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# Designer Babies and the Law: A Legal Analysis of Human Germline Editing in Light of the UK's Human Rights Obligations

Hillary Chua\*

## Abstract

In light of the UK's progressive embrace of new biotechnologies, and the recent scientific breakthrough of CRISPR/Cas-9 (a gene-editing technology), this paper investigates whether the UK could legalise the genetic editing of human embryos (intended for implantation and birth) in the near future, given its international human rights obligations. In particular, this paper examines the bans against human genome editing that are found in the Council of Europe's Oviedo Convention and UNESCO's *Universal Declaration on the Human Genome and Human Rights*. These bans reflect an existing European consensus against editing inheritable human genes (human germline editing). Therefore, this paper determines that the bans can be incorporated into the UK's European Convention on Human Rights (ECHR) obligations, to bind the UK. Nevertheless, this paper suggests that once gene-editing technologies are perfected, European attitudes may shift to embrace human germline editing. However, distinctions would have to be made between germline editing for (i) the treatment of physical suffering; (ii) the enhancement of healthy individuals; and (iii) discrimination against disabled groups. Whilst the latter two uses of the technology are dangerously eugenic, therapeutic gene-editing within carefully-defined limits is ethically justifiable, and is likely to be permitted by ECHR law in the near future. Hence, this paper predicts that the UK can and will legalise germline therapy in the near future. In doing so, Article 2 of the ECHR (the right to life) will require the UK to determine what constitutes an acceptable level of risk before legalising the therapy, whilst Article 8 (the right to private and family life) would support the therapy's legalisation, albeit for a narrow and carefully-decided list of genetic conditions.

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## Introduction

Over the last decade, technologies that can edit the human genome; the biological encoding of human characteristics, have divided both scientists and ethicists alike. On one hand, such technologies can treat multiple genetic disorders.<sup>1</sup> On the other hand, this characteristic lends itself to potentially eugenic uses,<sup>2</sup> raising concerns about tampering with the “heritage of humanity”.<sup>3</sup> The debate has intensified in recent years with the emergence of CRISPR/Cas-9: a relatively cheap and simple technique for editing DNA,<sup>4</sup> which, as of April 2015, has been used to edit the DNA of non-viable human embryos to treat  $\beta$ -thalassemia in China.<sup>5</sup> This process of modifying genes that can be inherited by future generations is known as ‘germline editing’.<sup>6</sup> Whilst germline editing of viable embryos and their subsequent implantation is currently illegal,<sup>7</sup> the UK has progressively legalised mitochondrial donation, i.e.: embedding the nuclei of affected human egg cells (with unhealthy mitochondria) into healthy donor eggs whose nuclei have been removed.<sup>8</sup> This suggests that the UK may be one of the first countries to legalise therapeutic germline editing. Yet this action would impinge upon the UK’s global human rights responsibilities.<sup>9</sup>

Since the UK is a party to the European Convention on Human Rights (ECHR), this paper seeks to determine whether the UK’s obligations under the ECHR would prohibit or support its legalisation of human germline editing, both presently and in the near future. Additionally, this paper proposes an ethically-defensible scope of permissibility which European and domestic laws *ought* to grant to human germline editing.

The analysis shall be undertaken in five parts. Part A shall outline the science of germline editing and the UK’s current laws surrounding it. Since the ECHR does not explicitly address germline editing, Parts B to D shall examine whether human rights instruments that ban the practice but do not bind the UK, such as the Oviedo Convention,<sup>10</sup> may indirectly determine the UK’s ECHR

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<sup>1</sup> Kenneth W Krause, ‘CRISPR-Cas9: Not Just Another Scientific Revolution’ (*The Doting Skeptic*, 3 February 2016) <<http://linkis.com/wordpress.com/bkc2S>> accessed 16 February 2016

<sup>2</sup> John Wyatt, *Matters of Life and Death* (2<sup>nd</sup> edn, IVP 2009) 131-132.

<sup>3</sup> UNESCO ‘Universal Declaration on the Human Genome and Human Rights’ (11 November 1997), Art 1

<sup>4</sup> Krause (n1)

<sup>5</sup> Puping Liang et al., ‘CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes’ [2015] 6 *Protein Cell* 363

<sup>6</sup> Audrey R Chapman and Mark S. Frankel, ‘Framing the Issues’ in Audrey R Chapman and Mark S. Frankel (eds), *Designing our Descendants: The Promises and Perils of Genetic Modifications* (JHUP 2003), 4

<sup>7</sup> The “UK” shall be used as shorthand for the jurisdiction of England and Wales.

<sup>8</sup> Human Fertilisation and Embryology Authority, *Mitochondrial donation: an introductory briefing note* (October 2014) 3

<sup>9</sup> UNESCO International Bioethics Committee ‘Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights’ (2 October 2015) SHS/YES/IBC-22/15/2 REV.2, 27 [115] Henceforth, “IBC Report”.

<sup>10</sup> 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 (Oviedo Convention) (entered into force 1 December 1999) European Treaty Series No 164. Henceforth, “Oviedo Convention”.

obligations in this regard and whether this is justifiable. Part E shall evaluate whether the UK has duties under Articles 2 (right to life) and 8 (right to private and family life) to restrict or promote the legalisation of germline editing for therapeutic purposes (germline therapy), respectively. How discriminatory or enhancing applications of germline editing may be prohibited as exceptions under Article 8(2) will also be considered.

This paper argues that presently, the UK cannot legalise any form of human germline editing without breaching its ECHR obligations,<sup>11</sup> but it may do so once the technology proves safe for therapeutic use. In that future time, ECHR law is likely to evolve with positive changes in European attitudes towards gene-editing, to permit therapeutic germline editing. Using germline editing to relieve physical suffering can and ought to be distinguished from its application for discriminating against the disabled and enhancing healthy individuals. While the latter two uses are dangerously eugenic, germline therapy, when construed appropriately and restrictively, would not be and may be legalised.

Since the latest advances in germline editing have been achieved with CRISPR/Cas-9,<sup>12</sup> this paper shall focus on that technology as applied to human embryos.

## **(A) Scientific and Legal Overview of Human Germline Editing**

### Scientific Background

CRISPR/Cas-9 is a precise gene-editing technique, which consists of ‘Clustered Regularly Interspaced Short Palindromic Repeats’ (CRISPR) and an associated protein-9 nuclease (Cas9).<sup>13</sup> It can be easily and cheaply programmed to target DNA, and then disable or snip away segments of DNA to remove unwanted genetic sequences, or to insert desired ones.<sup>14</sup> It can be used in conjunction with *in vitro fertilization* (IVF) and applied to human gametes (also known as germ cells), which are fertilised to form an embryo, or human embryos in the early stages of their development, inducing global changes to the cells of a resulting individual.<sup>15</sup> Such individuals can then transmit the edited DNA to the next generation, through sexual reproduction, thereby editing the human germline.

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<sup>11</sup> Rosario Isasi et al. ‘Editing Policy to fit the Genome’ (2016) 351 *Science* 337, 338-339

<sup>12</sup> Heidi Ledford, ‘CRISPR, the disruptor’ (2015) 522 *Nature* 20, 21

<sup>13</sup> Krause (n1)

<sup>14</sup> Ledford (n12) 21

<sup>15</sup> Eric Juengst and Erik Parens, ‘Germline Dancing: Definition Considerations for Policy Makers’ in Audrey R Chapman and Mark S. Frankel (eds), *Designing our Descendants: The Promises and Perils of Genetic Modifications* (JHUP 2003), 22

The attraction of legalising this use of CRISPR/Cas-9 is that it can correct diseases caused by gene mutations (more than 6000 of these are known to exist)<sup>16</sup>, for the benefit of a subject as well as his/ her offspring, on a one-off basis.<sup>17</sup> Since genes control the expression of physical and psychological characteristics, CRISPR/Cas-9 can also treat genetically-linked predilections to disease, psychological disorders,<sup>18</sup> and can make gene-based enhancements and diminutions.<sup>19</sup>

For the purposes of this paper, the two most likely initial applications of the technology shall be discussed:

1. Editing out fatal genetic diseases (e.g. Tay-Sachs)
2. Editing out genetically-caused, non-fatal disabilities (e.g. Blindness)

Admittedly, the existing technique of pre-implantation genetic diagnosis (PGD) can also prevent children from being born with these disabilities. PGD screens embryos created by IVF for genetic diseases, so that unhealthy embryos are discarded whilst the remaining ones are implanted in an intended mother. In fact, CRISPR/Cas-9 requires the use of PGD to identify embryos for editing.<sup>20</sup> However, PGD does not render CRISPR/Cas-9 redundant, as the latter offers a therapeutic alternative to discarding embryos.<sup>21</sup> It is also necessary where both parents share the same genetic mutation.<sup>22</sup>

However, germ-line editing poses unique human rights challenges because it can alter DNA, which is seen as a fundamental aspect of human heritage.<sup>23</sup> Additionally, there are some safety concerns: the use of CRISPR/Cas-9 comes with the risk of “off-targets”,<sup>24</sup> i.e.: where unintended parts of a subject’s genes are edited, causing new mutations. For example, the non-inheritable (somatic) use of gene-editing therapy in France was reported to have caused a child to develop a rare form of leukaemia, in October 2002.<sup>25</sup> Nevertheless, science is developing rapidly to address “off-

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<sup>16</sup> Nicholas Wright Gillham, ‘Hunting for Disease Genes’ (*FT Press*, 4 April 2011) <<http://www.ftpress.com/articles/article.aspx?p=1692537&seqNum=4>> accessed 18 March 2016

<sup>17</sup> Chapman and Frankel (n6) 4

<sup>18</sup> Nathaniel Comfort, ‘Better Babies’ (*Centre for Genetics and Society*, 17 November 2015) <<http://www.geneticsandsociety.org/article.php?id=8993>> accessed 16 February 2016

<sup>19</sup> John A Robertson, ‘Procreative Liberty in the Era of Genomics’ (2003) 29 *Am J Law Med* 439, 455. A discussion of diminutions lies outside the scope of this paper.

<sup>20</sup> Chapman and Frankel (n6) 6

<sup>21</sup> LeRoy Walters and Julie Gage Palmer, *The Ethics of Human Gene Therapy* (OUP 1997), 79. Derek Parfit’s “non-identity problem” raises the question of whether, instead of treating an embryo, gene editing causes a new individual to be formed. However, this discussion lies outside the scope of this paper.

<sup>22</sup> Chapman and Frankel (n6) 4

<sup>23</sup> UNESCO ‘Universal Declaration on the Human Genome and Human Rights’ (11 November 1997), Art 1

<sup>24</sup> Tetsuya Ishii, ‘Germline Genome-Editing Research and its Socioethical Implications’ [2015] 21 *Trends in Molecular Medicine* 473, 474

<sup>25</sup> Mark S Frankel, ‘Inheritable genetic modification and a brave new world: Did Huxley have it wrong?’ (2003) 33 *Hastings Centre Report* 31, 32

targets”,<sup>26</sup> and the therapeutic use of CRISPR/Cas-9 is gaining traction; in clinical trials in October 2016, a team of Chinese scientists modified a patient’s immune cells using CRISPR/Cas-9 to treat lung cancer.<sup>27</sup>

### Domestic Legal Background

The legal status of germline editing in England and Wales rests on fine distinctions. The Human Fertilisation and Embryology Act 1990 (“HFE Act 1990”) (as amended) sets out the definitions of gametes and embryos that can be used in IVF, in section 3ZA:

- (1) *A permitted egg is one—*
  - (a) *which has been produced by or extracted from the ovaries of a woman, and*
  - (b) *whose nuclear or mitochondrial DNA has not been altered.*
- (2) *Permitted sperm are sperm—*
  - (a) *which have been produced by or extracted from the testes of a man, and*
  - (b) *whose nuclear or mitochondrial DNA has not been altered.*
- (3) *An embryo is a permitted embryo if—*
  - (a) *it has been created by the fertilisation of a permitted egg by permitted sperm,*
  - (b) *no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and*
  - (c) *no cell has been added to it other than by division of the embryo's own cells.*

Sections 3ZA(1)(b) and 3ZA(3)(b) must be interpreted in light of sections 3, 4, 6 and 7 of the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (“HFE(MD)R 2015”). This extends the definition of permitted eggs and embryos to include eggs whose mitochondria have been replaced by a donor’s as well as embryos formed from such modified eggs. Significantly, mitochondria are extra-nuclear organelles which contain inheritable DNA. Thus, it is argued that, by legalising mitochondrial donation, the UK has permitted a scientifically-recognised form of germline editing.<sup>28</sup>

This seems to contradict s19(3) of The Medicines for Human Use (Clinical Trials) Regulations 2004, which bans deliberate germline edits.<sup>29</sup> However, the UK side-stepped this conflict and human rights issues, by redefining “genetic modification” to mean “*the germ-line modification of nuclear DNA...*”<sup>30</sup> Notably, the common feature of the definitions for permitted gametes and embryos, even in their extended form, is that deliberate changes to their *nuclear* DNA are explicitly

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<sup>26</sup> Krause (n1)

<sup>27</sup> David Cyranoski, ‘CRISPR gene-editing tested in a person for the first time’, (*Nature*, 15 November 2016), <<http://www.nature.com/news/crispr-gene-editing-tested-in-a-person-for-the-first-time-1.20988>>.

<sup>28</sup> Frankel (n25) 33

<sup>29</sup> Chapman and Frankel (n6) 8-9

<sup>30</sup> Department of Health, *Mitochondrial Donation: government response to the consultation on draft regulations to permit the use of new treatment techniques to prevent the transmission of a serious mitochondrial disease from mother to child* (Cm 10250, 2014) 15

disallowed.<sup>31</sup> This distinction is not as tenuous as it seems, because mitochondrial DNA contain 37 genes and are passed through the maternal line, whilst nuclear DNA contains 20,000 – 25,000 genes which are inherited from both parents.<sup>32</sup> Hence, the latter more strongly embodies an individual's genetic identity and editing nuclear DNA can be considered “full-blown” germline editing.<sup>33</sup> Henceforth the terms “germline editing” and “germline therapy” in this paper shall pertain to nuclear DNA.

Consequently, germline therapy is not yet legal in the UK, but mitochondrial donation has made its legalisation a realistic possibility.<sup>34</sup> In fact, on 1 February 2016, the Human Fertilisation and Embryology Authority (HFEA) (the UK's regulatory body for reproductive technologies) granted a license to researchers from the Francis Crick Institute to use CRISPR/Cas-9 on human embryos, albeit ones which must be destroyed after 14 days.<sup>35</sup> If germline therapy were to be legalised, the UK would need to seriously consider the implications in light of human rights law.

## **(B) Human Rights Bans on Germline Editing**

The ECHR does not explicitly mention germline editing. Instead, the clearest statement regarding human germline editing, in the corpus of European human rights, is found in a Council of Europe treaty for human rights and biomedicine, known as the Oviedo Convention. Article 13 of the Oviedo Convention states that:

*“An intervention seeking to modify the human genome may only be undertaken ... if its aim is not to introduce any modification in the genome of any descendants.”*

This ban does not extend to inadvertent germline editing via somatic therapies, or to editing germ cells (and by implication embryos) that are used in research and are not intended for procreation.<sup>36</sup> If the UK's narrow interpretation of ‘germline editing’ (as pertaining only to nuclear DNA) were to be accepted, then the UK's current germline editing practices would not be caught by Article 13. However, CRISPR/Cas-9 germline therapy would be. Significantly, the UK is not a party to the Oviedo Convention, but the UK could be indirectly subject to its provisions through its ECHR obligations, as discussed below.

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<sup>31</sup> HFE(MD)R 2005, s2(3)(c); s6(c)(i)

<sup>32</sup> ‘Difference Between Mitochondrial DNA and Nuclear DNA’ (*Major Differences*, 25 May 2015) <<http://www.majordifferences.com/2015/05/difference-between-mitochondrial-dna.html#.Vtys5pyLTWI>> accessed 6 March 2016

<sup>33</sup> Tetsuya Ishii, ‘Potential Impact of Human Mitochondrial Replacement on Global Policy Regarding Germline Gene Modification’ (2014) 29 *Reproductive BioMedicine Online* 150, 154

<sup>34</sup> *ibid.*

<sup>35</sup> HFE Act 1990 (as amended), ss. 3(3)– (4)

<sup>36</sup> 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 (Explanatory Report to the Oviedo Convention) ETS No 164, [92]

The main motivation behind the ban was a fear of “[producing] individuals or entire groups endowed with particular characteristics and required qualities.”<sup>37</sup> This implies a fear of eugenics, but what constitutes such a practice is not explicated, begging for further justifications.<sup>38</sup> Notably, the United Nations (UN) *Universal Declaration on the Human Genome and Human Rights*<sup>39</sup> (henceforth; ‘*UDHGHR*’) also bans ‘practices contrary to human dignity’,<sup>40</sup> of which germline editing is considered an example.<sup>41</sup>

Since Article 13 was implemented more than a decade ago, three other provisions in the Oviedo Convention could support a fresh evaluation of the suitability of the ban. Article 15 upholds a non-absolute right to freedom in biomedical research. It acknowledges a need to balance humanity’s right to knowledge and the development of new therapies on one hand, with the protection of the dignity of the human being on the other.<sup>42</sup> The justifications for scientific progress, as recognised in Article 15, imply that one could credibly question the germline editing bans on those grounds.

Additionally, Article 28 recommends public consultation in matters of new biotechnologies and Article 32 suggests that the Oviedo Convention may be amended following a review of scientific developments. Taken together, the three articles provide scope for the Oviedo Convention’s germline editing ban to be formally challenged. However, before delving into arguments against the ban, this paper must first determine the relevance of the Oviedo Convention to the UK and the extent to which the Article 13 ban may be invoked against it.

### **(C) Domestic and European Court of Human Rights (ECtHR) Enforceability of the Bans**

The UK is not a signatory to the Oviedo Convention and is not technically bound by its provisions. Similarly, the *UDHGHR* does not bind the UK, because it is merely a declaration. Nevertheless, both the Oviedo Convention and the *UDHGHR* may be used as interpretive tools for the scope of ECHR rights (which the UK is bound to respect), in the context of ECHR challenges.<sup>43</sup> If an ECHR challenge concerning germline editing were to be brought against the UK, compliance with the bans could then be made part of the UK’s ECHR obligations. This paper shall analyse how the domestic courts and the ECtHR might interpret Articles 2 and 8 of the ECHR (the most relevant rights to germline therapy) in a way that conforms to the germline editing bans.

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<sup>37</sup> *ibid.* [89]

<sup>38</sup> Isasi et al. (n11) 339

<sup>39</sup> UNESCO ‘Universal Declaration on the Human Genome and Human Rights’ (11 November 1997)

<sup>40</sup> *ibid.* Article 11

<sup>41</sup> *ibid.* Article 24

<sup>42</sup> Explanatory Report to the Oviedo Convention (n37) [95-96]

<sup>43</sup> Francesco Seatzu, ‘The Experience of the European Court of Human Rights with the European Convention on Human Rights and Biomedicine’ (2015) 31 *UJIEL* 5, 14



## (1) Domestic Enforcement

The Human Rights Act 1998 (“HRA 1998”) incorporates several ECHR fundamental rights into UK law,<sup>44</sup> so they can be enforced domestically. Section 2 of the Act requires the judiciary to take ECHR jurisprudence into account when determining questions concerning ECHR rights. Notably, the bans in Article 13 of the Oviedo Convention and the *UDHGHR* have not been previously invoked in an ECHR case. As such, the domestic courts might be unwilling to defer to these non-binding bans in construing ECHR rights, without a clear authority on the matter. Nevertheless, if the UK’s actions concerning germline editing were to be challenged in Strasbourg, the ECtHR would be likely to subsume the bans into the scope of ECHR rights, so the UK would be well-advised to heed these bans as a pre-emptory measure to secure its compliance with ECHR law.

## (2) ECtHR Enforcement

The ECtHR is likely to incorporate the international germline editing bans into a concept known as a member state’s “margin of appreciation”, so that breaches of ECHR Articles 2 or 8 are found whenever those bans have been violated.<sup>45</sup> This would work as follows:

- (i) The ECHR imposes minimum standards of human rights compliance upon the Council of Europe’s member states.
- (ii) Beyond that, states are granted a “margin of appreciation” to interpret and implement ECHR rights in their domestic legislation. The scope of this margin depends on whether there is a European consensus on the matter in question and the nature of the right asserted.<sup>46</sup>
- (iii) If there is a European consensus on the permissibility of a certain action, it will embody the standard for compliance with the ECHR, leading to the margin of appreciation for the matter being narrowed accordingly.<sup>47</sup> Since several member states are signatories to the Oviedo Convention and the *UDHGHR*, this could be evidential of a consensus as to the impermissibility of germline editing.

Article 2 of the ECHR is an absolute right, meaning that there is no scope for exceptions when member states interfere with it. Hence, if an Article 2 challenge were to be brought against the UK for legalising germline editing, the ECtHR could establish that the UK has no margin of

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<sup>44</sup> HRA 1998, s 1(1) and Sched. 1

<sup>45</sup> Douwe Korff, ‘A Guide to the Implementation of Article 2 of the European Convention on Human Rights’ (2006) Council of Europe Human Rights Handbooks No 8, 5

<sup>46</sup> *ibid.*

<sup>47</sup> Ursula Kilkelly, ‘A Guide to the Implementation of Article 8 of the European Convention on Human Rights’ (2003) Council of Europe Human Rights Handbooks No 1, 7

appreciation in the matter. Instead, legalising germline editing, in violation of Article 13 of the Oviedo Convention, would be deemed an automatic breach of the right to life.

Contrastingly, in actions for breach of Article 8, a qualified right, the margin of appreciation concept would apply to the two steps for determining a breach. Firstly, the court considers whether an alleged interference with the right (or a failure to take positive steps to secure the right) follows a legitimate aim on the public interest grounds in Article 8(2).<sup>48</sup> Secondly, the ECtHR considers if the alleged interference (or omission) is proportionate to what is ‘necessary in a democratic society’.<sup>49</sup> The Oviedo Convention could determine the UK’s margin of appreciation in these circumstances,<sup>50</sup> with three cases illustrating how this has been done in practice: *Evans v UK*<sup>51</sup>, *Glass v UK*<sup>52</sup> and *MAK and RK v UK*.<sup>53</sup>

*Evans*<sup>54</sup> was an appeal to the Grand Chamber by a woman who had harvested her eggs, so that she could still have children after an oophorectomy. She and her partner agreed to store the eggs fertilised with his sperm. Unfortunately, the relationship broke down and he withdrew his consent to the use of his sperm in forming a child. Evans challenged the UK’s consent requirements under Articles 2, 8 and 14 (discrimination; in conjunction with Article 8) of the ECHR.

The Grand Chamber dismissed the Article 2 claim, and ultimately decided that the UK’s legislation on consent did not breach Article 8. By allowing free withdrawals of consent to implantation at any time, the law struck a proportionate balance between the parties and respected human dignity and free will.<sup>55</sup> Significantly, Article 5 of the Oviedo Convention; which states that a person “*may freely withdraw consent [to a medical intervention] at any time*”, was cited as relevant international law and the UK’s law on consent was compliant. Thus, one could infer that the ECtHR used the Oviedo Convention to determine the standard for compliance with Article 8.<sup>56</sup>

The latter two cases confirm that the ECtHR does rely upon the Oviedo Convention as an interpretive tool for Article 8. In *Glass*,<sup>57</sup> a mother of a disabled son, David, claimed that the UK’s law of consent to medical treatment and the actions of David’s doctors breached her and David’s Article 8 rights to respect for family life. The ECtHR decided that the essence of the claim was against the doctors, for wrongly deeming the situation to be an emergency, which overrode the

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<sup>48</sup> *ibid.* 7

<sup>49</sup> Robert Spano, ‘Universality or Diversity of Human Rights? Strasbourg in the Age of Subsidiarity’ [2014] HRLR 1, 12

<sup>50</sup> Korff (n45) 5

<sup>51</sup> *Evans v UK* (2008) 46 EHRR 34

<sup>52</sup> *Glass v UK* (2004) 39 EHRR 15

<sup>53</sup> *MAK and RK v UK* (2010) 51 EHRR 14

<sup>54</sup> *Evans v UK* (2008) 46 EHRR 34

<sup>55</sup> *ibid.* [88] – [89]

<sup>56</sup> *Seatzu* (n43) 11

<sup>57</sup> *Glass v UK* (2004) 39 EHRR 15

need for the mother's consent.<sup>58</sup> However, the Court stated *obiter* that it did not consider the UK's regulatory framework on parental consent to treatment in emergency situations inconsistent with Chapter II of the Oviedo Convention on consent.<sup>59</sup> In *MAK and RK*, the ECtHR made similar comments, but once again as *dictum*.<sup>60</sup> Although the Oviedo Convention was not substantively invoked, the ECtHR displayed a willingness to use it as a yardstick for determining legitimate aims of domestic legislation under Article 8(2) of the ECHR.

These three cases suggest that the ECtHR may rely on the Oviedo Convention, in Article 8 challenges, to determine the margin of appreciation for what counts as a legitimate aim or a proportionate interference with Article 8. Thus, the ECtHR seems likely to find that a violation of Article 13 of the Oviedo Convention would also breach Article 8.

In summary, the ECtHR may presently enforce germline editing bans strictly against the UK, through challenges based on Articles 2 and 8 of the ECHR. Therefore, it can be argued that compliance with the bans would indirectly form part of the UK's ECHR obligations. However, if the validity of the bans could be normatively challenged, they need not have the last word on the permissibility of legalising germline therapy, under ECHR law.

#### **(D) Evaluation of the Germline Editing Bans**

The crux of the international bans, which allows the ECtHR to invoke them against the UK, is that they appear to represent a European consensus against germline editing. However, both the Oviedo Convention and *UDHGHR* came into force in the late 1990s, and they could be undermined should they be found not to represent contemporary European attitudes. On the other hand, underlying ethical concerns with the significance of the human genome and the identity of edited individuals may favour their retention and strict application.

##### (1) European Consensus

The bans came into force when germline editing technologies were still a matter of speculation.<sup>61</sup> Since then, the reproductive technologies of PGD and mitochondrial donation have been developed and accepted, confirming the trend of public attitudes towards such new technologies: horrified negation, followed by gradual study and steady acceptance.<sup>62</sup> The advent of CRISPR/Cas-9 and the recent proliferation of germline editing research suggests that the shift towards its acceptance is taking place, and Articles 28 and 32 of the Oviedo Convention and Article 24 *UDHGHR* would support a fresh review of the technology's evolution and public attitudes

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<sup>58</sup> *ibid.* [76]

<sup>59</sup> *ibid.* [58] & [75]

<sup>60</sup> *MAK and RK v UK* (2010) 51 EHRR 14, [77]

<sup>61</sup> IBC Report (n9) [34]

<sup>62</sup> Wyatt (n2) 129

towards it.<sup>63</sup> Unfortunately, such a survey has yet to be undertaken. Instead, most European countries still ban germline editing,<sup>64</sup> and in October 2015, the International Bioethics Committee affirmed the need for a moratorium.<sup>65</sup> However, the change in terminology to ‘*moratorium*’ indicates that the UN ban shall not last if germline editing were to prove safe for use in treatment.<sup>66</sup>

Given the rapid refinement of CRISPR/Cas-9 for use upon human embryos,<sup>67</sup> it is submitted that germline therapy might be more widely-accepted in Europe, in the near future. Europe’s current aversion to germline editing can be attributed in part to the Nazi connotations associated with trait selections.<sup>68</sup> However, like PGD, germline therapy would be a matter of personal choice, making it sufficiently distinct from state-enforced eugenic programmes to be viewed positively as an aspect of reproductive autonomy.<sup>69</sup>

Furthermore, Tetsuya Ishii has noted that countries currently permitting PGD have a strong incentive to legalise embryonic germline editing as a means to treat genetic diseases where PGD is inapplicable.<sup>70</sup> He identifies 16 Council of Europe member states that fit this description, including the UK and Germany. Whilst this remains a small proportion of Europe, some have argued that most of the European national laws that ban germline editing are ambiguously drafted and may be circumvented.<sup>71</sup> Ultimately, proof that CRISPR/Cas-9 can be safely used in treatment is likely to be decisive: triggering a change in global attitudes, following the potential lifting of the *UDHGHR* ban. Whilst this will not lead to universal acceptance of germline editing, the resulting lack of a European consensus, against the background of fast-moving scientific developments,<sup>72</sup> would undermine the enforceability of the Oviedo Convention ban. As such, the ECtHR may abandon Article 13 and grant the UK a wider margin of appreciation to legalise germline editing in the future.

## (2) Addressing Eugenic Concerns

The main motivation behind the Article 13 ban was fear of the “*intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities.*”<sup>73</sup> A concern with genetic improvement (or eugenics) similarly belies the *UDHGHR* ban<sup>74</sup>, as well as the human genome’s centrality to our common

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<sup>63</sup> IBC Report (n9) 5 [3]

<sup>64</sup> Ishii, ‘Germline Genome-Editing Research and its Socioethical Implications’ (n24) 478

<sup>65</sup> IBC Report (n9) [118]

<sup>66</sup> *ibid.* 3

<sup>67</sup> Krause (n1)

<sup>68</sup> Sonia M Suter, ‘A Brave New World of Designer Babies’ (2007) 22 BTLJ 897, 915

<sup>69</sup> *ibid.* 937

<sup>70</sup> Ishii, ‘Germline Genome-Editing Research and its Socioethical Implications’ (n24) 479

<sup>71</sup> Isasi et al. (n11) 338-339

<sup>72</sup> *SH and Others v Austria* App no 57813/00 (GC, 3 November 2011), [97]

<sup>73</sup> Explanatory Report to the Oviedo Convention (n37) [89]

<sup>74</sup> IBC Report (n9) [107]

humanity, i.e.: it represents human equality and freedom and should not be manipulated lightly.<sup>75</sup> These rationales prompt questions of whether the human genome is indeed sacrosanct, or whether exceptions should be made based on the distinction between germline editing's use for treatment, enhancement and discrimination (which the anti-eugenic rationale has glossed).

The sanctity of the human genome has been expressed in both creationist and evolutionary terms. The Judeo-Christian perspective sees a child as a unique gift from God, so genetically altering a child might disrespect God's will and would contradict the tenet of unconditional parental love towards the child, as created by God.<sup>76</sup> The principles of humility and respect for fellow humans, which underpin most faiths, could lead other religions to reject genetic alterations too.<sup>77</sup> However, compassion for humanity also makes the religious perspective sympathetic towards treatment (which may be seen as a God-given discovery), leading to an unresolved tension rather than a clear stance against germline editing.<sup>78</sup> Contrastingly, evolutionists view the genome as a product of nature. No consensus is found amongst them either: some strongly oppose interfering with the evolutionary process to potentially create a new species of human,<sup>79</sup> whilst others see germline editing as an extension of natural selection.<sup>80</sup>

Importantly, all of the above worldviews reject the fallacy of genetic determinism, which holds that humans are the mere product of their genes. In other words, personhood is seen instead as a multifaceted product of one's genetic, social, environmental and spiritual aspects.<sup>81</sup> Furthermore, feminists such as Mary Briody Mahowald argue that one's relationships are crucial to developing and *maintaining* individual personhood, more so than genes.<sup>82</sup> Hence, minimal germline edits may not go so far as to open a gulf of inequality between edited and unedited individuals, since there would be sufficient commonalities between these persons when viewed as a whole. Additionally, germline therapy; a matter of personal choice rather than population-wide enforcement, is unlikely to create a new *race* of edited beings.<sup>83</sup> This critically undermines the rationale behind the germline-editing bans and the evolutionists' concerns with preserving our sense of common "humanness" as a species. Nevertheless, the "Ship of Theseus" thought experiment serves as a warning to restrict germline editing's applications. According to this thought experiment, replacing all the planks of a ship may result in a different vessel, rather than an altered original.<sup>84</sup> Thus, it is submitted that genome editing should only be legalised for therapeutic use. This would be

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<sup>75</sup> *ibid*, 29 [128]

<sup>76</sup> Robertson (n19) 442

<sup>77</sup> George J Annas et al., 'Protecting the Endangered Human: Toward an International Treaty prohibiting Cloning and Inheritable Alterations' (2002) 28 *Am J Law Med* 151, 161

<sup>78</sup> Chapman and Frankel (n6) 10

<sup>79</sup> Annas et al. (n77) 153

<sup>80</sup> Robertson (n19) 451

<sup>81</sup> Wyatt (n2) 131; Frankel (n25) 33

<sup>82</sup> Mary Briody Mahowald, *Genes, Women Equality* (OUP 2000), 234

<sup>83</sup> Suter (n68) 937

<sup>84</sup> Andre Gallois, 'Identity Over Time' (*Stanford Encyclopaedia of Philosophy*, 17 March 2011) <<http://plato.stanford.edu/entries/identity-time/#4.1>> accessed 1 March 2016

acceptable to the groups surveyed above, and may be distinguished from two practices which can truly be characterised as eugenic,<sup>85</sup> i.e.: germline editing for discrimination or enhancement.

In order to distinguish between medical necessity and the broader notion of human flourishing, this paper defines therapy as relief from physical suffering (e.g. treating fatal genetic diseases to save the lives of sufferers), rather than the restoration of “good health” or the “absence of disease”. This is because the latter two notions encompass freedom from societal prejudice,<sup>86</sup> bringing too many physical conditions within germline treatment’s ambit. Dangerously, this could allow perfectionistic, societal notions of “good health” to drive germline treatment towards eliminating conditions whose disadvantages (such as minimal pain or societal prejudice) are outstripped by their positive significance to the identities of those who have them.<sup>87</sup> For example, the deaf and dwarf communities have asserted that they are minorities rather than disabled groups,<sup>88</sup> therefore, the genetic causes of their conditions ought to be *protected* as genetic “differences.”<sup>89</sup> This links to a principle illuminated by the Judeo-Christian objection to germline editing. That DNA represents the uniqueness of individuals (with the exception of identical twins), so germline editing should not be abused to achieve genetic homogeneity. In fact, this notion is cemented by Article 11 of the Oviedo Convention and Article 6 of the *UDHGHR*, which prohibit discrimination against individuals on the grounds of their genetic heritage. Thus, it is submitted that such conditions ought not to count as editable diseases. In addition, this paper suggests that germline editing is an extreme medical intervention (due to its cost and its impact on the human genome), so it may be too disproportionate a measure to be used for less-severe genetic disorders, whose symptoms could instead be treated post-birth by non-invasive means. For example, sickle-cell anaemia, which is non-fatal and whose symptoms can be managed by medication.

Germline editing should also not extend to enhancement, i.e. endowing humans with functions that go beyond what is necessary for good health,<sup>90</sup> because there are no conceptual limits to it. Genetic edits may range from increasing the intelligence of children to improving their physicality.<sup>91</sup> Since enhancements are not therapeutic, they would not be NHS subsidised and would open a genetic and socio-economic gulf between the few who could afford genetic enhancements and those who cannot.<sup>92</sup> This would substantiate the *UDHGHR* ban’s concern with inequality,<sup>93</sup> by eugenically improving a segment of the population. Making enhancements available to parents also reinforces the fallacy of genetic determinism, by emphasising the value of improved genes for the betterment

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<sup>85</sup> Suter (n68) 933

<sup>86</sup> Sara Goering, ‘Gene Therapies and the Pursuit of a Better Human’ (2000) 9 *CQHE* 330, 334

<sup>87</sup> Suter (n68) 936

<sup>88</sup> Goering (n86) 333

<sup>89</sup> *ibid.*, 338

<sup>90</sup> Eric T Juengst, “What Does Enhancement Mean,” in Erik Parens (ed), *Enhancing Human Traits: Ethical and Social Implications* (GUP 1998), 9

<sup>91</sup> Walters and Palmer (n21) 107

<sup>92</sup> IBC Report (n9) 4

<sup>93</sup> *ibid.* [107]

of children, while devaluing nurture. Furthermore, parents who seek enhancements may risk loving their children conditionally upon the expression of the intended traits, undermining the love which ought to be at the core of parent-child relationships.<sup>94</sup> The eugenic nature of germline enhancements and their negative implications upon families justify upholding the ban against germline editing for human enhancement.

The bans on germline editing rightly exhort against manipulating the human genome lightly,<sup>95</sup> since the preservation of our common humanness and genetic diversity are important goals. However, the bans were mainly instituted to prohibit eugenic practices, so their preclusion of germline therapy for physical suffering, which does not raise these concerns, is unjustifiable. Hence, the European Council should seriously consider amending the scope of the Oviedo Convention ban,<sup>96</sup> to only prohibit the eugenic dangers of discrimination and enhancement. Even if this does not occur, the arguments in favour of germline therapy and the loss of a European consensus on germline editing, would undermine the ECtHR's ability to enforce the bans against the UK in the near future. Consequently, the ECtHR's stance on germline editing would no longer be set in stone by the bans, and the notion that germline therapy should be permitted may well take root.

In other words, this paper hypothesises that the UK may legalise germline therapy and yet comply with ECHR law in the near future. Since specific ECHR Articles would no longer have to be interpreted to give effect to broad-brush germline editing bans, the UK's ECHR obligations in this matter are likely to become more nuanced. As such, this paper shall proceed to discuss the specific duties from Articles 2 and 8 ECHR, which the UK would have to discharge in legalising germline therapy.

### **(E) ECHR Rights: For and Against Germline Editing**

Articles 2 (right to life) and 8 (private and family life) are the most relevant ECHR rights to germline editing. Compliance with Article 2 may preclude the legalisation of germline therapy, since it has potentially fatal, congenital side-effects. Literature has also postulated that treating an unborn child violates its Article 8 right to consent to treatment,<sup>97</sup> but a discussion of this is beyond the scope of this paper. Contrastingly, if germline therapy were to become viable, the UK might have a duty to legalise it in order to promote the Article 8 rights of parents who seek the therapy; namely their rights to procreative liberty.<sup>98</sup>

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<sup>94</sup> Roy Gilbar, 'Between unconditional acceptance and responsibility: should family ethics limit the scope of reproductive autonomy?' [2009] CFLQ 309, 311

<sup>95</sup> IBC Report (n9) [128]

<sup>96</sup> As provided for by Article 32 of the Oviedo Convention.

<sup>97</sup> IBC Report (n9) [16]

<sup>98</sup> Robertson (n19) 447

## (1) Article 2 Obligations

In *LCB v UK*<sup>99</sup> (henceforth *LCB*), the ECtHR accepted that states have a duty to safeguard the lives of individuals from foreseeable, pre-conceptual harms under Article 2(1). The applicant in *LCB* suffered from leukaemia, which she alleged was caused by her father's exposure to radiation in nuclear tests carried out on Christmas Island, prior to her conception. Since the tests had been carried out at the behest of the UK government, she claimed that the State's failure to monitor her father's radiation dose levels and its failure to warn her parents of the health risk for their future children,<sup>100</sup> breached her Article 2(1) rights.<sup>101</sup> Eventually, her claim failed because she was unable to prove that her father's radiation caused her cancer.<sup>102</sup>

CRISPR/Cas-9 can also cause pre-conception injuries through "off-targets",<sup>103</sup> by inducing potentially-fatal genetic disorders in edited embryos. If the UK were to legalise germline therapy, and this risk were to eventuate, then affected individuals might similarly claim that this action breaches Article 2(1). Unlike *LCB*, such individuals could easily prove that faulty germline editing threatened their lives, since the risk of "off-targets" inheres in the treatment and is not caused by negligent use. They could simply show that they suffer from a genetic disease other than the one which CRISPR/Cas-9 was intended to treat. However, they would have difficulty proving that the mere legalisation of germline therapy breaches Article 2(1). This is because Article 2(1) probably does not impose the (impossible) duty of guaranteeing that medical treatments are risk-free, upon member states. Yet, one could infer that Article 2(1) requires the UK to ensure that the risk of harm to future lives, from germline therapy, is reasonably minimal, before legalising it. Additionally, Article 5 of the *UDHGHR* reinforces the need for rigorous assessments of the risks associated with gene therapy.

The UK's Article 2(1) duty can be read in line with the Warnock Report (which formed the basis of the HFE Act 1990). The report suggested that whilst early-stage embryos are not ends in themselves,<sup>104</sup> 'respect' is still owed to them under English law, in light of their potential, future personhood.<sup>105</sup> Thus, embryos' lives need not be protected to the same degree as a fully-realised person, but they should only be harmed in causes that achieve a net benefit.<sup>106</sup> Given this utilitarian framework, Cynthia Cohen's suggestion for what should constitute an acceptable level of risk is apt. Where the risk of harm from germline interventions is no greater than the risk of being born

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<sup>99</sup> *LCB v UK* (1999) 27 EHRR 212

<sup>100</sup> *ibid.* [24]

<sup>101</sup> *ibid.* [36]

<sup>102</sup> *LCB v UK* (1999) 27 EHRR 212, [39]

<sup>103</sup> Ishii, 'Germline Genome-Editing Research and its Socioethical Implications' (n24) 474

<sup>104</sup> Immanuel Kant, *Groundwork of the Metaphysic of Morals* (first published 1785, Jonathan Bennett tr, *Early Modern Texts*, September 2008) <<http://www.earlymoderntexts.com/assets/pdfs/kant1785.pdf>> accessed 5 October 2014, 28

<sup>105</sup> Emily Jackson, *Medical Law: Text, Cases, and Materials* (3<sup>rd</sup> edn, OUP Press 2013), 637

<sup>106</sup> John A Robertson, 'Human embryonic stem cell research: ethical and legal issues' (2001) 2 *Nature Reviews Genetics* 74, 75



with the genetic diseases to be treated,<sup>107</sup> germline therapy could be legalised without being seen as breaching Article 2(1). In summary, Article 2 requires the UK to heed the level of risk associated with germline therapy before legalising it, but does not otherwise preclude the legalisation of the technology.

## (2) Article 8 Obligations

Thus far, this paper has presumed that the UK would be willing to legalise germline editing, and has focused on the limits ECHR rights might place upon this action. This paper shall now explore whether Article 8 (interpreted without reference to the Oviedo Convention ban) might *require* the UK to legalise germline therapy once it becomes viable.

In *Costa and Pavan v Italy*<sup>108</sup> (henceforth “*Pavan*”) the ECtHR recognised that a couple’s choice of reproductive technology, for the sake of conceiving a child unaffected by genetic disease, is an expression of their private and family life.<sup>109</sup> On the basis of this case, Article 8 could impose a positive duty on the UK to legalise germline therapy, which achieves such a purpose. However, Article 8 is a qualified right and the judgement was fact-specific, so attention must be paid to the nuances of the Court’s reasoning in *Pavan* in order to confirm whether Article 8 would support germline therapy’s legalisation.

Ms Costa and Mr Pavan, who were healthy carriers of cystic fibrosis, sought PGD in order to select and conceive an embryo unaffected by the disease. However, Italian law had banned PGD and they successfully claimed that this interfered with their Article 8 rights. In establishing the breach, the ECtHR accepted that the Italian government’s reasons for banning PGD were “in accordance with law” and pursuant to legitimate aims (as stated in Article 8(2)),<sup>110</sup> but decided that the ban disproportionately interfered with the claimants’ rights, on three grounds.<sup>111</sup> Firstly, Italian law permitted the use of postnatal diagnosis (PND) to identify affected fetuses for abortion. Since PND had the same purpose as PGD (preventing the births of diseased babies), it was inconsistent for the Italian government to ban one but not the other.<sup>112</sup> Secondly, the ECtHR was persuaded of the legitimacy of PGD, because there was a European consensus in favour of the technology. Thirdly, the ECtHR found that PGD had comparative benefits over PND (it is less invasive than

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<sup>107</sup> Cynthia Cohen, ‘Designing Tomorrow’s Children: The Right to reproduce and Oversight of Germline Interventions’ in Audrey R Chapman and Mark S. Frankel (eds), *Designing our Descendants: The Promises and Perils of Genetic Modifications* (JHUP 2003), 304

<sup>108</sup> App no 54270/2010 (ECtHR, 22 August 2012)

<sup>109</sup> *ibid.* [57]

<sup>110</sup> *ibid.* [59]

<sup>111</sup> Adriana Di Stefano, ‘Bio-ethics under Human Rights Scrutiny: Toward a Right to Pre-implantation Genetic Testing under the ECHR?’ (*Strasbourg Observers*, 20 September 2012) <<http://strasbourgobservers.com/2012/09/20/bio-ethics-under-human-rights-scrutiny-toward-a-right-to-pre-implantation-genetic-testing-under-the-echr/>> accessed 30 March 2016

<sup>112</sup> Application no. 54270/2010, [71]

PND and causes less suffering to parents, particularly the mother),<sup>113</sup> so banning it clearly breached the couple's Article 8 rights.

The ECtHR's judgement in *Pavan* hints at the arguments one might use to construct a case in favour of legalising germline therapy. If germline therapy is shown to be analogous with the UK's permitted reproductive techniques (e.g.: mitochondrial donation and PGD), and if it has comparative benefits for couples who wish to conceive healthy children via these technologies, then Article 8 would require the UK to legalise it. Notably, the point in *Pavan* about a consensus in favour of a banned technology would not apply to germline editing in the future, as hypothesised by this paper.

Like germline therapy, mitochondrial donation alters the germline of individuals and treats diseases caused by gene mutation, albeit within the mitochondria and via methods which do not edit individual strands of DNA.<sup>114</sup> Yet, nuclear germline editing can treat more diseases and has greater potential to alter human characteristics,<sup>115</sup> so it would not be inconsistent to legalise one but not the other.

Germline therapy and PGD both prevent the transmission of a similar range of genetic disorders to future generations. However, these two technologies are not analogous to the same degree as PGD and PND were in *Pavan*.<sup>116</sup> The crucial difference between PGD and germline therapy is that the former screens out affected embryos, whilst the latter edits them and has the power to impact many future generations.<sup>117</sup> As such, the argument of inconsistency might not apply and Article 8 may not entail a duty to legalise germline therapy.

Alternatively, one may construe mitochondrial donation and PGD jointly, i.e.: it would be inconsistent for the UK to permit a scientifically-recognised form of germline editing,<sup>118</sup> and a screening technique for the very diseases that germline therapy can *treat*, and yet fail to legalise germline editing. This is especially because germline therapy achieves the same purpose as the permitted technologies: enabling couples to conceive healthy babies. Furthermore, this argument can be cemented by the comparative advantages which germline therapy has over PGD. Firstly, the live birth rate for PGD is a mere 31.6% per cycle,<sup>119</sup> and couples who opt for it usually experience emotional and physical pain before doing so. They are likely to have experienced

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<sup>113</sup> Application no. 54270/2010, [62]

<sup>114</sup> Human Fertilisation and Embryology Authority, *Mitochondrial donation: an introductory briefing note* (October 2014) (n8) 3

<sup>115</sup> Ishii, 'Potential Impact of Human Mitochondrial Replacement on Global Policy Regarding Germline Gene Modification' (n34) 154

<sup>116</sup> PND and PGD are both screening techniques which simply operate at different stages of a pre-natal "child's" development.

<sup>117</sup> Suter (n68) 934

<sup>118</sup> Frankel (n25) 33

<sup>119</sup> Jackson (n105) 810

several failed rounds of treatment, or witnessed the suffering of an affected first child (who alerted them to their carrier status).<sup>120</sup> Contrastingly, germline editing can treat whole batches of embryos, making them all suitable for implantation and increasing couples' chances of birthing a healthy child, thus reducing their suffering. Secondly, germline therapy better accords with the medical principle of non-maleficence by not discarding affected embryos,<sup>121</sup> and would thus cater to couples who believe that life starts at conception.<sup>122</sup> Thirdly, germline editing is the only effective method for parents, who share the same genetic mutation, to conceive a healthy child using their own gametes.<sup>123</sup> Given the advantages that germline therapy has over PGD, and the possible inconsistency of precluding it whilst permitting mitochondrial donation and PGD, Article 8 may require the UK to legalise germline therapy to promote the procreative liberty of couples.<sup>124</sup>

Pertinently, this broad right in favour of legalising germline therapy ought to be qualified, because the treatment of certain genetic conditions, such as muscular dystrophy and certain non-fatal genetic disabilities, may cross the line into the eugenic dangers of enhancement or discrimination. Hence, precluding germline therapy for these 'grey area' cases ought to count as exceptions necessary in a democratic society, under Article 8(2) ECHR. If parliament were to legalise germline therapy, it ought to be highly discerning in deciding which conditions should be editable by CRISPR/Cas-9.

### (3) Article 8(2) Exceptions

The HFEA permits the use of PGD for certain disabilities that attract social prejudice but cause minimal pain, e.g.: achondroplasia and Leber congenital amaurosis, causes of dwarfism and blindness, respectively.<sup>125</sup> Unfortunately, treating these conditions with germline therapy would amount to discrimination against the communities who embrace these conditions as part of their identities,<sup>126</sup> since germline editing could remove their share of genetic diversity across generations.<sup>127</sup> Thus, the mere availability of PGD for conditions like genetically-caused deafness, blindness and dwarfism, should not justify germline therapy for the same. Instead, germline therapy for these conditions should be disallowed under Article 8(2), since preventing eugenic discrimination would be necessary to protect "*the rights and freedoms*" of these minority groups.<sup>128</sup>

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<sup>120</sup> Sarah Franklin and Celia Roberts, *Born and Made: An Ethnography of Preimplantation Genetic Diagnosis* (PUP 2006), 108

<sup>121</sup> Walters and Palmer (n21) 82

<sup>122</sup> Suter (n68) 931

<sup>123</sup> Chapman and Frankel (n6) 4

<sup>124</sup> Robertson, 'Procreative Liberty in the Era of Genomics' (n19) 447

<sup>125</sup> 'PGD conditions licensed by the HFEA' (*HFEA Guide*, 19 March 2016) <<http://guide.hfea.gov.uk/pgd/>> accessed 19 March 2016

<sup>126</sup> Goering (n86) 333

<sup>127</sup> Suter (n68) 934. Also, this would contravene Article 11 of the Oviedo Convention and Article 6 *UDHGHR*.

<sup>128</sup> Goering (n86) 333

This preclusion might be objected to on the grounds of redundancy, i.e.: PGD can already be used to discriminate against these groups, by preventing the births of children with their conditions, generation-by-generation. Whilst that might be true, it is submitted that germline therapy can more drastically remove these conditions across several generations in a single blow, denying future generations the right to decide whether to embrace a child with such a disability. Thus, ECHR rights should preclude germline therapy for these ‘grey-area’ conditions.

Duchenne muscular dystrophy is another problem for the boundaries of germline editing. It is a fatal disease, so treating it with germline therapy would benefit sufferers and not be discriminatory. However, the disease is characterised by the progressive wasting away of muscles, so the genetic edits used to treat it may also be used to enhance muscles generally.<sup>129</sup> This could be used to create children with athletic strength and endurance, amounting to an impermissible eugenic enhancement. Therefore, germline muscle-treatments for purposes other than curing muscular dystrophy should be caught out by Article 8(2), since this fetter on procreative liberty would be “*necessary in a democratic society*”.

In most cases, Article 8 would entitle couples to germline therapy in the UK, due to the comparative benefits of germline therapy over PGD in enabling them to conceive healthy children. However, Article 8(2) should preclude germline therapy for disabling conditions, which have more to do with societal prejudice than physical pain, because editing away these conditions would be discriminatory. Additionally, the use of germline therapies to eugenically enhance healthy embryos should also be prohibited under Article 8(2).

## **Conclusion**

This paper has sought to determine whether the UK’s obligations under the ECHR would prohibit or support its legalisation of germline therapy, both in the present and when it is proven viable. In anticipation of germline therapy’s legalisation, this paper has also proposed the scope of permissibility, which ECHR and domestic law ought to establish in relation to this therapy.

Presently, the bans against germline editing, found in Article 13 of the Oviedo Convention and Articles 11 and 24 *UDHGHR* appear to uphold a European consensus on the matter. Thus, the ECtHR may be expected to enforce the bans strictly, in the context of ECHR challenges against the UK, to preclude the legalisation of germline therapy under ECHR law. However, when germline therapy becomes viable, such a consensus is likely to be lost by public opinion shifting in its favour. Additionally, the ECtHR would not be justified in upholding a ban against germline therapy for the relief of physical suffering, since this does not raise eugenic concerns, unlike germline editing for discrimination and enhancement. These factors suggest that the current

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<sup>129</sup> Frankel (n25) 33

germline editing bans may not form part of the UK's future ECHR obligations, so the UK would be permitted to legalise germline therapy.

In that future time, the UK would still have to discharge specific duties from Articles 2 and 8 of the ECHR in legalising germline therapy. Article 2 requires the UK to heed the level of risk associated with germline therapy before legalising it, but does not preclude the therapy's legalisation. In fact, legalising germline therapy would promote Article 8 rights to reproductive autonomy, by granting couples a better option to prevent the transmission of genetic disorders to future generations, compared to PGD or mitochondrial donation. Insofar as germline editing is used to treat fatal diseases and relieve physical suffering, this positive statement in favour of germline therapy is to be welcomed. However, germline treatments for certain conditions, such as genetically-caused blindness or muscular dystrophy, may amount to eugenic discrimination or enhancement. Both the UK and the ECtHR should rigorously identify such 'grey-area' cases and preclude them under Article 8(2). In order to ensure that this distinction is made once the future becomes a reality, this paper recommends that the Council of Europe revises its current stance on germline editing by amending the Article 13 ban pursuant to Article 32 of the Oviedo Convention. This would permit germline therapy for physical suffering, but forbid eugenic germline enhancements (of healthy individuals), discriminations and grey-area practices under ECHR law.