



Rewriting the human genome, rewriting human rights law? Human rights, human dignity, and human germline modification in the CRISPR era

Britta C. van Beers *

Department of Legal Theory, Faculty of Law, VU University Amsterdam, De Boelelaan 1105, Amsterdam 1081 HV, The Netherlands

Corresponding author: E-mail: b.c.van.beers@vu.nl

ABSTRACT

In most legal orders, human germline modification is either prohibited or severely restricted. A recurring thought in these legal frameworks is that heritable genome editing would result in practices that are at odds with principles of human rights, such as dignity, justice, and equality. However, now that CRISPR is bringing heritable genome editing within human reach, the question has risen as to whether these human rights bans still make sense. The call is growing louder to lift the ban on heritable genome editing for therapeutic purposes as soon as the technology is safe for introduction in the clinic. This article critically examines these recent proposals from a human rights perspective. First, it examines the question as to how realistic the proposed distinction between the therapeutic and the nontherapeutic uses of human germline modification is in the CRISPR era. Second, it

* **Britta van Beers** is professor of Biolaw and Bioethics at VU University Amsterdam, Faculty of Law, Department of Legal Theory. Britta van Beers teaches and writes about the legal–philosophical aspects of the governance of biomedical technologies. She is particularly intrigued by the legal and philosophical questions raised by assisted reproductive technologies, such as wrongful birth and wrongful life claims, selective reproduction, and reproductive tourism. In more recent work, she has focused on issues related to personalized medicine and human gene editing. She has actively contributed to public debates on new technologies by writing essays and op-eds, and speaking as an expert for the Dutch Senate and House of Representatives. Her publications include the volumes *Personalised Medicine, Individual Choice and the Common Good* (co-edited with Sigrid Sterckx and Donna Dickenson, Cambridge University Press 2018), *Symbolic Legislation and Developments in Biolaw* (co-edited with Bart van Klink and Lonneke Poort, Springer 2016), and *Humanity across International Law and Biolaw* (co-edited with Wouter Werner and Luigi Corrias, Cambridge University Press 2014).

argues that these proposals rely on a one-dimensional understanding of the meaning of human rights for this issue. Finally, it suggests that this one-dimensional understanding paves the way for a regime of self-regulation by the scientific community that leaves little room for public debate on the question as to whether or how human germline modification fits in the long-term aspirations of society.

KEYWORDS: assisted reproductive technologies, CRISPR, human dignity, human germline gene editing, human nuclear genome transfer, human rights

I. INTRODUCTION

In November 2018, biophysicist, He Jiankui, announced on *YouTube*¹ that two genetically modified babies, ‘beautiful little Chinese girls named Lulu and Nana,’ had come ‘crying into the world as healthy as any other babies.’² The Chinese scientist had used the genetic cut-copy-paste technology CRISPR-Cas9 to modify the DNA of human embryos and then implanted these for a pregnancy. With his ‘genetic surgery,’ as he calls it himself, He had targeted a gene called CCR5 in an effort to create babies who are resistant to infection from HIV. In total, he involved eight couples in this project, of whom the male partner is HIV-positive. Two days after his *YouTube* announcement, while speaking during the International Summit on Human Genome Editing in Hong Kong, He informed a stunned audience that a third genetically modified baby was on its way.³

The news on the Chinese ‘CRISPR babies’ sent a shockwave throughout the world. Members of the global scientific community responded with a mixture of indignation and horror upon learning how He had defied scientific conventions, ignored basic rules for research on human subjects, and violated multiple norms of medical practice. The technology that He used is still in a very experimental stage, and much work needs to be done to make it safe and effective. Indeed, his data suggest that the procedure was only partially successful, if at all, resulting in a mosaic of altered and unaltered cells for both embryos⁴ and off-target genetic changes.⁵ Moreover, the on-target modifications lead to a novel genetic variation of CCR5 that is similar but not identical to the known mutation of CCR5 that confers natural HIV resistance.⁶ As such, He and his team created genetic ‘changes that had never been seen in humans before.’⁷ Yet He chose to go ahead, thereby exposing the health of the twins to huge risks. As Jennifer Doudna, one of the inventors of CRISPR-Cas9, summarizes the scientific upheaval: ‘He’s fateful

1 The He Lab, *About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos*, www.youtube.com/watch?v=th0vnOmFltc (accessed July 19, 2019).

2 Antonio Regalado, *Chinese Scientists Are Creating CRISPR Babies*, MIT TECHNOLOGY REVIEW, Nov. 25, 2018.

3 Charlotte Jee, *A Second CRISPR Pregnancy Is Already Under Way, Claims Chinese Scientist*, MIT TECHNOLOGY REVIEW, Nov. 28, 2018.

4 Gina Kolata & Pam Belluck, *Why Are Scientists So Upset About the First Crispr Babies?*, NEW YORK TIMES, Dec. 5, 2018; Kiran Musunuru, *We need to know what happened to CRISPR twins Lulu and Nana*, MIT TECHNOLOGY REVIEW, Dec. 3, 2019.

5 Henry Greely, *CRISPR’d babies: human germline genome editing in the ‘He Jiankui affair’*, 6 J. L. & BIOSCI. 111, 116–117 (2019); Antonio Regalado, *China’s CRISPR babies: Read exclusive excerpts from the unseen original research*, MIT TECHNOLOGY REVIEW, Dec. 3, 2019.

6 *Id.*

7 Greely, *CRISPR’d babies*, *supra* note 5, at 117.

decision to ignore the basic medical mantra of “do no harm” and risk the unintended consequences will likely be remembered as one of the most shocking misapplications of any scientific tool in our history.”⁸

Nevertheless, it is clear that the birth of a genetically modified baby ‘was something everyone in the burgeoning, multibillion-dollar field of genome editing knew would come one day.’⁹ In contrast, for the public at large, the news served as a wake-up call on the possibilities of human germline gene editing (HGGE) and its potentially far-reaching implications for the future of human reproduction. If He’s claims are true, then it can be said that he has single-handedly brought humankind a significant step closer to taking genetic fate into its own hands. Admittedly, reproductive technologies such as noninvasive prenatal testing (NIPT) and preimplantation genetic diagnosis (PGD) have made it technologically possible to genetically select a certain type of child for quite some time. Yet in those cases of selective reproduction, the child’s entire genetic profile is still the outcome of a biological recombination of parental genes. CRISPR opens up the possibility of genetically modifying one’s offspring. That means that it becomes possible to override the outcomes of the genetic lottery.

How should legal orders respond to the birth of the ‘CRISPR babies’? Interestingly, both national and international legal systems have long anticipated the arrival of this groundbreaking technology. Already since the late 1990s, when the first legal frameworks for the regulation of biomedical developments came into existence, the use of HGGE technologies for reproductive purposes has been prohibited in many national and international jurisdictions. A recurring thought in these legal frameworks is that genetically modifying offspring results or may result in practices that are at odds with human rights and their underlying principles, such as dignity, justice, and equality. However, now that HGGE has come within human reach, a worldwide debate has erupted about the question as to whether these human rights bans still make sense in the CRISPR era. As I will discuss hereafter, the first cracks in existing human rights legal frameworks are starting to appear. Moreover, in scientific, political, and academic circles, the call is growing louder to move from prohibition to regulation of HGGE. According to these recent proposals, the ban on heritable genome editing can be lifted for therapeutic purposes as soon as the technology is safe for introduction in the clinic.

In this article, I examine the shift that is currently taking place in the discussion on human rights and HGGE. I argue that many of the calls to lift or reconsider existing bans and restrictions on HGGE are rooted in a novel, but impoverished understanding of the meaning of human rights for this issue. To substantiate that claim, I compare the understanding of human rights which underlies these recent proposals with the human rights approaches to HGGE as contained in existing legal frameworks in this field, such as UNESCO’s Universal Declaration on the Human Genome and Human Rights (1997) and the Council of Europe’s Convention of Human Rights and Biomedicine (1997).

8 Jennifer Doudna, *He Jiankui*, TIME MAGAZINE, Apr. 29, 2019.

9 Sharon Begley & Andrew Joseph, *The CRISPR shocker: How Genome-Editing Scientist He Jiankui Rose From Obscurity to Stun the World*, STAT, Dec. 18, 2018.

I start with an overview of the technological (Section II) and legal developments (Section III) that preceded the birth of the first CRISPR babies. This is followed by an examination of proposals to allow HGGE for therapeutic purposes once the technology is safe for clinical application (Section IV). In the remainder of the article, I offer a critical analysis of these proposals on three levels. First, I examine the question as to how realistic the proposed distinction between the therapeutic and the nontherapeutic uses of human germline editing is in the CRISPR era (Section V). Second, I argue that these proposals rely on a one-dimensional understanding of the meaning of human rights for this issue (Section VI). Finally, I suggest that this one-dimensional understanding paves the way for a regime of self-regulation by the scientific community that leaves little room for public debate on the question as to whether or how HGGE fits in the long-term aspirations of society (Section VII).

II. THE GERMLINE GENE EDITING SCIENCE RACE

For a few years now,¹⁰ scientists worldwide are using CRISPR-Cas9 to modify the genetic code of organisms. As CRISPR offers the possibility of cut, copy, and paste with the letters C, G, A, and T in which DNA is encoded, this process is also known as gene editing. This revolutionary technology is relatively cheap and easy to use. Even amateurs have discovered CRISPR. Do-It-Yourself CRISPR kits are available online, offering so-called biohackers the opportunity to experiment with DNA in their home labs and garages, including their own DNA.¹¹ Members of the biohacking movement have embraced CRISPR as a means to bring an end to the biotech sector's monopoly on genetic engineering and thereby 'democratize' the life sciences. Yet, also for the biotech sector, the possibilities of CRISPR are myriad. The commercial stakes are high in the pursuit of CRISPR applications, as is strikingly illustrated by the CRISPR 'patent wars'¹² that are currently taking place.

Correspondingly, CRISPR is already having a real impact on the world of plants and animals. Various types of apes, dogs, birds, insects, and fish have been 'welcomed to the CRISPR zoo'.¹³ Wild plans are made, ranging from bringing back extinct animals such as the mammoth to producing 'micropigs' that grow to only around 15 kilograms, as a new type of pet. Indeed, as a 2016 article in the journal *Nature* on the subject concludes, 'the CRISPR zoo is expanding fast and the question now is how to navigate the way forward'.¹⁴

In the light of the birth of the genetically modified babies in China, these last words have acquired a new urgency. If, at some point in the future, the technology is deemed safe for application on human life, would there be convincing reasons against welcoming the human species to the CRISPR zoo too? If there are not, how can legal orders

10 In 2012, CRISPR-Cas9 was mentioned for the first time in scientific literature (Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 *SCIENCE* 816 (2012)).

11 Alex Pearlman, *Biohackers Are Using CRISPR On Their DNA and We Cannot Stop It*, *NEW SCIENTIST*, Nov. 15, 2017.

12 For a brief overview of these patent wars, see Ana Nordberg et al., *Cutting Edges and Weaving Threads in the Gene Editing (X)evolution: Reconciling Scientific Progress With Legal, Ethical, and Social Concerns*, 5 *J. L. & BIOSCI.* 35, 68–71 (2018).

13 Sara Reardon, 'Welcome to the CRISPR Zoo', 531 *NATURE* 160 (2016).

14 *Id.* at 163.

guide this process of human 'self-domestication'¹⁵ into the right direction, ensuring a sustainable, responsible, and equitable usage of this technology? Will existing legal bans on genetic modification have to make place for regulatory frameworks in that process? If so, will the formulation of a set of 'rules for the human zoo' be necessary in order to actively confront the challenges of human genetic modification, as German philosopher Peter Sloterdijk argued two decades ago in his provocative essay of the same name?¹⁶

In this discussion, two possible applications of CRISPR on humans should be distinguished. CRISPR can be used for the purpose of 'somatic gene editing'. This type of genetic intervention affects the genes in the targeted cells of existing patients. As such, somatic modifications are not inherited by future generations. This article focuses on a different, more radical form of genetic modification: the use of CRISPR to alter the DNA of human embryos or gametes. This type of intervention is commonly known as human germline gene editing because it involves the genetic modification of germ cells. Unlike somatic gene editing, HGGE affects all body cells of the future individuals in question, from their brains and organs to their vessels and skin. Moreover, because the changes will equally come to expression in their gametes, the genetic modifications are also inherited by their offspring and their offspring's offspring. In that sense, rewriting the human germline also means 'rewriting the gene pool of future generations'.¹⁷

Despite legal bans on germline editing, breakthroughs in this field have followed one after the other in recent years as part of what appears to be an international science race. That race took off in April 2015, when Chinese stem cell researcher Junjiu Huang and his team published an article in which they described their attempts to genetically modify human embryos. Although the researchers had used nonviable embryos for their study (thereby excluding the possibility of initiating a pregnancy),¹⁸ and although they had failed to repair the targeted genetic deficiency, their CRISPR experiment created a huge upheaval: they had broken the taboo on using CRISPR to genetically modify human life.

Exactly a year later, in April 2016, a genetically modified Jordanian baby was born in Mexico. The boy's birth did not become known until September 2016, when John Zhang, the New York-based Chinese-American fertility doctor who was responsible for the genetic modification, came forward with the news.¹⁹ Zhang had not used CRISPR for the modification, but a procedure called 'human

15 PETER SLOTERDIJK, *REGELN FÜR DEN MENSCHENPARK. EIN ANTWORTSCHREIBEN ZU HEIDEGGERS BRIEF ÜBER DEN HUMANISMUS* (1999). For an English translation, see Peter Sloterdijk, *Rules for the Human Zoo: A Response to the Letter on Humanism*, 27 ENVIRON. PLANN. D 12 (2009).

16 *Id.*

17 David Cyranoski, *The CRISPR-Baby Scandal: What's Next for Human Gene-Editing*, 566 NATURE 440 (2019).

18 David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, 250 NATURE 593 (2015).

19 Jessica Hamzelou, *World's First Baby Born With New '3 Parent' Technique*, NEW SCIENTIST, Sept. 27, 2016.

nuclear genome transfer' (HNGT) also known as 'mitochondrial replacement therapy'.²⁰

First, Zhang and his team transplanted the nucleus of the intending mother's egg cell into an enucleated egg cell donated by a third party. They then fertilized the resulting, composite egg cell with the intending father's sperm. This particular HNGT technique is known as 'maternal spindle transfer'. Because the gametes of three parties are brought together during HNGT, popular media referred to the event as the birth of the first 'three parent baby'.

The parents had contacted Zhang because the mother is carrier of a mitochondrial disorder: Leigh Syndrome. By replacing her dysfunctional mitochondrial DNA with the egg donor's healthy mitochondrial DNA, Zhang aimed to prevent the transmission of the mitochondrial disorder to the boy. How successful the intervention was, especially given possibly adverse long-term effects on the boy's health,²¹ remains to be seen.

It should be noted at this point that only 15–20 per cent of all mitochondrial diseases are caused by mutations in mitochondrial DNA. For the remaining 80–85 per cent, nuclear genome transfer is useless.²² However, HNGT can also be used for other purposes. Indeed, a few months after the birth of the Jordanian boy, in January 2017, another 'three parent baby' was born, a Ukrainian girl, as part of a fertility treatment. This time, a different HNGT technique was used, pronuclear transfer, which involves transferring the nuclear material of the intending mother's fertilized egg into a fertilized enucleated donor egg. The Ukrainian fertility clinic in question had used HNGT because the 34-year-old intending mother had been suffering from 'unexplained infertility'.²³ In a similar vein, the aforementioned John Zhang was making plans to offer HNGT on a commercial basis for the rejuvenation of egg cells through his start-up 'Darwin Life',²⁴ until the US Food and Drug Administration sent him a warning.²⁵

HNGT has a much smaller genetic impact than CRISPR germline editing. It only affects mitochondrial DNA, which constitutes less than 1 per cent of a person's total DNA, thereby leaving the nuclear DNA unaffected. Even so, there are convincing

20 I use the term 'human nuclear genome transfer' instead of 'mitochondrial replacement therapy' for reasons explained by Françoise Baylis, *Human Nuclear Genome Transfer (So-Called Mitochondrial Replacement): Clearing the Underbrush*, 31 *BIOETHICS* 7 (2017).

21 See Sara Reardon, *Genetic Details of Controversial 'Three-Parent Baby' Revealed*, 544 *NATURE* 17 (2017); Steve Connor, *When Replacement Becomes Reversion*, 35 *NAT. BIOTECHNOL.* 1012 (2017).

22 Françoise Baylis & Alana Cattapan, *Personalised Medicine and the Politics of Human Nuclear Genome Transfer*, in *PERSONALISED MEDICINE, INDIVIDUAL CHOICE AND THE COMMON GOOD* 26 (Britta van Beers, Sigrid Sterckx & Donna Dickenson eds., 2018).

23 Susan Scutti, *Controversial IVF Technique Produces a Baby Girl; And for Some, That's a Problem*, CNN, Jan. 18, 2018, <https://edition.cnn.com/2017/01/18/health/ivf-three-parent-baby-girl-ukraine-bn/index.html> (accessed July 19, 2019).

24 Emily Mullin, *The Fertility Doctor Trying to Commercialize Three-Parent Babies*, MIT TECHNOLOGY REVIEW, June 13, 2017.

25 The FDA sent the following letter to Zhang: https://www.fda.gov/media/106739/download?source=govdelivery&utm_medium=email&utm_source=govdelivery (accessed July 19, 2019).

reasons to regard HNGT as a form of human germline genetic modification.²⁶ First, it is hard to deny that the procedure affects the genetic composition of germline cells. Second, if daughters are born, as was the case in Ukraine, they will pass on these genetic changes to their offspring (inheritance is generally²⁷ through the maternal line).

In the summer of 2017, the first successful CRISPR modification of embryonic nuclear DNA took place. The Kazakh–American biologist Shoukhrat Mitalipov and his American–Chinese–South-Korean team managed to repair a genetic mutation that is linked to a serious heart disease.²⁸ The resulting ‘CRISPR embryos’ were, however, not implanted for a pregnancy. With the birth of the Chinese ‘CRISPR babies’ in November 2018, this last step now also seems to have been taken.

Although He’s actions were widely condemned, the science race still appears to be in full swing. In June 2019, the Russian molecular biologist Denis Rebrikov announced his intentions to genetically modify human embryos for reproductive purposes before the end of the year, targeting the same gene as He did.²⁹ In addition, he unfolded plans to use HGGE to prevent the transmission of deafness.³⁰ Rebrikov is already conducting experiments on human egg cells to be able to achieve this goal.³¹ His long-term plans include using HGGE to target genes related to dwarfism and blindness.³²

III. LEGAL APPROACHES TO HUMAN GERMLINE EDITING

From a legal perspective, the widespread condemnation of He’s efforts to create genetically modified babies is quite understandable. ‘Globally’, as Françoise Baylis writes, ‘the political consensus on heritable human genome editing—such as it is—inclines toward an outright ban, and if not a ban, at least a moratorium.’³³ Interestingly, the oft-heard expression that the law inevitably lags behind technological developments proves false in the case of HGGE. Most existing legal bans and restrictions have been effective for quite a while. Indeed, from the very first debates on the regulation of biomedical developments, the possibility of genetically designing children played a vital role within the public imagination.³⁴ Moreover, in that context, human rights and human dignity are often invoked as main frame of reference. However, even if the

26 Many scientists also regard nuclear genome transfer as germline genetic modification (e.g. Guido de Wert et al., *Responsible Innovation in Human Germline Gene Editing: Background Document to the Recommendations of the ESHG and ESHRE*, 26 EUR. J. HUM. GENET. 550 (2018)). However, the UK Government maintained that while MRTs ‘do result in germ-line modification, the techniques [do not] constitute genetic modification’ (see Rosamund Scott & Stephen Wilkinson, *Germline Genetic Modification and Identity: the Mitochondrial and Nuclear Genomes*, 37 OJLS 886, 887 (2017)).

27 Although the rule is that mitochondrial disorders are generally inherited through the maternal line, occasionally, these disorders may be transmitted by the father as well (see: Thomas McWilliams & Anu Suomalainen, *Mitochondrial DNA Can Be Inherited from Fathers, Not Just Mothers*, 565 NATURE 296 (2019)).

28 Heidi Ledford, *CRISPR Fixes Disease Gene in Viable Human Embryos*, 548 NATURE 13 (2017).

29 David Cyranoski, *Russian Biologist Plans More CRISPR-Edited Babies*, 570 NATURE 145 (2019).

30 Michael Le Page, *Five Couples Lined Up for CRISPR Babies to Avoid Deafness*, SCIENTIST, July 4, 2019.

31 David Cyranoski, *Russian Scientist Edits Human Eggs in Effort to Alter Deafness Gene*, 574 NATURE 465 (2019).

32 Jon Cohen, *Russian Geneticist Answers Challenges to His Plan to Make Gene-Edited Babies*, SCIENCE, June 13, 2019.

33 Françoise Baylis, *Human Genome Editing: Our Future Belongs to All of Us*, 35 ISSUES SCI. TECHNOL. 42, 42 (2019).

34 RINIE VAN EST ET AL., *RULES FOR THE DIGITAL HUMAN PARK: TWO PARADIGMATIC CASES OF BREEDING AND TAMING HUMAN BEINGS—HUMAN GERMLINE EDITING AND PERSUASIVE TECHNOLOGY* 15 (2017).

first bans on HGGE were established already in the late 1990s and are typically rooted in human rights discourse, these legal frameworks are currently under pressure. The first cracks are starting to appear ever since CRISPR and HNGT put human germline genetic modification back on the legal–political agenda. In this section, I first explore national legal frameworks in this field (Section III.A). I then examine the international legal landscape (Section III.B). Finally, I address several pressing questions with regard to these legal frameworks (Section III.C).

III.A. National legal approaches to human germline modification

Most countries with legal frameworks for the regulation of biomedical developments either ban or severely restrict HGGE technologies.³⁵ Admittedly, the scope, means, and nature of these national bans and restrictions vary greatly.³⁶ At one end of the spectrum, there are countries where human germline modifications are categorically prohibited and accompanied by criminal sanctions, such as many European countries, Australia, Canada, and Brazil.³⁷ At the other end of the spectrum, there are countries which allow, for example, HGGE for research purposes. Yet, also these more permissive national orders, of which China, the USA, and the UK are the most prominent, have laws and regulations that impose strict limits to the use of this technology. A brief look at the regulatory situations in the latter three countries can make that clear.

As mentioned earlier, the first attempt at human germline modification was made in China, and the first genetically modified babies were born in China. Hence, one would expect the Chinese rules on germline editing to be lax. However, China equally bans genetically modifying offspring. A Chinese ministerial guideline provides that ‘gene manipulation on human gametes, zygotes and embryos for the purpose of reproduction is banned.’³⁸ The National Health and Family Planning Commission is responsible for the enforcement of this rule. Accordingly, Chinese officials have denounced He Jiankui’s actions as ‘extremely abominable in nature’ and in violation of Chinese laws and science ethics.³⁹ For a long time, it was unclear how He Jiankui would be punished. The existing rules do not mention any penalties for violating the aforementioned ban. Nevertheless, in December 2019, He Jiankui was sentenced to 3 years in prison. Moreover, in response to the scandal, Chinese authorities have proposed to tighten the rules and introduce penalties.⁴⁰

35 Rosario Isasi, Erika Kleiderman & Bartha Knoppers, *Editing Policy to Fit the Genome?*, 351 *SCIENCE* 337 (2016); Motoko Araki & Tetsuya Ishii, *International Regulatory Landscape and Integration of Corrective Genome Editing Into In Vitro Fertilization*, 12 *REPROD. BIOL. ENDOCRINOL.* 108 (2014).

36 As Isasi, Kleiderman and Knoppers characterize the legal diversity: ‘Internationally, policies extend across a continuum that distinguishes between degrees of permissiveness, that is, between legally binding legislation and regulatory and/or professional guidance or research versus clinical applications’ (Isasi, Kleiderman & Knoppers, *supra* note 35, at 337).

37 *Id.*

38 Artt. 3.7 & 3.9 of the 2003 ‘Technical Norms of Human Assisted Reproductive Technologies’ (see NUFFIELD COUNCIL ON BIOETHICS, *GENOME EDITING AND HUMAN REPRODUCTION: SOCIAL AND ETHICAL ISSUES* 111 (2018); Di Zhang, & Reidar K. Lie, *Ethical Issues in Human Germline Gene Editing: A Perspective from China*, 36(1–4) *MONASH BIOETHICS REVIEW*, 23 (2018).

39 *Research Activities of Persons Halted Over Gene-Edited Babies Incident*, XINHUA.NET, Nov. 29, 2018, http://www.xinhuanet.com/english/2018-11/29/c_137640174.htm (accessed July 19, 2019).

40 Ian Sample, ‘Chinese scientist who edited babies’ genes jailed for three years’, *GUARDIAN*, Dec. 31, 2019, <https://www.theguardian.com/world/2019/dec/30/gene-editing-chinese-scientist-he-jiankui->

Also in the USA, the most prolific country with regard to basic genome editing research,⁴¹ several legal limits to HGGE are in place. These limits are part of what has been called ‘a complex regulatory and statutory web concerned with human embryo research in general and human germline modification in particular.’⁴² Although HGGE is not formally prohibited, currently several mechanisms, taken together, practically impede the clinical introduction of this technology. First, the National Institutes of Health, which is responsible for research funding in the USA, has stated that it ‘will not fund any use of gene-editing technologies in human embryos.’⁴³ Second, the US Food and Drug Administration, which has the authority to regulate products and drugs involving gene editing, including human gene editing, has so far stood in the way of using HGGE for reproductive purposes and is also not likely to change its policy in the near future. Since December 2015, US Congress has regularly added an amendment to the FDA’s funding bill, a so-called ‘bill rider’, making it impossible for the FDA to consider any application which involves ‘research in which a human embryo is intentionally created or modified to include a heritable genetic modification.’⁴⁴ Without the FDA’s approval, implantation of a genetically modified human embryo is illegal in the USA. However, genetically modifying human embryos for research purposes are permitted, even though such experiments remain ineligible for public funding.⁴⁵

Finally, the UK legal situation is worth mentioning in this context. The UK can be said to be at the forefront of germline editing because of its status as first country in the world to explicitly permit HNGT. In 2015, after many years of political debate, the UK Parliament gave green light to the clinical use of HNGT,⁴⁶ resulting in the ‘Mitochondrial Donation Regulations 2015.’⁴⁷ The UK’s decision to legalize HNGT for the purpose of preventing mitochondrial disorders was much discussed worldwide. As legal scholar Samvel Varvaštian explains the controversy: ‘the UK has not only become the first state to explicitly allow mitochondrial donation, but the first to openly challenge the fragile global policy with regard to germline gene modification.’⁴⁸

Nevertheless, HGGE for reproductive purposes, in general, remains prohibited in the UK. According to the ‘Human Fertilisation and Embryology Act 1990’ (HFE Act), all uses of gametes and embryos outside the body are prohibited unless carried out on the basis of a license issued by the Human Fertilisation and Embryology

jailed-three-years (accessed Mar. 24, 2020); David Cyranoski, ‘China to Tighten Rules on Gene Editing in Humans’, *NATURE*, Mar. 6, 2019, <https://www.nature.com/articles/d41586-019-00773-y> (accessed July 19, 2019).

41 Nuffield Council, *supra* note 38, at 109.

42 I. Glenn Cohen & Eli Adashi, *The FDA Is Prohibited From Going Germline*, 353 *SCIENCE* 545 (2016).

43 See statement by NIH Director Francis Collins, *Statement on NIH Funding of Research Using Gene-editing Technologies in Human Embryos*, Apr. 28, 2015, <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> (accessed July 19, 2019).

44 Greely, *CRISPR’d babies*, *supra* note 5, at 128–129. For a critical discussion of this legal situation, see Glenn Cohen & Adashi, *supra* note 42. Also see Nuffield Council, *supra* note 38, at 109–110.

45 Glenn Cohen & Adashi, *supra* note 42.

46 Rowena Mason & Hannah Devlin, *MPs Vote in Favour of ‘Three-Person Embryo’ Law*, *GUARDIAN*, Feb. 3, 2015.

47 The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (S.I 2015 No. 572).

48 Samvel Varvaštian, *UK’s Legalisation of Mitochondrial Donation in IVF Treatment: A Challenge to the International Community or a Promotion of Life-saving Medical Innovation to Be Followed by Others?*, 22 *EUR. J. HEALTH L.* 405, 424 (2015).

Authority. Some activities cannot be licensed according to the HFE Act and are therefore absolutely prohibited. One of these activities is placing embryos or gametes other than ‘permitted embryos or gametes’ in a woman. According to Section 3ZA(4b) of the HFE Act, an embryo can only qualify as a ‘permitted embryo’ if ‘no nuclear or mitochondrial DNA of any cell of the embryo has been altered’. However, in 2008, an opening was created for HNGT when, during the 2008 revision of the Act, Section 3ZA(5) was added, which stipulates the following:

Regulations may provide that an egg can be a permitted egg, or an embryo can be a permitted embryo, even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

This is exactly what happened in 2015: Parliament voted in favor of regulations that make an exception to the general ban on germline editing to allow HNGT to prevent passing on serious mitochondrial diseases.⁴⁹ Nevertheless, also under this regulation, the use of HNGT for fertility treatment remains off-limits.

In sum, despite the wide variety of regulatory frameworks, there is broad consensus that HGGE is a technology with potentially far reaching consequences and that bans and restrictions are in order. Moreover, in most legal orders, the ban on reproductive HGGE appears to be firmly established: an extensive legislative procedure will be needed to lift it. The latter is also the case for the UK. The possibility that was built into the HFE Act in 2008 to amend the definition of ‘permitted embryo’ was, as explained, a constrained one. If the UK government ever wanted to lift the ban on editing the nuclear DNA of human embryos, it would have to go through the much more drastic process of changing its primary legislation.

However, this is not the case for all countries, as the legal situations in China and the USA indicate. In these countries, the existing legal frameworks can be adapted much more easily. As the Chinese prohibition is contained in a ministerial guideline, it can presumably be amended without having to pass through a legislative, parliamentary procedure. Moreover, as the UK Nuffield Council on Bioethics writes, ‘encouraged by international competition and given its Confucian traditions, China appears to be a candidate to lift the ban on intergenerational genome editing if sufficient evidence was adduced to support a move into clinical use.’⁵⁰

As to the US restrictions on HGGE, these may be changed without any rigorous legislative revisions, for example, if the NIH changes its funding policy or if the FDA would be able to consider an application for human germline editing. Indeed, in June 2019, several Democratic lawmakers proposed to eliminate the bill rider which currently stands in the way of the FDA to consider trials for HGGE.⁵¹

If the bans in these countries were lifted, and the Rubicon thus be crossed, it is likely that other countries will follow their example in today’s competitive ‘knowledge

49 The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 (S.I 2015 No. 572).

50 Nuffield Council, *supra* note 38, at 112.

51 Lev Facher, *Why Democrats Reopened the Debate About Germline Gene Editing*, STAT, June 18, 2019, <https://www.statnews.com/2019/06/18/democrats-reopened-debate-about-germline-editing/> (accessed July 1, 2019).

economy'. Moreover, it can be expected that medical tourism will bolster this legal 'domino effect', thereby creating the risk of a race to the bottom. This makes the question as to the international legal norms in this field all the more urgent.

III.B. International legal approaches to human germline modification

Characteristic for existing international human rights frameworks on biomedical technologies is the thought that with the application of germline genetic modification, a fundamental line would be crossed for humankind from which there is no turning back.⁵² A striking illustration is the legal approach chosen by the Council of Europe, whose European Convention on Human Rights is effective in 47 states. Already in 1982, the Parliamentary Assembly of the Council of Europe considered in its 'Recommendation on genetic engineering' that 'the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed.'⁵³ These words are an early expression of the idea that human rights are of special importance within the regulation of human genetic technologies and that restrictions to the use of genetic technologies may be in order to ensure the protection of the fundamental values and rights protected by human rights discourse.⁵⁴ However, the Recommendation left the question unanswered as to what the exact scope of the proposed restrictions to germline interventions should be.⁵⁵ Instead, it recommended that the Committee of Ministers performs this task at a later stage by drawing up a European agreement on the topic, based on the rights and principles that are contained in the European Convention on Human Rights.⁵⁶

In 1997, this European agreement would take on the form of the 'Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine'. As this treaty was opened for signature in Oviedo, Spain, it is more commonly known as the 'Oviedo Convention'. The Oviedo Convention is the first international legally binding instrument in the field of biomedical law. According to Article 13 of this convention, 'an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.' The emphasized words imply a categorical ban on using HGGE for reproductive purposes.

52 Roberto Andorno & Alicia Ely Yamin, *The Right to Design Babies? Human Rights and Bioethics*, OPEN GLOBAL RIGHTS, Jan. 8, 2019, <https://www.openglobalrights.org/the-right-to-design-babies-human-rights-and-bioethics/> (accessed July 19, 2019).

53 Parliamentary Assembly of the Council of Europe, *Recommendation on Genetic Engineering*, Recommendation 934 (1982), sub 4a.

54 Roberto Andorno, *Biomedicine and International Human Rights Law: In Search of a Global Consensus*, 80 BULLETIN OF THE WORLD HEALTH ORGANIZATION 959 (2002).

55 According to Scott & Wilkinson, *supra* note 26, this Recommendation leaves the door open for forms of germline editing that aims to prevent diseases, because of par. 4c: 'the explicit recognition of this right must not impede development of the therapeutic applications of genetic engineering (gene therapy), which holds great promise for the treatment and eradication of certain diseases which are genetically transmitted'.

56 Parliamentary Assembly of the Council of Europe, *Recommendation on Genetic Engineering*, *supra* note 53, sub 4a & 7a.

According to the Oviedo Convention's Explanatory Report, the prohibition contained in Article 13 goes back to the thought that misuse of HGGE 'may endanger not only the individual but also the species itself.' This sentence is a direct reference to the following, central phrase within the convention's preamble: 'convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being.' In the light of this reference, it appears that human dignity is one of the prohibition's underlying principles, even if it is not mentioned explicitly by the Explanatory Report at this point. Indeed, the concept of human dignity is generally interpreted as a principle which protects the interests of both the individual and humanity, as is discussed more elaborately in Section VI. This raises the question as to how human dignity would be at stake in the context of the ban on HGGE. An answer is provided by the subsequent phrase in the Explanatory Report: 'the ultimate fear is of intentional modification of the human genome so as to produce individuals or entire groups endowed with particular characteristics and required qualities'.⁵⁷

More recently, the ban on reproductive HGGE has been reaffirmed by both the Council of Europe's Parliamentary Assembly⁵⁸ and Committee on Bioethics.⁵⁹ At this point, it should be noted, however, that the Oviedo Convention has actually entered into force in only 29 of the 47 Council of Europe's member states. The states that are missing in this list have diverging reasons for not signing or ratifying the convention. Germany, for example, abstained from signing because the treaty was deemed too permissive.⁶⁰ The UK, on the contrary, did not sign because the convention was considered too restrictive.⁶¹ Another interesting case is Ukraine, where the first baby after pronuclear transfer was born, as described above. This country signed the Oviedo Convention but failed to ratify it.

Nevertheless, member states that have not signed or ratified the Oviedo Convention are still faced with a ban on HGGE, albeit in a different form, if they are also European Union member states.⁶² For over two decades, the EU has regarded germline gene modification as conflicting with fundamental values of the European legal order. 'There is', in the words of the preamble of the 'Biotech Directive' (1998), 'a consensus within the Community that interventions in the human germ line and the cloning of human beings offend against "ordre public" and morality'.⁶³ Correspondingly, Article 6 of the Biotech Directive excludes from patentability 'processes for modifying the germ line genetic identity of human beings' and 'processes for cloning human beings'. Also, within this context, human dignity played an important role in the legislative process. Recital

57 *Explanatory report to the Convention on Human Rights and Biomedicine*, EUROPEAN TREATY SERIES, nr. 164, sub 89, <https://rm.coe.int/16800ccde5> (accessed Aug. 1, 2019).

58 Parliamentary Assembly of the Council of Europe, *The Use of New Genetic Technologies in Human Beings*, Recommendation 2115 (2017), sub 3.

59 Committee on Bioethics (DH-BIO), *Statement on Genome Editing Technologies*, Dec. 2, 2015, <https://rm.coe.int/168049034a> (accessed Aug. 1, 2019).

60 Roberto Andorno, *The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law*, 2 J. INT. BIOTECH. L. 134 (2005).

61 *Id.*

62 28 out of 47 Council of Europe member states are EU member states.

63 Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, C/2016/6997, OJ C 411, preamble sub 40.

16 of the Biotech Directive emphasizes that ‘patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.’ The Court of Justice has taken this to mean that ‘the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected.’⁶⁴

Within the EU ‘Charter of Fundamental Rights’ (2000), the interconnections between human rights, human dignity, and biomedical developments in EU law are further elaborated. The Charter’s first chapter, entitled *Human dignity*, includes a ‘prohibition of eugenic practices, in particular those aiming at the selection of persons’ [Article 3(2) sub b]. Of more direct importance to human germline editing are the EU rules on clinical trials that were introduced in 2001. According to both the ‘Clinical Trials Directive’⁶⁵ and its successor, the ‘Clinical Trials Regulation,’⁶⁶ ‘no gene therapy clinical trials may be carried out which result in modifications to the subject’s germ line genetic identity.’⁶⁷ As a clinical trial is indispensable for the safe introduction of HGGE in the clinic, it could be said that the reproductive use of germline modification technologies is effectively blocked by this legal provision. Even so, there is discussion on the question as to whether the EU rules on clinical trials formally apply to trials involving HGGE, as those will be discussed in the next subsection.

Also outside Europe international human rights norms have been established for HGGE, with UNESCO’s ‘Universal Declaration on the Human Genome and Human Rights’ (1997) as main example. The declaration is not a legally binding instrument. Like the Oviedo Convention, it expresses the thought that germline editing touches upon the collective interests of humanity, albeit in a slightly different way. As Article 1 states, ‘The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.’ What these words mean for HGGE is suggested by Article 24, in which the International Bioethics Committee (IBC) is assigned the task to disseminate the principles set out in the declaration. According to this provision, the task also entails giving ‘advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line intervention.’

If there were any remaining doubts on UNESCO’s position on HGGE, these are taken away in a recent report. In this report from 2015, the IBC offers reflection on the relation between human rights and the human genome in the light of recent technological developments, including not only the rise of personalized medicine, NIPT, and direct-to-consumer genetic testing but also human germline editing. As to the latter, the IBC expresses its support for the Oviedo Convention’s ban. Building on Article 1 of the Declaration and its notion of the human genome as the heritage

64 Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, EU:C:2011:669, sub 34.

65 Directive 2001/20/EC of the European Parliament and of the Council of Apr. 4, 2001 on the approximation of the laws, regulations, and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121, 1.5.2001, at 34 (hereafter: Clinical Trials Directive).

66 Regulation (EU) No 536/2014 of the European Parliament and of the Council of Apr. 16, 2014 on clinical trials on medical products for human use, and repealing Directive 2001/20/EC (hereafter: Clinical Trials Regulation).

67 Previously art. 9 par. 6 Clinical Trials Directive; replaced by art. 90 Clinical Trials Regulation.

of humanity, the IBC states that making any genetic changes which are passed on to descendants should be prohibited.⁶⁸ According to the committee, ‘the alternative would be to jeopardize the inherent and therefore equal dignity of all human beings and renew eugenics, disguised as the fulfillment of the wish for a better, improved life’.⁶⁹

III.C. Persisting ambiguities and current discussions

Although various formulations are used within the international legal frameworks in this field, it is clear that human dignity emerges as a core idea. According to UNESCO, the Council of Europe, and the EU, this legal principle is compromised as soon as eugenic practices emerge, human reproduction degenerates into the production of humans, or children are reduced to objects of design.

Yet, many questions remain. UNESCO’s IBC, for example, is ambiguous about its exact position on HGGE. As discussed, the IBC supports the Council of Europe’s ban on the use of this technology for reproductive purposes. However, in its report’s final recommendations, the IBC appears to take a slightly different position than the Council of Europe by advocating a differentiated approach to human cloning⁷⁰ and HGGE. In the IBC’s words:

The IBC reaffirms the necessity for a *ban* on human cloning for reproductive purposes and recommends a *moratorium* on genome editing of the human germline. There is no medical or ethical argument to support the former. As to the latter, the concerns about the safety of the procedure and its ethical implications are *so far* prevailing’ (emphasis added).⁷¹

Unfortunately, what the exact implications of the IBC’s distinction between ‘ban’ and ‘moratorium’ are in this context and what its words ‘so far’ allude to remains unexplained. Does this mean that the IBC could change its position depending on the circumstances and that it does not endorse a categorical ban? If so, then these recommendations are at odds with the IBC’s firmly expressed concerns about HGGE, dignity and justice, as expressed earlier in the report.

Furthermore, discussion is possible on the exact scope of the various existing prohibitions, also in EU law. For example, what is exactly meant by the term ‘eugenic practices’ to which the EU Charter of Fundamental Rights refers? According to the explanatory memorandum, ‘the reference to eugenic practices, in particular those aiming at the selection of persons, is related to possible situations in which selection programs are organized and implemented, involving campaigns for sterilization, forced pregnancy, and compulsory ethnic marriage among others’.⁷² This list seems to suggest that cases in which selective reproduction is the outcome of individual, voluntary decision-making, in other words, instances of ‘liberal eugenics’, do not qualify as ‘eugenic practices’ under this provision. At the same time, the words ‘among others’ indicate that this list of possible eugenic situations is not exhaustive.

68 International Bioethics Committee, *Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights*, UNESCO, SHS/YES/IBC-22/15/2 REV.2 (Paris, October 2, 2015), sub 107.

69 *Id.* sub 107.

70 A prohibition on reproductive cloning can be found in the Additional Protocol to the Oviedo Convention on the Prohibition of Cloning Human Beings.

71 *Id.* sub 111.

72 *Explanations Relating to the Charter of Fundamental Rights*, 2007/C 303/02.

More specific questions have risen about both the EU Biotech Directive's and the Clinical Trials Regulation's references to 'the germ line genetic identity'. When can it be said that a germline intervention affects the future person's germline genetic identity? Is this the case for all types of germline interventions, or only more radical ones? A possible line of reasoning is that HNGT falls into a category of germline interventions that do not affect the future person's genetic identity, and therefore remains outside the scope of both provisions. However, as a number of ethicists point out, this line of reasoning has serious weaknesses.⁷³ In their words, 'modification of the mitochondrial DNA is not substantively different from modification of the nuclear DNA in terms of its effects on the identity of the future person.'⁷⁴

Nevertheless, both UK and Dutch legislature, for example, have come to a different conclusion. In the UK and The Netherlands, modifications of nuclear embryonic DNA are banned, whereas modifications of nuclear mitochondrial DNA are not. It seems that the lawmakers of both EU states (at the time, the UK still was an EU member state) have interpreted the EU legislation's references to 'genetic identity' to mean that only modifications of nuclear embryonic DNA are targeted by the current bans, thus leaving the possibility open for member states to permit modifications of mitochondrial DNA.⁷⁵ Even so, despite the absence of a national legal ban, The Netherlands has, as of yet, neither explicitly nor actively endorsed this technology. This is due to other legal provisions that impede the use of HNGT.⁷⁶ In the UK, on the contrary, clinical trials were given the green light in December 2016 by the HFEA, which was hailed by the journal *Nature* as a 'historic decision.'⁷⁷

However, media reports from 2019 suggest that the UK was probably not even the first EU member state to permit clinical trials in this field.⁷⁸ Equally in 2016, Greek health authorities gave permission for clinical trials involving HNGT. This information was not shared with the general public until a Spanish–Greek team of fertility doctors announced in April 2019 that a genetically modified baby had been born in Greece after an IVF procedure with HNGT. This boy is not only the 'first three parent baby

73 E.g. Annelien Bredenoord et al., *Ethics of Modifying the Mitochondrial Genome*, 37 J. MED. ETHICS 97 (2011); Scott & Wilkinson, *supra* note 26.

74 Bredenoord et al., *supra* note 73, at 97.

75 For a further analysis of how this distinction between nuclear and mitochondrial DNA has affected the UK's regulation of HNGT, see Scott & Wilkinson, *supra* note 26, especially at 897–898. For the Dutch legislature's position, see the *travaux préparatoires* of the Dutch Embryo Act (Parliamentary document *Kamerstukken II* 2000/01, 27 423, nr. 5, p. 99–100).

76 According to the Dutch minister of Health, this has to do with the Dutch ban on creating embryos for research purposes. This ban has made it impossible for Dutch scientists to do research in this field ensuring that the technology is safe for introduction in the clinic (see Parliamentary document *Kamerstukken II* 2016/17, 29 323, nr. 105, p. 12–13). For a further analysis of the Dutch policy in this field, see Britta van Beers, Charlotte de Kluiver & Rick Maas, *The Regulation of Human Germline Genome Modification In the Netherlands*, in: HUMAN GERMLINE MODIFICATION AND THE RIGHT TO SCIENCE. A COMPARATIVE STUDY OF NATIONAL LAWS AND POLICIES 309–344 (Andrea Boggio, Cesare Romano, & Jessica Almqvist (eds.), 2020).

77 Ewen Callaway, *Historic Decision Allows UK Researchers to Trial 'Three Person' Babies*, NATURE (2016), <https://www.nature.com/news/historic-decision-allows-uk-researchers-to-trial-three-person-babies-1.21182> (accessed Aug. 1, 2019).

78 Emily Mullin, *Pregnancy Reported in the First Known Trial of 'Three-Person IVF' for Infertility*, STAT, Jan. 24, 2019.

born in clinical trial to treat infertility’, as media headlined,⁷⁹ but also the first ‘three parent baby’ born in the EU. The purpose of the nuclear genome transfer had not been to prevent passing on mitochondrial disorders, which is the sole purpose for which HNGT can be used in the UK. Instead, like the Ukrainian case, the fertility doctors sought to increase the chances of a successful fertility treatment. The team that initiated the procedure, the Spanish company Embryotools, had decided to move the trials to Greece because of legal hurdles in Spain.⁸⁰ The Greek National Authority of Assisted Reproduction formally approved these clinical trials at the end of 2016,⁸¹ apparently assuming that EU clinical trials legislation permits this kind of germline intervention.

In addition to these discussions about the meaning of ‘genetic identity’, there is disagreement about the meaning of the terms ‘clinical trials’ and ‘subject’ as used in the EU Clinical Trials Directive⁸² and Regulation.⁸³ For example, in its 2018 report on HGGE, the British Nuffield Council of Ethics raises the question as to whether HGGE clinical trials would fall within the EU law’s definition of a clinical trial, given the centrality of the notion ‘subject’ in that definition.⁸⁴ The authors of the report have doubts because the germline intervention is performed on embryos and not fully grown individuals.⁸⁵ Against this view, the argument can be made that the subject in question is not so much the embryo but rather the future person that will be born after the genetic intervention.

During the parliamentary debates on HNGT, the UK Department of Health used a different line of reasoning to arrive at the same conclusion. It argued that trials for HNGT are actually, not clinical trials in the sense of the EU Clinical Trials Regulation and that, therefore, the ban does not apply to this situation. In essence, the Department argued that when Article 90 of that Regulation posits that ‘no gene therapy clinical trials may be carried out which result in modifications to the subject’s germ line genetic identity’, the Regulation does not mean to imply anything for trials in the field of germline interventions. For this position, the Department offers two reasons.

First, this regulation is formally known as the ‘Regulation on clinical trials on medicinal products for human use’ (emphasis added). According to the Department, no medicinal products are involved with HNGT. *Ergo*, the Regulation does not apply. Second, the Health Department points out that Article 2(1) defines clinical trials as having ‘the objective of ascertaining the safety and/or efficacy of [...] medicinal products’. The Department argues that the licenses which the HFEA issues to clinics to perform HNGT cannot qualify as ‘clinical trials’ because they ‘will not be licensed with

79 Helen Thomson, ‘First 3-parent baby born in clinical trial to treat infertility’, *NEW SCIENTIST*, Apr. 11, 2019, <https://www.newscientist.com/vu-nl.idm.oclc.org/article/2199441-first-3-parent-baby-born-in-clinical-trial-to-treat-infertility/> (accessed July 19, 2019).

80 Embryotools Achieves the World’s First Pregnancy With a New Nuclear Transfer Technique for Treating Infertility, Jan. 17, 2019, http://www.pcb.ub.edu/portal/en/noticies/-/noticia/no_embryotools-aconsegueix-el-primer-embaras-del-mon-amb-una-nova-tecnica-de-transferencia-nuclear-per-tractar-la-infertilitat (accessed July 19, 2019).

81 Mullin, *Pregnancy Reported in the First Known Trial*, *supra* note 78.

82 For full reference, *supra* note 65.

83 For full reference, *supra* note 66.

84 See Art. 2(2) Clinical Trials Regulation; and Art. 2(a) Clinical Trials Directive.

85 Nuffield Council, *supra* note 38, at 122–123.

the objective of ascertaining the safety and/or efficacy” of the treatment. The primary objective will be to prevent the transmission of serious mitochondrial disease’.

Nonetheless, the licenses that the HFEA has issued in the meantime are widely perceived as official permissions to perform clinical trials in this field.⁸⁶ Furthermore, the Health Department’s interpretation is questionable because the broad wording of Article 90 suggests ‘that it was intended to prohibit all gene therapy clinical trials involving germline editing, irrespective of whether they relate to medicinal products.’⁸⁷ Finally, the Department’s position that no medicinal products are involved in case of HNGT can be challenged in the light of ongoing discussions about the meaning of the term ‘medicinal products.’⁸⁸ Varvaštian observes in this context ‘that the compliance of the Mitochondrial Donation Regulations 2015 with the EU legislation on clinical trials could indeed be questioned by the European Court of Justice, should a case be brought before it.’⁸⁹

Such a court decision could have a huge impact. Either the UK and Greece rely on a wrong interpretation of Article 90 and would have to stop their clinical trials (that is, as long as the UK is still a member state), or the UK and Greece are right, in which case the ruling would not only affect the governance of HNGT, but, possibly, of HGGE at large. After all, many of the arguments made to allow HNGT trials under the Clinical Trials Regulation, equally remove clinical trials for HGGE from the scope of the clinical trials directive.

A final important question that needs to be addressed is what the existing prohibitive or restrictive legal approaches to germline modification imply for research in this field. For example, although EU law prohibits clinical trials in which the subject’s germ line genetic identity is affected, the question remains unanswered as to what the rules are for preclinical or basic research in this field. According to the European Group on Ethics in Science and New Technologies (EGE), which is the European Commission’s advisory body on ethical matters, not only the clinical application of this technology would be ground for serious concerns, but also the research activities in this field, ‘given the profound potential consequences of this research for humanity.’⁹⁰ However, the EGE fails to indicate how these concerns should be translated in either law or policy and what this means for the various stages of research.

The Oviedo Convention is less ambiguous in that regard. This treaty contains, what could be called, a *de facto* ban on research in this field. Article 18(2) of the Oviedo Convention prohibits the creation of embryos for research purposes. Nonetheless, research aimed at developing HGGE requires one-cell stage embryos, which can only be obtained by creating embryos for research purposes.⁹¹ Embryos that are left over from an IVF treatment are not suitable for this purpose. This means that this kind

86 See for example the title of the article in *Nature* in which the news on the licences is shared (Callaway, *supra* note 77).

87 RUMIANA YOTOVA, THE REGULATION OF GENOME EDITING AND HUMAN REPRODUCTION UNDER INTERNATIONAL LAW, EU LAW AND COMPARATIVE LAW (BACKGROUND REPORT FOR THE NUFFIELD COUNCIL ON BIOETHICS) (2017).

88 Varvaštian, *supra* note 48, at 421–422 (note 92).

89 Varvaštian, *supra* note 48, at 99.

90 European Group on Ethics in Science and New Technologies, *Statement on Gene Editing*, https://ec.europa.eu/research/ege/pdf/gene_editing_ege_statement.pdf (accessed July 19, 2019).

91 De Wert et al, *supra* note 26, at 456.

of research is practically impossible in those countries that have ratified the Oviedo Convention.

In several countries that have not signed the Oviedo Convention, such as Germany and Canada, a more explicit, overall prohibitive approach can be found.⁹² In these countries, editing the human germline involves crossing a red line, regardless of whether the intervention serves research or reproductive purposes. Isasi, Kleiderman, and Knoppers suggest that this type of prohibitive approach, with 'upstream' limitations on research activities in this field, is ultimately based on 'a critical attitude toward science because of fears of commodification of potential life,'⁹³ be it unborn life (ban on creating research embryos) or the life of the person-to-be (ban on germline editing). However, one can also imagine a different line of reasoning: research in this field is prohibited because it can be regarded as lacking purpose as long as the reproductive use of HGGE is categorically prohibited in these countries.

IV. FROM PROHIBITION TO REGULATION OF HGGE?

As discussed in the previous section, both national and international legal orders have been well prepared for the rise of HGGE technologies. In this case, it can be said that law outpaced technology, instead of, as is often claimed, the other way around. At the same time, it is clear that the first cracks are becoming visible within the existing legal frameworks in this field. A clear sign is that two EU member states, the UK and Greece, are currently at the global forefront of HNGT, even though the European legal order is among the strictest when it comes to the governance of genetic modification technologies.

For now, the challenges to existing human rights frameworks mostly take on the form of legal-technical disputes on the exact scope and meaning of terms such as 'germline genetic identity' and 'clinical trials' or the distinction between bans and moratoria. Yet, it is quite evident that behind this façade of legal technicalities a substantial, normative shift is taking place. Indeed, where most legal discussions have so far focused on the terms used within existing laws, discussions elsewhere focus on the question as to whether it is time to revise these laws altogether.

Ironically, just when technological developments in this field have finally caught up with existing legal frameworks and legal bans and restrictions could thus start to play the role as originally intended by the legislatures, these frameworks are being called into question by various parties. A straightforward explanation for this situation is offered by legal scholar Henry Greely: at the time, when the bans and restrictions on this technology were called into existence, many people were still in favor because 'it wasn't hard to renounce something that you could not do.'⁹⁴

Whatever the reason is, fact is that the call for a revision of existing laws on HGGE is growing louder, especially among scientific and medical-professional bodies, academies, and societies.⁹⁵ Examples are manifestos and open letters from groups

92 Isasi, Kleiderman & Knoppers, *supra* note 35, at 337.

93 Isasi, Kleiderman & Knoppers, *supra* note 35, at 337.

94 Quoted in Antonio Regalado, *Engineering the Perfect Baby*, MIT TECHNOLOGY REVIEW, Mar. 5, 2015.

95 For an overview of the ethics statements on HGGE, see Carolyn Brokowski, *Do CRISPR Germline Ethics Statements Cut It?*, 1 CRISPR JOURNAL 115 (2018); and Nuffield Council, *supra* note 38, at 129–132;

of biomedical scientists,⁹⁶ statements from medical-professional organizations,⁹⁷ advisory reports from various national science academies,⁹⁸ concluding statements from international summits organized by science academies,⁹⁹ and recommendations from health and ethics councils.¹⁰⁰

What these proposals have in common is that they ‘do not favor an international treaty that would ban all clinical uses of germline editing’,¹⁰¹ such as the Oviedo Convention’s ban. Such a prohibitive approach would be ‘too rigid’.¹⁰² Instead, they advocate a ‘responsible’,¹⁰³ ‘prudent path forward’.¹⁰⁴ This entails defining a ‘translational pathway to germline editing’,¹⁰⁵ along with developing a ‘pathway to effective governance’¹⁰⁶ of this technology. According to this line of thought, bans on HGGE for reproductive purposes will be needed for the time being, for example through a self-imposed temporary ban (‘moratorium’)¹⁰⁷ from the science community. However, the idea is that this ban can be lifted as soon as clinical requirements are met. From that moment on, a governance model for HGGE will replace the existing bans on this technology. In essence, the proposals for regulation instead of prohibition rest on three tiers.

First, basic and preclinical research in this area should be facilitated in order to make a safe introduction of this technology in the clinic possible. On a practical level, this also means that bans on the creation of embryos for research purposes, such as, for example, contained in Article 18 of the Oviedo Convention, have to be lifted.

96 E.g. David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36 (2015); Hinxton Group Statement, *Statement on genome editing technologies and human germline genetic modification*, 2015, http://www.hinxtongroup.org/Hinxton2015_Statement.pdf (accessed July 19, 2019); George Daley, Robin Lovell-Badge, Julie Steffann, *After the Storm: A Responsible Path for Genome Editing*, 380 NEW ENG. J. MED. 897 (2019); Eric Lander et al., *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165 (2019).

97 De Wert et al., *supra* note 26.

98 E.g. in the US: NATIONAL ACADEMIES OF SCIENCES, ENGINEERING AND MEDICINE, *Human Genome Editing: Science, Ethics, and Governance* (2017); in Germany: LEOPOLDINA, ACATECH, & UNION, *THE OPPORTUNITIES AND LIMITS OF GENOME EDITING* (2015); and in the Netherlands: KNAW, *GENOME EDITING. POSITION PAPER OF THE ROYAL NETHERLANDS ACADEMY OF ARTS AND SCIENCES* (2016).

99 E.g. Organizing Committee for the International Summit on Gene Editing, *On Human Gene Editing: International Summit Statement*, Washington Dec. 1–3, 2015, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a> (accessed July 19, 2019); Federation of European Academies of Medicine, *The Application of Genome Editing in Humans*, October 2017, <https://www.feam.eu/the-application-of-genome-editing-in-humans/> (accessed July 19, 2019); Organizing Committee for the International Summit on Gene Editing, *On Human Genome Editing II. Statement by the Organizing Committee of the Second International Summit on Human Genome Editing*, Hong Kong Nov, 29, 2018, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b> (accessed July 19, 2019).

100 E.g. Nuffield Council, *supra* note 38; NETHERLANDS COMMISSION ON GENETIC MODIFICATION (COGEM) & HEALTH COUNCIL OF THE NETHERLANDS (GEZONDHEIDSRaad), *EDITING HUMAN DNA: MORAL AND SOCIAL IMPLICATIONS OF GERMLINE GENETIC MODIFICATION* (2017).

101 Lander et al., *supra* note 96, at 168.

102 *Id.*

103 See the subtitle of Daley, Lovell-Badge, Steffann, *supra* note 96: ‘A Responsible Path for Genome Editing’.

104 See the title of Baltimore et al., *supra* note 96: ‘A Prudent Path Forward for Genomic Engineering and Germline Gene Modification’.

105 See statement from Organizing Committee for the International Summit on Gene Editing, *supra* note 99.

106 Robin Alta Charo, *Rogues and Regulation of Germline Editing*, 380 NEW ENG. J. OF MED. 977 (2019).

107 There is disagreement among those who propagate a pathway approach as to the need of a moratorium (for more details on this discussion, see Eli Adashi & I. Glenn Cohen, *Heritable Genome Editing: Is a Moratorium Needed?*, 322 JAMA 104 (2019)).

Second, as soon as HGGE is found safe enough for introduction in the clinic, these proposals recommend lifting the ban on this technology. From then on, HGGE should be made available for strictly therapeutic purposes, that is, to eliminate serious genetic diseases and conditions. Reproductive use of HGGE for nonmedical reasons, such as improving intelligence or appearance, must remain prohibited, at least initially.¹⁰⁸ Third, the proposals underline the importance of a public debate on the issue. That public debate should focus on the conditions under which reproductive HGGE should be allowed.

How should these proposals for a regulatory pathway to reproductive HGGE be viewed from a human rights perspective? Evidently, they conflict with the existing bans on the clinical use of this technology, as contained in the Oviedo Convention and as suggested by UNESCO's IBC. Nevertheless, both the Council of Europe's Committee on Bioethics¹⁰⁹ and UNESCO's IBC¹¹⁰ have stressed the need for an ongoing public debate about the human rights questions raised by these technological developments. Indeed, Article 28¹¹¹ of the Oviedo Convention explicitly recognizes the general need for public debate on such questions. Moreover, it is widely recognized that even fundamental rights and their underlying principles are open to dynamic or evolutive interpretation.¹¹² Therefore, notwithstanding the current human rights bans on genetically modifying offspring, the need for a debate on the meaning of human rights for this technology has never been more urgent.

By means of this article, I hope to contribute to the debate. Hereafter, I formulate three concerns about the recent proposals for a regulatory pathway to HGGE, using human rights discourse as my main frame of reference. First, I argue that this model is based on a distinction between healing and enhancing offspring that may be useful and realistic enough for the regulation of PGD but is much more problematic in the case of human germline editing (Section V). Second, although these proposals also refer to human rights, they rely on an impoverished understanding of what human rights and human dignity mean in the context of biolaw (Section VI). Third and finally, I discuss how this impoverished understanding of human rights sets the stage for a type of deliberation on HGGE in which the voice of the scientific community dominates at the cost of more public perspectives (Section VII).

V. THE BLURRING BOUNDARY BETWEEN TREATMENT AND ENHANCEMENT

Have existing bans on HGGE become 'outdated'¹¹³ in the light of recent technological developments? Should we 'update' these legal frameworks 'to recognize, permit, and

108 The UK Nuffield Council on Bioethics takes a different stance and rejects the medical boundary between healing and enhancing as a useful red line. This will be discussed in further detail in Section V.

109 Committee on Bioethics, *supra* note 59.

110 International Bioethics Committee, *supra* note 68, sub 117 & 118.

111 'Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.'

112 See, e.g., ECtHR, Apr. 25, 1978, *Tyrer v. UK*, application no. 5856/72.

113 Peter Sykora & Arthur Caplan, *The Council of Europe Should Not Reaffirm the Ban on Germline Genome Editing in Humans*, 18 EMBO REPORTS 1871 (2017).

regulate new techniques to allow safe HGGE for therapeutic and preventive aims’?¹¹⁴ At first sight, these thoughts, which can be recognized in publications from, for example, the US National Academies of Sciences, Engineering and Medicine (NASEM), the UK Nuffield Council on Bioethics, the Hinxton Group, the European Society of Human Reproduction and Embryology (ESHRE), the European Society of Human Genetics (ESHG), and several prominent scholars,¹¹⁵ seem convincing. After all, how can one oppose the prevention of grave diseases?

Moreover, under most of these proposals, the use of HGGE with the purpose of enhancing offspring remains off-limits. From a human rights perspective, the distinction between healing and enhancing is a highly relevant one. For example, while Article 13 of the Oviedo Convention categorically bans heritable genome editing, it also states that human genetic modifications in general can only be undertaken for preventive, diagnostic, or therapeutic purposes. Similarly, Article 14 prohibits ‘the use of techniques of medically assisted procreation [. . .] for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease is to be avoided.’

Furthermore, it can be argued that a regulatory model will be more realistic and effective than a prohibitive model. Alta Charo, for example, writes that ‘calling for a moratorium may feel satisfying, [but] it does little to stop rogue actors, nor does it help scientists who [. . .] wish to pursue the technology cautiously and responsibly.’ According to this pragmatic line of reasoning, a comprehensive regulatory approach ‘will do more to control and guide this technology than a moratorium or formal ban.’¹¹⁶ In a similar vein, several authors fear that a prohibitive approach would fuel CRISPR tourism.¹¹⁷

Finally, the fear for a slippery slope toward eugenics seems unfounded if a sound regulatory framework is established with strict and transparent limits to the use of HGGE. Indeed, the proposed regulatory frameworks show strong resemblance to the regulatory schemes that have been developed in many countries to regulate PGD. Hence, some refer to this governance model for HGGE as the ‘PGD model’.¹¹⁸ Genetically selecting embryos for reproductive purposes through PGD are, typically, only permitted according to medically determined requirements, such as the gravity of the genetic condition for which PGD is used and whether it is untreatable.¹¹⁹ These legal limits of PGD are usually established through a regulatory mix of national laws and medical-professional guidelines and appear to work quite effectively and convincingly in these countries.

114 *Id.*

115 E.g. Isasi, Kleiderman & Knoppers, *supra* note 35; Alta Charo, *Rogues*, *supra* note 93; Sykora & Caplan, *supra* note 99.

116 Alta Charo, *Rogues*, *supra* note 106, at 976.

117 E.g. Eli Adashi & I. Glenn Cohen, ‘Germline Editing: Could Ban Encourage Medical Tourism?’, 569 *NATURE* 40 (2019). Elsewhere, I critically discuss the pragmatic line of reasoning with regard to reproductive tourism, see Britta van Beers, *Is Europe ‘Giving in to Baby Markets’? Reproductive Tourism in Europe and the Gradual Erosion of Existing Legal Limits to Reproductive Markets*, 23 *MED. L. REV.* 103 (2015).

118 Isasi, Kleiderman & Knoppers, *supra* note 35, at 339.

119 *Id.*

However, in order to make the PGD model truly effective and feasible in case of HGGE, a clear demarcation of the terms ‘serious disease or condition’ is necessary.¹²⁰ If this turns out to be practically impossible, then those who, like Lanphier *et al.*, ‘oppose germline modification on the grounds that permitting even unambiguously therapeutic interventions could start us down a path toward nontherapeutic genetic enhancement’¹²¹ have a valid point.¹²²

Upon closer inspection, there are several substantial differences between PGD and human germline editing that suggest that it is problematic to apply the PGD model without reservations to germline editing. First, the risk of a slippery slope is much greater in case of HGGE. Contrary to PGD, HGGE breaks with the principle of reproduction through genetic recombination. Consequently, the number of possible choices increases exponentially. For example, as discussed, the Chinese genetically modified twins have a novel variation of the CCR5 gene that has not been seen in humans before. Moreover, in theory, it is possible to introduce not only nonparental DNA but also even nonhuman DNA. The Nuffield Council offers an interesting list of several possibilities opened up by CRISPR, including creating ‘supersenses or superabilities’ and ‘tolerance for adverse environmental conditions (such as those that might be envisaged as a result of climate change or in space flight)’. As the Nuffield Council explains, ‘what opens up these possibilities is a change in perspective from one focused on the achievement of a limited purpose—one that may have animated the initial research and innovation—to a vision animated by the exploitation of a technology to secure the maximum value from its use.’¹²³ Accordingly, it can be said that the eugenic potential of HGGE exceeds that of PGD multiple times.¹²⁴

Second, compared with PGD, it will be even more difficult to define what ‘therapeutic’ means in case of HGGE. The Chinese CRISPR babies offer a striking illustration of that difficulty. Did He Jiankui’s intervention serve a medical purpose? The biophysicist sought to make the babies resistant to infection from HIV. In other words, he was not trying to cure them from a disease. Instead, he exposed these babies, with whom in principle nothing was wrong, to serious health risks. At the same time, the intervention could perhaps be labeled as medical, because its main purpose was the prevention of a disease: AIDS.¹²⁵

If the possible side effects of the genetic intervention are also taken into account, the discussion becomes even more complex. According to neurobiologists, it is quite likely that He’s intervention also affected various brain functions. More specifically, the inhibition of that particular gene has been linked to greater recovery of neurological

120 For an analysis of and possible human rights approach to this issue, see Erika Kleiderman, Vardit Ravitsky & Bartha Knoppers, *The ‘Serious’ Factor in Germline Modification*, 45 J MED ETHICS 508 (2019).

121 Edward Lanphier *et al.*, *Do not Edit the Human Germline*, 519 NATURE 411 (2015).

122 Likewise, the European Group on Ethics writes in its 2016 *Statement on Gene Editing* that ‘the blurring of the lines between clinical applications in pursuit of therapeutic or enhancement goals [. . .], must be considered’ (see European Group on Ethics, *supra* note 90).

123 Nuffield Council, *supra* note 38, at 47.

124 However, according to the Nuffield Council, concerns about function creep and slippery slopes can be countered through reliable regulation (see Nuffield Council, *supra* note 38, at 53–55).

125 For a more elaborate discussion of the difficulty to define ‘therapeutic’ in the context of HGGE, see Eric T. Juengst, *Crowdsourcing the Moral Limits of Human Gene Editing?*, 47(3) HASTINGS CENT. REP. 15, 21 (2017).

impairments and improvement of cognitive functions.¹²⁶ It is, therefore, possible that He's genetic modifications also resulted in human enhancement, more specifically, cognitive enhancement.¹²⁷ Such 'incidental enhancements' complicate line drawing substantially.¹²⁸

Third, in many cases of HGGE, it will be hard, if not impossible, to decide whether the interference yields an overall positive impact on the future child's health, with positive effects outweighing the negative ones. Again, He's 'genetic surgery' offers the perfect example of the complexities. Even if his genetic modification turns out to be successful, with off-target effects kept to a minimum, there still is a reason to doubt whether it has truly benefitted the twins. According to geneticists, the intended genetic mutation may provide resistance against HIV infection, but it also increases the vulnerability to infection from the West Nile virus and influenza.¹²⁹ As such, the Chinese case offers a glimpse of the complex trade-offs and vexing dilemmas with which the reproductive use of CRISPR would confront parents-to-be.¹³⁰

In short, HGGE is likely to result in a further blurring of the medical boundary between healing and enhancing. Moreover, it can be argued, as the Nuffield Council does, that 'we have to take care when applying categories such as "therapy" and "enhancement" [...] to the anticipation of people who do not yet (and may never) exist.'¹³¹

What does all of this imply for the governance of HGGE? For the Nuffield Council, the conclusion is that the medical boundary is too problematic to be able to function as a red line for human germline modification.¹³² The advisory body proposes a new legal-ethical standard: the genetic intervention should serve the welfare of the future child. As the Nuffield Council explains, this means that 'there is no *a priori* reason that preferences beyond the avoidance of disease should not also be consistent with the welfare of the future person.'¹³³

It has to be said that the Nuffield Council's proposal for governing HGGE is more realistic than the PGD model that is recommended by most scientific and professional bodies and organizations. However, the UK proposal is also much more radical: the medical boundary (which only allows interventions of a therapeutic or preventive nature) is abandoned, with the result that human enhancement also becomes one

126 Mary Joy et al., *CCRS Is a Therapeutic Target for Recovery after Stroke and Traumatic Brain Injury*, 176 CELL 1143 (2019).

127 Antonio Regalado, 'China's CRISPR twins might have had their brains inadvertently enhanced', MIT TECHNOLOGY REVIEW, Feb. 21, 2019.

128 For this expression, and for an elaborate discussion of this issue, see Eric T. Juengst et al., *Is Enhancement the Price of Prevention in Human Gene Editing?*, 1 CRISPR JOURNAL 351, 353 (2018).

129 Kolata & Belluck, *supra* note 4.

130 Given these complexities, future parents may come to rely on algorithms for reproductive decisionmaking, not only in the case of 'easy PGD' (a combination of in vitro gametogenesis, PGD and genome sequencing, see HENRY GREELY, *THE END OF SEX AND THE FUTURE OF HUMAN REPRODUCTION* (2016)), as Sonia Suter has set out in a recent article (*The Tyranny of Choice*, 5 J. LAW BIOSCI. 262 (2018) but also in the context of heritable germline editing.

131 Nuffield Council, *supra* note 38, at 71.

132 *Id.* at 71 and 91–92.

133 *Id.* at 76.

of the possibilities.¹³⁴ This is also problematic from a human rights perspective. As UNESCO's IBC writes:

The goal of enhancing individuals and the human species by engineering the genes related to some characteristics and traits [...] impinges upon the principle of respect for human dignity in several ways. It weakens the idea that the differences among human beings, regardless of the measure of their endowment, are exactly what the recognition of their equality presupposes and therefore protects. It introduces the risk of new forms of discrimination and stigmatization for those who cannot afford such enhancement or simply do not want to resort to it.¹³⁵

Evidently, another conclusion is also possible. If it is practically impossible to draw a sharp line between therapy and enhancement in this context, is the promise of a strictly regulated and limited use of HGGE not fundamentally illusory? Moreover, if HGGE remains prohibited, the interests of prospective parents with serious genetic diseases in their families can continue to be taken seriously. In almost all cases, PGD already offers these couples the possibility of reproducing without passing on their genetic disorders, with the added benefit that such an arrangement is considerably less risky and radical in nature.

VI. INDIVIDUAL AND COLLECTIVE DIMENSIONS OF HUMAN RIGHTS LAW

A second set of questions elicited by the recent proposals to revise current laws on human germline editing relates to their understanding of the concept of human rights and human dignity. While this understanding tacitly informs many of these proposals, it is explicitly addressed by legal scholar Robin Alta Charo, who is a member of the organizing committee of the Hong Kong International Summit on Human Genome Editing and co-author of the 2017 NASEM report. In an essay she wrote on the occasion of a symposium the seventieth anniversary of the Universal Declaration on Human Rights, Alta Charo argues 'that the current human rights law on germline editing misunderstands both the mechanisms of genetics and the moral basis for human rights, suggesting a more nuanced approach as we move forward and keep pace with new gene-editing technologies.'¹³⁶ In other words, Alta Charo is open about the fact that her interpretation breaks with existing human rights approaches to this issue. Interestingly, as will be discussed hereafter, her exploration of the moral basis of human rights even leads her to suggest that, ultimately, the concept of humanity may not be necessary for the proper functioning of human rights discourse at all.

It seems Alta Charo is not alone in her line of reasoning. In a similar vein, the recent calls for a regulatory pathway to HGGE do not or hardly make mention of humankind, human dignity, or the human species. To come to a better understanding of the normative shift that is thus taking place in this context, I first describe the vision of human rights and human dignity as implied by the existing human rights law on

134 For a comparison between the NASEM report and the Nuffield Council Report, see Eli Adashi & I. Glenn Cohen, *The Ethics of Heritable Genome Editing: New Considerations in a Controversial Area*, 320 JAMA 2531 (2018).

135 International Bioethics Committee, *supra* note 68, sub 111.

136 Robin Alta Charo, *Germline Engineering and Human Rights*, 112 AJIL UNBOUND, 344 (2018).

germline editing. I then juxtapose it with the vision on human rights as unfolded in the recent proposals to replace the bans on genetically modifying offspring with regulatory schemes.

Within the Oviedo Convention and the Universal Declaration on the Human Genome and Human Rights, fundamental interests of both an individual and a collective nature are protected. According to its Explanatory Report, the Oviedo Convention aims to address concerns about biomedical developments at three levels: the level of the individual; the level of society; and the level of the human species.¹³⁷ Similarly, UNESCO's IBC states that the rise of HGGE necessitates reflection about the possible consequences of this technology 'on human rights and freedoms as well as on the future of humanity itself.'¹³⁸ Moreover, the IBC stresses that 'ethics is not simply a matter of individual morality but it involves society as a whole' and 'must therefore also pursue the common good.'¹³⁹ In that context, the committee warns for 'a radical conception of autonomy, according to which any medical progress should be at the disposal of patients, who are turned into consumers (clients).'¹⁴⁰

Accordingly, human dignity is explained within this approach as a legal principle that not only affords protection to individual rights and freedoms (referred to within scholarly literature as 'the individual dimension of human dignity' or 'dignity as empowerment') but also to the collective interests of humanity upon which human rights are built ('collective dimension of human dignity' or 'dignity as constraint').¹⁴¹ Concerns about both dimensions of human dignity can be detected in the Council of Europe's and UNESCO's approach to human germline editing.

As to dignity's individual dimension, both human rights bodies, evidently, subscribe to the necessity of clinical safety. They also underline that new genetic technologies 'are likely to offer unprecedented tools against diseases.'¹⁴² However, they are concerned that HGGE may give rise to new forms of discrimination and may impact negatively on the self-perception and sense of freedom of the resulting individuals. UNESCO's IBC, for example, expresses the fear that social-economic inequalities will become engrained on a genetic level¹⁴³ and expresses concern about 'the significant effects on the life of individuals who could be considered designed on demand by someone else without their consent.'¹⁴⁴

As to dignity's collective dimension, these human rights bodies stress that, while genome editing in general is 'one of the most promising undertakings of science for the sake of all humankind',¹⁴⁵ reproductive HGGE may lead to a renewal of eugenics.¹⁴⁶

137 Explanatory Report Oviedo Convention, *supra* note 57, sub 14.

138 International Bioethics Committee, *supra* note 68, sub 34.

139 *Id.* sub 30.

140 *Id.* sub 28.

141 E.g. DERYCK BEYLEVELD & ROGER BROWNSWORD, HUMAN DIGNITY IN BIOETHICS AND BIOLAW (2002); Roberto Andorno, *Human Dignity and Human Rights as a Common Ground for a Global Bioethics*, 34 J. MED. PHILOS. 223 (2009); Micha Werner, 'Individual and collective dignity', in: THE CAMBRIDGE HANDBOOK OF HUMAN DIGNITY: INTERDISCIPLINARY PERSPECTIVES 343 (Marcus Duenwell, Jens Braarvig, Roger Brownsword & Dietmar Mieth eds., 2014).

142 International Bioethics Committee, *supra* note 68, sub 128.

143 *Id.* sub 108.

144 *Id.* sub 105.

145 *Id.* sub 103.

146 *Id.* sub 107.

More specifically, as discussed above, international bans on this technology aim to prevent practices in which individuals or entire groups are produced with particular characteristics and required qualities.¹⁴⁷ The underlying logic appears to be that human dignity is affected by HGGE to the extent that this technology opens up the possibility of one person designing the other.

Within this approach, the collective and individual dimensions of human dignity are regarded as inextricably and fundamentally connected, even though it is clear that certain tensions may arise between both sides. The underlying thought which unites both dimensions is that fundamental freedoms cannot be exercised to the detriment of the collective foundations of these freedoms, which is the humanity of humankind. The IBC expresses this fundamental thought in the context of germline editing as follows: 'the human genome [is] one of the premises of freedom itself and not simply [...] raw material to manipulate at leisure.'¹⁴⁸ The other way around, collective dignity should always serve the long-term goal of protecting individual dignity,¹⁴⁹ just as human dignity as empowerment and human dignity as constraint both serve to protect the individual. Without this caveat, there is a danger that individual freedoms are sacrificed to preserve 'the dignity of the whole.'¹⁵⁰ Accordingly, Article 2 of the Oviedo Convention states that 'the interests and welfare of the human being shall prevail over the sole interest of society or science.'

In line with the emphasis on both individual and collective interests, a recurring thought within this approach is that 'the human genome, metaphorically speaking, belongs to all of us',¹⁵¹ and that, 'in a symbolic sense, it is the heritage of humanity' (Article 1 Universal Declaration on the Human Genome and Human Rights). As these technologies touch upon the future of human reproduction, they merit a broad international and societal debate. In other words, from this perspective, 'no one has the moral warrant to go it alone' when it comes to HGGE.¹⁵²

In contrast, many who advocate lifting the ban on HGGE neglect or even negate the collective dimensions of human rights. More specifically, whereas the Oviedo Convention addresses concerns at the level of the individual, of society, and of the human species, the recent proposals rely exclusively on the first two. In this vein, the Nuffield Council's main line of reasoning with regard to HGGE rests on two principles: the principle of the welfare of the future person and the principle of social justice and solidarity. Accordingly, it recommends lifting the ban on HGGE, first, for purposes that are in line with the future child's welfare (i.e. level of the individual)¹⁵³ and, second, in circumstances in which it cannot be reasonably expected to produce or exacerbate social inequalities (i.e. level of society).¹⁵⁴ As to concerns at the level of the human

147 Explanatory Report Oviedo Convention, *supra* note 57, sub 89.

148 International Bioethics Committee, *supra* note 68, sub 128.

149 Andorno, *Human Dignity*, *supra* note 141, at 233; GERMAN ETHICS COUNCIL, INTERVENING IN THE HUMAN GERMLINE: EXECUTIVE SUMMARY & RECOMMENDATIONS sub 55 (2019).

150 Andorno, *Human Dignity*, *supra* note 141, at 233; TERESA IGLESIAS, THE DIGNITY OF THE INDIVIDUAL: ISSUES OF BIOETHICS AND LAW 3 (2001).

151 Baylis, *Human Genome Editing*, *supra* note 33, at 44.

152 Katie Hasson & Marcy Darnovsky, *Gene-Edited Babies: No One Has the Moral Warrant to Go It Alone*, GUARDIAN, Nov. 27, 2018. Also see International Bioethics Committee, *supra* note 68, sub 116.

153 Nuffield Council, *supra* note 38, at 75.

154 Nuffield Council, *supra* note 38, at 87.

species, the Nuffield Council actively dismisses human dignity as a guiding principle for the governance of HGGE,¹⁵⁵ because of reasons that will be discussed below.

A similar line of reasoning can be detected in the NASEM report on human gene editing. The authors of this report describe their own normative framework as follows:

The committee focused on principles that are aimed at protecting and promoting the health and well-being of individuals; approaching novel technologies with careful attention to constantly evolving information; respecting individual rights; guarding against unwanted societal effects; and equitably distributing information, burdens, and benefits.¹⁵⁶

No mention is made of the various collective interests of humankind. Moreover, where the report does mention human dignity, it brings only dignity's individual dimension to the fore, as in the following sentence: 'The principle of respect for persons requires recognition of the *personal* dignity of all individuals, acknowledgment of the centrality of personal choice, and respect for individual decisions' (emphasis added).¹⁵⁷

In brief, in both the NASEM and Nuffield Council report, the collective dimensions of human rights discourse and human dignity are pushed aside. What remains are considerations related to safety risks, individual rights, reproductive autonomy, and social justice. How can this normative shift be explained? The Nuffield Council invokes the well-known line of thinking that human dignity is a vague or even useless concept¹⁵⁸ and that it does not have added value to the functioning of human rights: 'Whereas human dignity has been advanced by some as the basis of human rights, the coherent functioning of human rights discourse does not depend on accepting this claim'.¹⁵⁹ Moreover, even if it can be agreed that human dignity is the basis of human rights, then it would still not be at stake with HGGE. This is because 'entitlement to human rights does not depend on the possession of a "human genome"'.¹⁶⁰ To suggest otherwise, would be to engage in 'genomic essentialism', the authors of the report argue.¹⁶¹ Other authors,¹⁶² including Alta Charo,¹⁶³ argue along similar lines.

I agree that such essentialism would indeed be problematic: the human species has evolved over time and it would be reductionist to understand both dignity and humanity in genetic terms. However, that is not what the existing human rights law in this field claims to protect. Indeed, Article 3 of the Universal Declaration on the Human

155 Especially see box 3.4 in the report, that is entirely devoted to this argument (Nuffield Council, *supra* note 38, at 93–94).

156 National Academies, *supra* note 98, at 32.

157 *Id.* p. 34.

158 At this point the Nuffield Council refers to Ruth Macklin, *Human Dignity Is a Useless Concept*, 327 *BRITISH MED J* 1419 (2003); and Mirko Bagaric & James Allan, *The Vacuous Concept of Dignity*, 5 *J. HUMAN RIGHTS* 257 (2006).

159 'Whereas human dignity has been advanced by some as the basis of human rights, the coherent functioning of human rights discourse does not depend on accepting this claim' (Nuffield Council, *supra* note 38, at 94).

160 Nuffield Council, *supra* note 38, at 96.

161 *Id.* at 92.

162 E.g. Iñigo de Miguel Beriain, *Human Dignity and Gene Editing*, *EMBO REPORTS*, e46789, (2018); Peter Mills, *Genome Editing, Human Rights and the 'Posthuman'*, 3 October 2017, <http://nuffieldbioethics.org/blog/genome-editing-human-rights-posthuman> (accessed July 19, 2019).

163 Alta Charo, *Germline Engineering*, *supra* note 136, at 348–349.

Genome and Human states that ‘the human genome, which by its nature evolves, is subject to mutations.’ Accordingly, as discussed in Section III.B, the ban on HGGE as contained in human rights law is not so much about the preservation of the human genome, but about the fear that HGGE would give rise to new forms of discrimination and eugenics.¹⁶⁴

Furthermore, questions can be asked about the NASEM’s and Nuffield Council’s own understanding of humanity and dignity. As already discussed, in these reports, human dignity is equated with the protection of individual freedoms, thereby ignoring the collective dimension of that principle. This does impoverish not only human rights discourse but also the public debate on this issue, as will be discussed in the next section.

Moreover, these proposals appear to pave the way for a more transhumanist or posthumanist approach. As already discussed, the Nuffield Council is not willing to hold on to the medical boundary between healing and enhancing. Additionally, when discussing transhumanism in its report, the UK ethics body suggests that if human germline editing were to result in ‘the self-overcoming of the human species,’¹⁶⁵ this would not necessarily be problematic. Indeed, it may be warranted because of the huge impact that humankind is having on the environment in an age that is already being referred to as the ‘Anthropocene’. According to the Nuffield Council, if certain parts of the world became inhabitable because of air pollution or climate change, ‘genome editing could offer a remedy to this predicament by allowing the introduction of characteristics that will fit future generations better for the conditions in which they may be required to live.’¹⁶⁶ Even though the authors of the report admit that ‘such a project would be reckless at present’, they argue that the precautionary principle ‘would at least seem to mandate further research and development of genome editing technologies as a way of hedging against future threats.’¹⁶⁷ In other words, based on this remarkable view of the role that the precautionary principle would have to play in the Anthropocene, the authors argue that a good response to the negative impact that humans are having on the natural world would be to also subject ‘human nature’ to human intervention. This is in sharp contrast with views held by, for example, the German Ethics Council. According to the Council, given the fact that the current geological epoch is already referred to as the Anthropocene, and given the manner in which the human genome is strongly linked to individual and collective self-images of humankind, more extensive reflection processes are needed to be able to bear responsibility for the heavy decisions to come.¹⁶⁸

In a similar vein, Peter Mills, assistant director of the Nuffield Council, openly questions the humanist foundations of human rights discourse altogether. He argues that:

whatever the ground of ‘human’ rights is, it should be seen as a threshold rather than a property exclusive to natural kind or class. It follows, therefore, that such rights as are

164 Françoise Baylis & Lisa Ikemoto, *The Council of Europe and the Prohibition on Human Germline Genome Editing*, 18 EMBO REPORTS 2084 (2017).

165 Nuffield Council, *supra* note 38, at 91.

166 *Id.* at 90–91.

167 *Id.*

168 German Ethics Council, *supra* note 149, at 4.

currently enjoyed by humans should equally extend to a non-human, a posthuman or even an artificial intelligence, who is capable of being welcomed into our moral community.¹⁶⁹

Alta Charo agrees with Mills on this. In the closing words of her essay on germline engineering and human rights, she raises the possibility of a human rights discourse that dispenses with the notion of the human altogether:

Understanding that *Homo sapiens* is a species with blurry boundaries, and that we carry within us genetic traits that trace back to Neanderthals and even far more primitive life forms, should make us question whether germline editing in any way undermines the basis for according human rights, and indeed, whether being human is essential to human rights at all.¹⁷⁰

Evidently, the idea of a human rights approach without a notion of the human is a radical departure from the humanist foundations of human rights discourse. Moreover, Alta Charo's, Mills', and the Nuffield Council's line of argumentation raises the question as to whether their understanding of human rights and human dignity does not give rise to a self-destructive dynamic within human rights discourse: what, initially, appears as merely a reinterpretation of humanist notions such as human rights and freedoms gives rise, in the long run, to the possibility of an abandonment of humanism altogether or even a self-overcoming of the human species.¹⁷¹

VII. FROM HUMAN RIGHTS TO SELF-REGULATION BY THE SCIENTIFIC COMMUNITY?

The neglect of the more communal or collective dimensions of human rights, as they come to expression in principles such as human dignity or the view of the human genome as heritage of humankind, also has repercussions for the terms in which the public deliberation about this issue is framed. Instead of asking the question which kind of future the human community wants to build for itself, the issue is narrowed to questions of safety risk, reproductive rights of prospective parents, and health interests of future children. Evidently, the health and rights of those directly involved in HGGE are of great concern and need to be taken very seriously. However, more is at stake. Human rights law in this field does aim to protect not only the rights of prospective parents and their future offspring but also the rights and interests of future generations. It does aim to protect not only our health but also our humanity. In other words, 'human genome editing raises questions that cannot be dealt with only in terms of medical ethics principles relating to safety, informed consent and individual reproductive rights'.¹⁷²

Moreover, because this technology may determine the future of human reproduction, it is a collective responsibility of society to take 'stock of alternative imaginable

169 Mills, *supra* note 162.

170 Alta Charo, *Germline Engineering*, *supra* note 136, at 349.

171 This is also one of the central theses of Harari's bestseller *Homo Deus*: 'The rise of humanism also contains the seeds of its downfall. While the attempt to upgrade into gods takes humanism to its logical conclusion, it simultaneously exposes humanism's inherent flaws' (YUVAL HARARI, *HOMO DEUS: A BRIEF HISTORY OF TOMORROW* 65 (2016)).

172 Van Est et al., *supra* note 34, at 15.

futures' and to decide 'which ones are worth pursuing and which ones should be regulated, or even prevented.'¹⁷³ As such, HGGE is one of the most striking examples of the more general need to 'reclaim biotechnology for the common good.'¹⁷⁴ Accordingly, the future of HGGE deserves a broad, democratic debate in which society's long-term aspirations and visions of the good life can be explored and imagined.¹⁷⁵

However, so far, a certain perspective dominates. Characteristic for the recent proposals to move from prohibiting to regulating HGGE is the central position afforded to biomedical professionals and scientific bodies in that process. Not only is self-regulation by the biomedical community propagated in the form of 'the Asilomar'¹⁷⁶ model,¹⁷⁷ but also the voice of biomedical researchers and professionals becomes decisive within regulation as soon as it is based primarily on medical standards such as clinical safety and prevention of serious diseases.¹⁷⁸ Indeed, the position taken by certain scientific bodies has gradually become more outspoken over the years. Even the birth of the genetically modified twins in China has not been able to break this trend thus far. Especially, striking in that regard is the changing view on the need and purpose of broad societal discussion and consensus. The evolving position of the national science academies of the USA, China, and the UK can serve as an example.

In December 2015, the US National Academy of Sciences, the US National Academy of Medicine, the Chinese Academy of Sciences, and the UK Royal Society together hosted the first International Summit on Human Gene Editing in Washington, DC. During this 3-day event, experts from around the world came together to discuss the scientific, ethical, and legal questions raised by human gene-editing. The event was concluded with a so-called summit statement, which included recommendations with regard to HGGE. According to the organizing committee:

it would be irresponsible to proceed with any clinical use of germline editing unless and until (i) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad societal consensus about the appropriateness of the proposed application.¹⁷⁹

Moreover, the committee stressed the need for an international forum to discuss these matters and called upon national academies of China, the UK, and the USA to take the

173 Sheila Jasanoff, J. Benjamin Hurlbut & Krishanu Saha, *CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation*, 32 ISSUES SCI. TECHNOL. 25 (2015).

174 See DONNA DICKENSON, *ME MEDICINE VS. WE MEDICINE: RECLAIMING BIOTECHNOLOGY FOR THE COMMON GOOD* (2013); and BRITTA VAN BEERS, SIGRID STERCKX AND DONNA DICKENSON (EDS.), *PERSONALISED MEDICINE, INDIVIDUAL CHOICE AND THE COMMON GOOD* (2018).

175 Elsewhere, I offer further reflection on the need for public imagination in the debate on human germline genetic modification (see Britta van Beers, *Imagining Future People in Biomedical Law: From Technological Utopias to Legal Dystopias Within the Regulation of Human Genetic Modification Technologies*, in: *RISK AND THE REGULATION OF UNCERTAINTY IN INTERNATIONAL LAW* 117 (Monika Ambrus, Rosemary Rayfuse & Wouter Werner eds. 2017)).

176 Jasanoff, Hurlbut & Saha, *supra* note 173.

177 See, for example, Baltimore et al., *supra* note 96.

178 Jasanoff, Hurlbut & Saha, *supra* note 173.

179 *On Human Gene Editing: International Summit Statement*, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a> (accessed Aug. 1, 2019).

lead in this. Accordingly, in the following years, national science bodies from the USA and UK issued reports on the subject.

First, the NASEM published a report on gene editing in February 2017. The report indicates a subtle, yet important shift. Whereas the 2015 Summit statement endorses a ‘not allowed, unless’ approach to human germline editing, the NASEM seem to switch to ‘allowed, if’, as becomes clear in the following excerpt from the report’s public summary:

Given both the technical and societal concerns, the committee concludes there is a need for caution in any move toward germline editing, but that caution does not mean prohibition. It recommends that germline editing research trials might be permitted, but only after much more research to meet appropriate risk/benefit standards for authorizing clinical trials. Even then, germline editing should only be permitted for compelling reasons and under strict oversight.¹⁸⁰

Even if the NASEM equally underlines the importance of input by the public, a partially new stance now seems to be taken compared with the 2015 Summit statement, which narrows the scope of the propagated public debate considerably. The tacit normative shift in the NASEM approach to human germline editing is aptly described in a 2017 report on human germline editing from the German Ethics Council:

It is clear that the US-American academies are no longer focusing on a partially fundamental, partially risk-related strong rejection of germline therapy by genome editing but on a fundamental permission guided by individual formal and material criteria. [...] Apparently, speculations now concentrate less on whether but rather only on when the first genetically modified [babies] by genome editing will be born.¹⁸¹

In July 2018, the UK Nuffield Council on Bioethics issued its report on HGGE, in which, as discussed in the previous sections, the Nuffield Council takes an even more permissive approach than the NASEM by also leaving the door open to HGGE for enhancement purposes.

In November 2018, the Second International Summit on Human Gene Editing took place in Hong Kong, only days, as mentioned, after He’s shocking announcement. A day before the 3-day summit’s official kick-off, the organizing committee issued a statement in response to the news on the Chinese CRISPR babies.¹⁸² The statement, in which little of the general indignation about He’s actions can be recognized, was criticized by many as rather ‘bland’.¹⁸³ A stronger condemnation followed, however, in the committee’s concluding statement. Even so, it is evident from the words used in that

180 See *Report Highlights*, p. 3, available at: <https://www.nap.edu/resource/24623/Human-Genome-Editing-highlights.pdf> (accessed Aug. 1, 2019). Also see National Academies, *supra* note 98, at 134–135 and 189–190.

181 DEUTSCHER ETHIKRAT, GERMLINE INTERVENTION IN THE HUMAN EMBRYO: GERMAN ETHICS COUNCIL CALLS FOR GLOBAL POLITICAL DEBATE AND INTERNATIONAL REGULATION 3 (2017).

182 *Statement from the Organizing Committee on Reported Human Embryo Genome Editing*, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11262018> (accessed Aug. 1, 2019).

183 E.g. Ed Yong, *The CRISPR Baby Scandal Gets Worse by the Day*, THE ATLANTIC, Dec. 3, 2018, <https://www.theatlantic.com/science/archive/2018/12/15-worrying-things-about-crispr-babies-scandal/577234/> (accessed July 19, 2019).

concluding statement that the trend toward a more permissive approach has not been reversed by the news from China. On the contrary, unlike its predecessor, this summit's organizing committee proposes that a 'translational pathway' be developed toward the clinical use of this technology.

The organizing committee concludes that the scientific understanding and technical requirements for clinical practice remain too uncertain and the risks too great to permit clinical trials of germline editing at this time. Progress over the last three years and the discussions at the current summit, however, suggest that it is time to define a rigorous, responsible translational pathway toward such trials.

A translational pathway to germline editing will require adhering to widely accepted standards for clinical research, including criteria articulated in genome editing guidance documents published in the last three years [reference at this point to aforementioned NASEM and Nuffield Council reports]. Such a pathway will require establishing standards for preclinical evidence and accuracy of gene modification, assessment of competency for practitioners of clinical trials, enforceable standards of professional behavior, and strong partnerships with patients and patient advocacy groups.¹⁸⁴

The first summit's requirement of 'broad societal consensus' is barely mentioned anymore beyond underlining the need for 'strong partnerships with patients and patient advocacy groups'. Therefore, as Greely writes, the second summit's concluding statement can be read as saying: 'There are a lot of technical things scientists need to figure out before this can be done. The public should have a chance to comment, but they will not make the decisions. We will.'¹⁸⁵

In brief, although the need for public debate and democratic deliberation on the matter is formally recognized, the common tenor within the scientific community is that the main question to be answered is not whether HGGE should be pursued, but how and under which circumstances.¹⁸⁶ Moreover, the general thought seems to be that the answer to the 'how question' can also largely be provided by the scientific community itself, for example, through the erection of self-regulating oversight bodies and the development of protocols.

Although scientists will need to be involved in the decision-making on this issue, primarily to provide inside information on the latest technological developments and on possible health risks, the dominance of the voice of scientists in current debates on heritable genome editing is a reason for concern. For Petra De Sutter, a Belgian professor of gynecology and Rapporteur for the Council of Europe's Parliamentary Assembly, the risk of conflicts of interest is the main problem:

There is a natural tendency for scientists to want to be the pioneers of genetic technology developments, to endeavour to publish papers thereon and to reap economic benefits from their research (for example by participating in technological companies). This raises the question of possible conflicts of interest. In my opinion, science provides knowledge,

184 Statement by the Organizing Committee of the Second International Summit on Human Genome Editing, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b> (accessed Aug. 1, 2019).

185 Henry Greely, *How Should Science Respond to CRISPR'd Babies?*, 35 ISSUES SCI. TECHNOL. 32, 36 (2019).

186 J. Benjamin Hurlbut, *Human Genome Editing: Ask Whether, Not How*, 565 NATURE 135 (2019); Donna Dickenson & Marcy Darnovsky, *Did a Permissive Scientific Culture Encourage the 'CRISPR Babies' Experiment?*, 37 NAT. BIOTECHNOL. 355 (2019).

but it should not be left to scientists alone to decide on research policies (for example on where to set the limits of such research) and how the research is used.¹⁸⁷

Others argue that proposals for self-regulation rely on an outdated understanding of scientific practice according to which the development of new technologies takes place in a political and legal vacuum.¹⁸⁸ The danger is that reckless scientists such as He Jiankui will interpret such an approach to science as an encouragement to further push the boundaries of what is legally and ethically accepted. Commercially, they have a reason to persist in that thought. He, for example, raised around 40 million dollars from investors for his biotech start-ups.

Furthermore, the birth of the genetically modified twins does not give reason for much optimism on the capacity of the scientific community to prevent human germline editing from spiraling out of control. In the wake of the scandal, several doubts have been expressed. For example, why did the various scientists, whom He had consulted for his CRISPR experiment, remain silent about the dangerous path that he had embarked upon?¹⁸⁹ Moreover, can it be said that ‘the implicit endorsement of reproductive gene editing in [the NASEM and Nuffield] reports facilitated the work of rogue actors such as He, providing ethical cover for his work?’¹⁹⁰ Indeed, He has defended his actions by claiming that they are in line with the guidelines from the NASEM report on gene editing.¹⁹¹ Perhaps, this can explain in part why He chose to defy the existing Chinese guidelines and regulations.¹⁹² The Chinese biophysicist argues that he genetically modified the twins only to prevent a serious disease in the absence of reasonable alternatives, exactly as prescribed by the NASEM. Although He’s rather loose interpretation of these guidelines can be regarded as mere rationalization, his claim is not entirely without ground. Responding to the birth of the genetically modified twins, Victor Dzau, president of the US National Academy of Medicine, admitted that the existing guidelines are not clear enough and too open for interpretation.¹⁹³ As such, the event did serve as a ‘wake-up call from Hong Kong’ for the NASEM.¹⁹⁴

All of this suggests that attempts at self-regulation from the biomedical community have so far not only failed to prevent He’s reckless experiment with the twins but also even helped to create ‘an increasingly permissive climate among elite scientists that may well have emboldened He’¹⁹⁵ in the first place. At worst, this scientific elitism

187 Petra De Sutter, *The Use of New Genetic Technologies in Human Beings (Explanatory Memorandum to Recommendation 2115 of the Parliamentary Assembly of the Council of Europe)*, doc. 14328, May 24, 2017, sub 32.

188 Jasanoff, Hurlbut & Saha, *supra* note 173.

189 Natalie Kofler, *Why Were Scientists Silent Over Gene-Edited Babies?*, 566 NATURE 427 (2019).

190 Hasson & Darnovsky, *supra* note 152.

191 Antonio Regalado, *Rogue Chinese CRISPR Scientist Cited US Report As His Green Light*, MIT TECHNOLOGY REVIEW, Nov. 27, 2018.

192 Another important factor is the failure to implement and enforce the Chinese regulations, see Zhang & Lie, *supra* note 38; and Erika Kleiderman & Ubaka Ogbogu, *Realigning Gene Editing with Clinical Research Ethics: What the “CRISPR Twins” Debate Means for Chinese and International Research Ethics Governance*, 26(4) ACCOUNTABILITY IN RESEARCH 257.

193 Sharon Begley, *After ‘CRISPR babies’, International Medical Leaders Aim to Tighten Genome Editing Guidelines*, STAT, Jan. 24, 2019.

194 Victor Dzau, Marcia McNutt & Chunli Bai, *Wake-Up Call From Hong Kong*, 362 SCIENCE 1215 (2018).

195 Dickenson & Darnovsky, *supra* note 186, at 356.

may take on the shape of outright contempt for the idea of legal rules and democratic deliberation itself. A striking example is the approach taken by the Russian scientist Denis Rebrikov, who, as discussed, plans to follow in He's footsteps to create genetically modified babies. In an interview with *SCIENCE*, he offers the following views on the regulation of scientific progress and human enhancement:

'We cannot stop progress with words on paper. So even if we say, let us not do the nuclear physics, because it can make a bomb, a lot of scientists will still do this. We cannot stop it. A lot of groups will try to do experiments with embryos to transfer to women, and maybe it will not be in my group, but we will see in the next years that they will have some results, and they will publish it. That's maybe the problem for humans on the planet, that we cannot stop the progress. [. . .] [Human enhancement] will be the next step. But in 20 to 30 years. Now, I'm opposed to it. In 2040, I'll support it. I'm not against the idea itself. And these people who are opposed want to have all these things in their children but only by "divine providence," not by science. They are liars or stupid.'¹⁹⁶

VIII. CONCLUSION

Should individuals have the possibility to change the genetic constitution of their descendants? Since the rise of CRISPR, this question is no longer theoretical. Traditionally, national and international legal orders have answered this question with a clear and adamant 'no'. Most of the existing bans and restrictions on this technology go back to the human rights frameworks that were adopted in the late 1990s to regulate biomedical developments. A recurring idea in these frameworks is that reproductive HGGE is at odds with the human rights principles of freedom, equality, and dignity, as this technology would make it possible to produce individuals to fit certain requirements. In other words, it could open the door for unprecedented forms and practices of eugenics.

However, now that CRISPR has taken the biotechnology world by storm, these provisions are under increasing pressure. Even the uproar created by He Jiankui's attempts at genetically modifying offspring has not been able to break this trend. Especially, among scientific and medical-professional bodies, academies, and societies, the view is gaining ground that the existing bans should be lifted and that reproductive gene editing should be allowed for therapeutic purposes as soon as the technology is safe for clinical application.

How should these proposals be viewed from a human rights perspective? Interestingly, in most of the reports, articles, and manifestos that advocate a regulatory pathway approach to HGGE, human rights are equally invoked. The Nuffield Council's report, for example, explicitly refers to human rights discourse as its prime ethical framework,¹⁹⁷ while the NASEM report states that its overarching framework is 'embedded within the larger context of international conventions and norms for protection of human rights.'¹⁹⁸ In other words, these proposals rely on human rights to justify why the existing human rights ban on reproductive gene editing should be lifted. This suggests that conflicting views on the meaning of human rights and human dignity are at the

¹⁹⁶ Cohen, *supra* note 32.

¹⁹⁷ Nuffield Council, *supra* note 38, at 59.

¹⁹⁸ National Academies, *supra* note 98, at 29.

heart of current legal-ethical debates on HGGE. As such, HGGE indeed touches on the normative foundations of human rights law.

It is widely recognized that the meaning of human rights and their underlying principles may evolve over time. In this vein, the European Court of Human Rights has characterized the European Convention on Human Rights as a 'living instrument, which must be interpreted in the light of present day conditions', even when it comes to core human rights such as the prohibition on torture and inhuman or degrading treatments or punishments.¹⁹⁹ The same line of thinking necessarily applies to the principles underlying these rights, such as human dignity.

Similarly, the meaning of human rights and human dignity for the issue of human germline editing is not set in stone and may evolve over time. This is also recognized by bioethics committees of both the Council of Europe and UNESCO, when they emphasize the vital importance of a public debate on this matter. In this article, I have aimed to contribute to that debate by addressing three human rights concerns about the recent proposals for a regulatory pathway approach to reproductive gene editing.

First, I have discussed the distinction that many of these proposals make between human germline editing for therapeutic and nontherapeutic purposes. According to this line of thought, using genetic modification for enhancement purposes would conflict with human rights law, whereas using this technology to prevent serious diseases and conditions would not. Although the medical boundary between healing and enhancing can indeed be recognized in the human rights frameworks for the regulation of biomedical technologies, I have argued that the medical boundary will be much harder to maintain in case of HGGE than PGD. Hence, once the ban on HGGE is lifted, it will be hard to prevent the practice from gradually sliding down toward more eugenic applications.

Second, I have focused on the view and concept of human rights that underlie the recent proposals to go from prohibition to regulation of heritable gene editing. Some authors have argued that editing the human germline is tantamount to editing human nature and that this would therefore disrupt the foundation of human rights.²⁰⁰ This paper goes back to a different thought, namely, that proposals to lift the ban on germline editing are mostly rooted in a one-dimensional reading of human rights that radically parts with existing human rights discourse on biomedical technologies. Existing human rights approaches, as laid down in international law documents from the Council of Europe and UNESCO, address concerns at the level of the individual, society, and humanity. The recent proposals, however, only take into account the individual and societal dimensions of human rights discourse. References to humanity, humankind, human dignity, or the idea of the human genome as heritage of humanity are conspicuously absent. If human dignity is mentioned, it is reduced to a principle that only protects individual freedoms and rights. In other words, the collective dimension of human dignity is ignored. For a proper debate on the meaning of human rights for heritable genome editing, both sides need to be taken into account. A careful balance needs to be found between, on the one hand, the health and rights of prospective

199 ECtHR, Apr. 25, 1978, *Tyrer v. UK*, application no. 5856/72.

200 E.g. FRANCIS FUKUYAMA, *OUR POSTHUMAN FUTURE* (2002); George Annas, Lori Andrews & Rosario Isasi, *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*, 28 AM. J.L. & MED. 151 (2002).

parents and their future offspring and, on the other hand, the long-term interests of society, future generations, and humankind.

Third, I have argued that this dismissal of the collective dimensions of human rights discourse also has repercussions for the public deliberation on this matter. Once the issue is framed as one concerning exclusively the health and rights of those directly involved, vital questions are lost from view. Questions such as: what kind of lives do we wish for future generations? And: how can we protect our humanity in an increasingly technological and data-obsessed society? Moreover, the way in which the issue is reframed, with a strong focus on medical standards such as safety and the medical boundary between healing and enhancing, bolsters the tendency to leave the discussion and governance to the scientific community itself.

From this perspective, democratic interests appear to be at stake as well. In a way, CRISPR is turning democracy upside-down. In a 'CRISPR democracy',²⁰¹ citizens take the place of scientists when they, as biohackers, start tinkering with DNA, under the guise of 'democratizing' the life sciences. The other way around, scientists take the place of citizens when their voice becomes decisive in the governance of highly controversial technologies that may have a lasting impact on no less than the future of humankind.

201 See title of Jasanoff, Hurlbut & Saha, *supra* note 173.