the permanent correction of the disease variant indicates that HHGE is capable of removing TSD from the future genetic lineage of this family (noting that the parents remain carriers). This is a significant outcome for families carrying the *HEXA* mutation. Where a treatment option exists that removes future risk of this fatal disease, prospective parents may ascribe a greater weight to this benefit, thereby increasing their overall risk tolerance. Fourth, the application of HHGE for this purpose promotes intergenerational justice for future generations, who will not inherit or be affected by TSD, preventing death and alleviating disease burden (and its accompanied economic benefits).

The application of non-maleficence necessitates an important exercise in identifying the primary risks and benefits of HHGE in this scenario. This is an integral component enhancing the understanding of HHGE as a treatment and ultimately informs decision-making. Following the identification of these primary risks and benefits – do the benefits outweigh risks? The benefits of HHGE in this hypothetical scenario arguably outweigh its risks for two reasons. First, this is an instance in which the risks of HHGE are no worse than the fate of the viable embryos, if affected by TSD.[53] As such, where there are no effective treatments and death is inevitable, why not attempt to prevent this fatal disease? To do so prioritises the welfare of the future offspring, preserving their human dignity. It also promotes the reproductive autonomy and desires of prospective parents who are unable to otherwise conceive a genetically related child without TSD. Second, HHGE provides an invaluable opportunity to remove a severe, fatal genetic disease for this family. The benefits of correction and disease prevention are significant in magnitude, type and duration. The implementation of long-term monitoring following HHGE will enable risks to be identified and managed. From an ethical and narrative perspective, HHGE may be framed as a potential lifesaving treatment for subsequent generations, enhancing their welfare, by providing them with a future free of TSD. For these reasons, the benefits of HHGE arguably outweigh its risks.

[53] Savulescu, "An Ethical Pathway."

5.3 Beneficence

Generally, this principle denotes an obligation to help others, to promote the distribution of benefits and maximise welfare and interests.[54] TSD is a rare disease, with a frequency of approximately one in 25 Australians of Ashkenazi Jewish descent.[55] Its status as a rare disease, with a recessive inheritance, does not diminish its candidacy as a disease target for HHGE. Rather, where a treatment option exists that corrects and alleviates disease burden and suffering, a strong ethical case is established. Further, in the absence of any effective cures or treatments, prospective parents are tasked with balancing the risks of a new treatment against potential benefits that are non-existent with current treatment approaches. In this case, HHGE provides benefits of such a great magnitude. For this reason, an ethical imperative to pursue HHGE to prevent TSD exists. A decision to permit HHGE upholds the principle of beneficence, promoting the future interests and welfare of offspring and subsequent generations.

5.4 Justice

With respect to equitable access and economic justice (cost of treatment), it may be presumed that the costs of HHGE fall within the ambit of Medicare rebates. However, this is an assumption and does not reflect current or indicate future approaches. This discussion will be confined to intergenerational and social justice. Intergenerational justice advocates for the betterment of wellbeing for future generations[56] – in this case, to prevent a specific fatal monogenic genetic disease. As noted above, the ability to prevent and remove a fatal monogenic genetic disease from the future genetic lineage is significant. Over time, the reduction in disease burden, suffering and mortality are key endpoints that promote intergenerational justice. In this context, intergenerational justice is achieved by taking steps to ensure TSD is prevented to maximise the future welfare of generations.

Social justice concerns the need for prudent scientific progress to occur. Françoise Baylis refers to this understanding of social justice in the context of 'slow science', which advocates for research to slow down, enabling time to deliberate ethical and social questions and implications.[57] The application of HHGE for TSD will result in the accumulation of valuable data, which will shape and inform future research development and capability. This promotes social justice through the expansion of knowledge regarding the risks, benefits and outcomes of HHGE. A slow and cautious approach to its regulation and development enables ethical deliberations to occur within a society. Greater knowledge will also inform public perceptions and the acceptance or refusal of HHGE. Notably, this will contribute to a more informed, accurate and descriptive narrative concerning HHGE, which will likely shift its undertone away from fear and uncertainty.

5.5 Should Australia Legally Sanction Heritable Human Genome Editing for Tay-Sachs Disease?

The case study provides a strong argument that an ethical imperative exists to pursue HHGE for the purpose of preventing TSD. Ethical justification for this conclusion is derived from the application of the fundamental principles of medical ethics. These principles served as a useful discourse to articulate this narrative. When narrating this case study through the lens of these principles, it reframes arguments to actively consider and promote key rights, such as human dignity and reproductive autonomy. Further, it shifts the dominant narrative away from fear and uncertainty by describing how HHGE can be a lifesaving therapeutic.

This case study has offered a clear example of circumstances in which the possible harms of HHGE are not, and cannot be, worse than the fate of an affected embryo with TSD. This is an integral distinction to highlight. If death is perceived to be the gravest harm, any attempt to prevent it gains ethical legitimacy. For this reason, an ethical imperative exists. Notably, this strengthens the argument against a blanket prohibition on HHGE in Australia. To refrain from lifting this prohibition under these circumstances would arguably be unethical. The ethical support underpinning this narrative advances the argument for the legal permissibility of HHGE in *certain circumstances*, such as TSD. Therefore, the lifting of a blanket prohibition on HHGE ought to be considered as the technology matures. This would require legislative reform to Australia's current statutes,[58] in addition to greater consideration for regulators tasked with approval of novel therapeutics using a frontier technology.

Tay-Sachs Disease offers a clear example in which the case for ethical and legal permissibility is highly persuasive. From a safety perspective, its narrative is certainly more palatable than polygenic genetic diseases, which are more complex in their aetiology. Such a clear-cut inviolable red line, as observed with TSD, is not always encountered. The complexity of a case

[54] Beauchamp, Principles of Biomedical Ethics, 151, 202.
[55] Lew, "Tay-Sachs Disease."
[56] Gyngell, "Moral Reasons."
[57] Baylis, Altered Inheritance, 123–124.
[58] *Gene Technology Act 2000* (Cth); *Research Involving Human Embryos Act 2002* (Cth); *Prohibition of Human Cloning for Reproduction Act 2002* (Cth).

study will be contingent upon the specific application (disease candidate) targeted by HHGE and the jurisdiction in which it is debated. The above analysis has exemplified the importance of societal consultation and participation in the shaping of a narrative and possible outcomes. Societal dialogue is critical to better articulate and understand the various contingencies, possibilities and alternatives associated with HHGE for a specific application. Consequently, the narrative will inevitably change depending on the jurisdiction in which it is narrated. Differences in ethics, values, social structures, religiosity, politics, language and culture will influence the discourse used to narrate the story of HHGE for TSD prevention. This is consistent with a known truism of narratives presented as a case study: the puzzle it seeks to examine is generally resolved within existing community norms.[59] A resolution is therefore dictated by a narrative consistent with that community's values and norms, gaining legitimacy and trust. Alternatively, Sharon Crasnow proposes '[d]ifferent narratives of the same case carry with them frameworks within which the story needs to make sense'.[60] In context, these frameworks are representative of a community's values and norms.

In light of the nuances associated with the ways in which a case study may be narrated, it reveals an important attribute of narrative theory. It is sufficiently adaptable to cater for a specific jurisdiction's circumstances. While the discourse adopted to narrate this case study reflects universal ethical principles, their subsequent enforcement in practice may differ according to the jurisdiction in which they are applied.

6. Conclusion: The Path Not Taken

The advent of a frontier technology presents a myriad of untold possibilities. Inevitably, there will be many forks in the road – points of time at which society must consider and decide the path to take. In the context of frontier technologies and their application/s, this decision is often fraught and complex. Further, it requires ethical, legal and societal deliberations to ascertain the appropriate pathway forward. Narrative theory has introduced itself as a valuable approach to forecast and navigate these deliberations. Its utility is reflected in its capacity to articulate the subject-matter and investigate various possibilities, considerations and pathways.

This article argues that the framing and expression of ethical considerations as a narrative guides the establishment of a legal and regulatory approach to HHGE. Public scrutiny and consultation often involve an interrogation of relevant ethical and social considerations accompanying a frontier technology. Consequently, it is unsurprising that the dominant narrative propagated within a particular society may change, as it is context-specific and shaped by ethical, social, cultural and political values. Currently in Australia, HHGE is criminalised and prohibited. This legal and regulatory position is fuelled by a prevailing narrative concerned with unscrupulous applications of HHGE and its safety and efficacy. This is a very reasonable narrative to espouse in light of the uncertainty attributed to knowledge and data deficits. However, this article has sought to advance a thought experiment through the case study, to prompt discussions of an acceptable application of HHGE as it continues to mature. Responsible development and refinement of the technology will begin to fill knowledge and data gaps, improving its safety and efficacy profile. Using a case study as the form of narrative, this article identifies one instance in which HHGE ought to be legally permitted. The application of HHGE to prevent TSD, a fatal monogenic genetic disease, is accompanied by ethical support. This argument was framed through the lens of the four key principles of medical ethics. These principles were selected as an appropriate discourse to narrate the case study, as future legal and regulatory decisions pertaining to HHGE will be made within the realm of human medical research. Importantly, the case study captured a variety of viewpoints, possibilities and considerations in relation to arguments supporting the use of HHGE in this circumstance. This provides a strong basis to justify the path taken – that is, to lift the blanket prohibition on HHGE in Australia and the path not taken – to support the continued legal ban.

Often, risks associated with a frontier technology play the protagonists in narratives commonly conveyed in the context of technology regulation. To progress as a society and change our circumstances, we must be open to editing the narrative of HHGE as a potential lifesaving treatment for fatal monogenic genetic disease/s. This may be achieved by relying upon a regulatory discourse that legally authorises such applications, with necessary precaution that does not hinder ongoing research and advancements. Narratives are the impetus driving ethical evaluation, whilst the law and regulation act as the gatekeepers and facilitators of change. Heritable Human Genome Editing provides an opportunity to write an exciting new chapter in society's history. Although not unaccompanied by risks, our future global society may look back upon this time to learn about the importance of honest and accurate facts underpinning the CRISPR narrative. Prior to legal and regulatory reforms, case studies can be used to investigate potential applications of HHGE, as a litmus test to determine acceptable and unacceptable use/s.

[59] Morgan, "Narrative Ordering," 94.
[60] Crasnow, "Process Tracing," 6.

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Bibliography

Primary Legal Sources

Gene Technology Act 2000 (Cth).
Prohibition of Human Cloning for Reproduction Act 2002 (Cth).
Research Involving Human Embryos Act 2002 (Cth).

Secondary Sources

The American College of Obstetricians and Gynecologists. "Perinatal Risks Associated With Assisted Reproductive Technology." 2016. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2016/09/perinatal-risks-associated-with-assisted-reproductive-technology.

Baylis, Françoise. *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Cambridge, MA: Harvard University Press, 2019.

Baylis, Françoise, Marcy Darnovsky, Katie Hasson and Timothy M Krahn. "Human Germline and Heritable Genome Editing: The Global Policy Landscape." *The CRISPR Journal* 3, no 5 (2020): 365–77. https://doi.org/10.1089/crispr.2020.0082.

Beatty, John. "What are Narratives Good For?" *Studies in History and Philosophy of Biological and Biomedical Sciences* 58 (2016): 33–40. https://doi.org/10.1016/j.shpsc.2015.12.016.

Beauchamp, Tom L. and James F. Childress. *Principles of Biomedical Ethics*, 7th ed. Oxford: Oxford University Press, 2013.

Birnbacher, Dieter. "Prospects of Human Germline Modification by CRISPR-Cas9: An Ethicist's View." In *Between Moral Hazard and Legal Uncertainty: Ethical, Legal and Societal Challenges of Human Genome Editing*, edited by Matthias Braun, Hannah Schickl and Peter Dabrock, 53–66. Dordrecht: Springer, 2018.

Council of Europe. *Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997*. Brussels: Council of Europe, 1997.

Crasnow, Sharon. "Process Tracing in Political Science: What's the Story?" *Studies in History and Philosophy of Science* 62 (2017): 6–13. https://doi.org/10.1016/j.shpsa.2017.03.002.

Drabiak, Katherine. "Untangling the Promises of Human Genome Editing." *The Journal of Law, Medicine & Ethics* 46 (2018): 991–1009. https://doi.org/10.1177/1073110518822001.

European Medicines Agency. *ICH Guideline E2C (R2) on Periodic Benefit-Risk Evaluation Report (PBRER)*. The Hague: European Medicines Agency, 2013.

Food and Drug Administration. *Benefit-Risk Assessment for New Drug and Biological Products: Guidance for Industry Guidance*. Washington, DC: US Department of Health and Human Services Food and Drug Administration, 2021.

Grayling, A.C. *The History of Philosophy: Three Millenia of Thought from the West and Beyond*. Harmondsworth: Penguin, 2019.

Greely, Henry T. "CRISPR'd Babies: Human Germline Genome Editing in the "He Jiankui Affair."" *Journal of Law and the Biosciences* 6, no 1 (2019): 111–83. https://doi.org/10.1093/jlb/lsz010.

Gyngell, Christopher, Hilary Bowman-Smart, and Julian Savulescu. "Moral Reasons to Edit the Human Genome: Picking up from the Nuffield Report." *Journal of Medical Ethics* 45, no 8 (2019): 514–23. https://doi.org/10.1136/medethics-2018-105084.

Hajek, Kim M. "What is Narrative in Narrative Science? The Narrative Science Approach." In *Narrative Science: Reasoning, Representing and Knowing Since 1800*, edited by Mary S. Morgan, Kim M. Hajek and Dominic J. Berry, 31–57. Cambridge: Cambridge University Press, 2022.

Johnson, Harold R. "Harold R. Johnson on How We Tell Our Own Stories." https://lithub.com/harold-r-johnson-on-how-we-tell-our-own-stories/.

Lew, Raelia M., Leslie Burnett, Anné L. Proos, and Martin B. Delatycki. "Tay-Sachs Disease: Current Perspectives from Australia." *The Application of Clinical Genetics* 8 (2015): 19–25. https://doi.org/10.2147/tacg.s49628.

Lovell-Badge, Robin, David Baltimore, Françoise Baylis, Ewan Birney, Alta Charo, George Daley, Javier Guzman, et al. Statement from the Organising Committee of the Third International Summit on Human Genome Editing. https://www.ncbi.nlm.nih.gov/books/NBK593530.

Morgan, Mary S. "Narrative: A General-Purpose Technology for Science." In *Narrative Science: Reasoning, Representing and Knowing Since 1800*, edited by Mary S. Morgan, Kim M. Hajek and Dominic J. Berry, 31–57. Cambridge: Cambridge University Press, 2022.

Morgan, Mary S. "Narrative Ordering and Explanation." *Studies in History and Philosophy of Science* 62 (2017): 86–97. https://doi.org/10.1016/j.shpsa.2017.03.006.

Morgan, Mary S. and M. Norton Wise. "Narrative Science and Narrative Knowing: Introduction to Special Issue on Narrative Science." *Studies in History and Philosophy of Science* 62 (2017): 1–5. https://doi.org/10.1016/j.shpsa.2017.03.005.

National Academies of Sciences, Engineering and Medicine. *Human Genome Editing: Science, Ethics and Governance Report*. London: National Academies of Sciences, Engineering and Medicine, 2017.
National Academies of Sciences, Engineering and Medicine, and The Royal Society. *Heritable Human Genome Editing Report*. London: National Academies of Sciences, Engineering and Medicine, and The Royal Society, 2020.
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979.
National Health Service. "Tay-Sachs Disease." 2021. https://www.nhs.uk/conditions/tay-sachs-disease.
National Organization for Rare Disorders. "Tay Sachs Disease." https://rarediseases.org/rare-diseases/tay-sachs-disease.
Nicol, Dianne. "Regulation of Human Germline Genome Modification in Australia." In *Human Germline Genome Modification and the Right to Science*, edited by Andrea Boggio, Cesare P.R. Romano and Jessica Almqvist, 543–567. Cambridge: Cambridge University Press, 2020.
Nuffield Council on Bioethics. *Emerging Biotechnologies: Technology, Choice and the Public Good Report*. 2012. https://cdn.nuffieldbioethics.org/wp-content/uploads/Emerging_biotechnologies_full_report_web_0.pdf.
Nuffield Council on Bioethics. *Genome Editing and Human Reproduction Report*. 2018. https://cdn.nuffieldbioethics.org/wp-content/uploads/Genome-editing-and-human-reproduction-report.pdf.
Online Mendelian Inheritance in Man. "Tay-Sachs Disease (TSD)." 2022. https://www.omim.org/entry/272800?search=tay%20sachs%20disease&highlight=disease%20sach%20tay#editHistory.
Pandos, Olga C. "Heritable Human Genome Editing: Friend or Foe? Navigating the Legal, Ethical and Regulatory Challenges in Australia." PhD dissertation, University of Adelaide, 2025.
Pandos, Olga C. "Navigating the Ethics of Genome Editing and Heritability." *Medical Research Archives* 12, no 5 (2024): 1–13. https://doi.org/10.18103/mra.v12i5.5336.
Pandos, Olga C. "Traversing Uncharted Territory? The Legislative and Regulatory Landscape of Heritable Human Genome Editing in Australia." *Federal Law Review* 52, no 1 (2024): 75–102. https://doi.org/10.1177/0067205X241236212.
Rebar, Robert W. "What are the Risks of the Assisted Reproductive Technologies (ART) and How Can They Be Minimized?" *Reproductive Medicine and Biology* 12, no 4 (2013): 151–158. https://doi.org/10.1007/s12522-013-0156-y.
Rheenen, Wouter van, Wouter J Peyrot, Andrew J Schork, S Hong Lee, and Naomi R Wray. "Genetic Correlations of Polygenic Disease Traits: From Theory to Practice." *Nature Reviews Genetics* 20 (2019): 567–581. https://doi.org/10.1038/s41576-019-0137-z.
Savulescu, Julian, and Peter Singer. "An Ethical Pathway for Gene Editing". *Bioethics* 33 (2019): 221–222. https://doi.org/10.1111/bioe.12570.
Therapeutic Goods Administration. "How the TGA Regulates." 2023. https://www.tga.gov.au/how-we-regulate/advertising/legal-framework/act-regulations-and-code-offences/how-tga-regulates.
Victorian State Government Department of Health. "Tay-Sachs Disease." 2019. https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/tay-sachs-disease.
WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. *Human Genome Editing: A Framework for Governance Report*. Geneva: World Health Organization, 2021.