The Policy Debate on Heritable Human Genome Editing:

A Literature Review of Critical Perspectives

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Abstract

This literature review aims to investigate the sociocultural context of the policy debate on heritable genome editing. It covers a collection of contemporary critical perspectives on formal guidelines for the use of heritable genome editing that have been recommended by influential scientific organizations. The perspectives covered stem from the humanities and social sciences. Together they explore the modes of deliberation and governance which have led to the formal guidelines recommended. The literature review concludes that the policy debate about heritable genome editing so far, has not been focused enough on achieving broad and inclusive deliberation about the ethics and governance of a potentially dangerous technology. Likewise, it seems as though formal guidelines have inherently been developed through technical competencies about molecular biology, and only marginally through moral competencies. It is regrettable that diverse moral imaginaries and social value conflicts have not been able to feature a significant role in the policy debate for such a controversial procedure that is heritable genome editing.

1.0 Introduction

The lives we produce or save or prolong with scientific and technological know-how may not be the ones we deem most worth living.

-Sheila Jasanoff (2018, 175)

Heritable genome editing in reproduction is prohibited by law and highly discouraged internationally. The controversial procedure involves the deliberate modification of the DNA in reproductive cells or human embryo's. In a scenario in which the manipulated cells are implanted into a woman's uterus in order to initiate a pregnancy, the resulting child, as well as subsequent generations, would inherit any of the genetic edits made in the lab. With the emergence of the CRISPR genome editing technology, many prominent scientists and bioethicists have begun a policy debate about whether heritable genome editing should be permitted for certain cases. Despite no formal guidelines having been issued about the use of heritable genome editing, the Chinese biophysicist He Jiankui took it upon himself to create the first three genome-edited human babies in 2018, two of which were twins (CGS Staff 2019). Using the CRISPR technology, He manipulated embryos and used them to initiate two pregnancies in the hope of creating HIV resistant children. He revealed his experiment in the popular press, mentioning only the birth of the two twins and claiming they were born healthy. The case received worldwide disapproval for the reckless use of a poorly understood and potentially dangerous technology for medically unnecessary purposes. Questions were also raised about whether morally informed consent was reached by the research participants and about who else within the scientific community was to blame (Cohen 2019a). He Jiankui and two of his colleagues have since been sentenced to three years in prison for their actions. Little is known about the well-being of the children which were brought to term and whether or not the edits made will provide any of the intended benefits, cause pain or suffering, or have no effects at all (Cheng 2020; Darnovsky and Hasson 2020). Yet, many more critics have argued that He's experiment did not happen in a vacuum. Far from acting alone, they contend, He was prompted by a permissive scientific culture that has been deliberating the ethics and governance of heritable genome well before the birth of the first "CRISPR babies" was announced (Andorno et al 2020, Darnovsky and Hasson 2020; Hurlbut 2020).

A decision for heritable genome editing in the intention of initiating pregnancy is also a decision to change the human germline. In effect, it is a decision that entails a particular understanding of human life, both in the contemporary as well as in the future. Deliberating ethics and governance of a technology that can metaphorically, change humanity is therefore contingent to a person's knowledge and sense making about what life is and what it is for; about what constitutes well-being; about which lives are desirable or undesirable, both today and tomorrow. In the case of He Jiankui, one might assume that the knowledge that led to the moral reason to change the human germline was solely knowledge about the genome: the knowledge that the CCR5 protein played a key role in a cell becoming infected with the HIV virus was cause enough to manipulate the germline with CRISPR. The case shows how the terms of debate and narrative frames about biological processes are not neutral or value-free but deeply implicated in moral imaginaries about the human condition. It prompts the question of which modes of deliberation and narrative frames dominate the policy debate on heritable genome editing? Or, which types of expertise are deliberating the ethics and governance of this technology? And, what role have prominent scientists and social institutions played in developing the proposed guidelines? These and similar thoughts served to inspire this paper, which sets out to investigate the nature and implications of the policy debate on heritable genome editing.

2.0 Methodology

The investigation of the sociocultural context of the policy debate and its implications will be done through a literature review of contemporary critical analysis from the social sciences and humanities. Their perspectives are used to review the lines of inquiry, the dominant types of framings, the types of questions posed and answered, the power relationships involved and the main stakeholders implicated in recent deliberations on the ethics and governance of heritable genome editing. Heritable genome editing and other forms of genome editing have received much attention for their potential to cure and prevent diseases and disabilities and provide a type of volitional evolution. Hubris, techno-optimism and unbridled enthusiasm about gene editing has been increased through the development of CRISPR, a novel genome editing tool. Major position statements, both in print and in debate, have been made about how and for what purposes heritable genome editing should be used and guidelines have been developed and recommended. This deliberation has been guided for the most part by experts and their explanations and translations of the scientific underpinnings of genome editing. As such, the efficacy and ingenuity of heritable genome editing has been the primary focus of the policy debate thus far. However, the ethical inquiry has not happened on a cosmopolitan level: the engagement of the broader sociocultural contexts in which individuals presumed to be genuine candidates for the technology may be implemented in, has been reserved. As a consequence, humility towards complex constructs of human well-being and more broadly, human life has been a marginal concern. It is the purpose of this literature review to use perspectives from the social sciences and humanities to critically examine the scope of ethical inquiry that has happened and investigate how these critiques can help in developing formal guidelines on heritable genome editing going forward. The following **research questions** have guided this literature review:

1. What is the nature of the interaction between science and society in the policy debate on heritable genome editing?
2. Building on the first question, what are the implications of the policy debate for the moral imagination about heritable genome editing?

3.0 Background

3.1 Definition of Key Terms

CRISPR A widely accessible tool/technology used by researchers to edit the human genome

In-vitro Fertilisation (IVF) An assisted reproductive procedure that involves the creation of embryo's in a laboratory and their transfer into a woman's womb.

Eugenics The aim of improving the genetic quality of the human population by preventing the inheritance of socially undervalued traits through various (often controversial) social and reproductive practices.

Heritable Genome Editing Also known as human germline genome editing, genome editing in human reproduction or germline therapy, it is a form of genome editing in which the DNA of gametes or embryos is deliberately altered in a laboratory for the purpose of human reproduction. Because the procedure involves germ cells or reproductive cells, the genetic material that is changed is passed on to subsequent generations. In effect the procedure alters the human germline, if the altered cells are used in assisted reproduction. Heritable genome editing in human reproduction is practically prohibited by international law for safety and ethical reasons. Proponents of its development and implementation envision a future in which heritable genome editing may be used to cure and prevent the inheritance of congenital genetic disorders (Meister 2020). In question are mostly deleterious disorders caused by a single abnormal gene. Huntington's disease, cystic fibrosis and hypertrophic cardiomyopathy are amongst the most widely identified conditions for which heritable genome editing should be pursued, according to its proponents. However, the procedure has proven to be far from safe and effective as evidence by recent basic research on nonviable embryos showed, "significant unintended insertions or deletions" with the potential of damaging the function of the cells genes (Hasson 2020, para. 2). Its imminent reliable use in fertility clinics is highly questionable and its effect on the wellbeing and health of prospective children are unproven. Despite international standards prohibiting the

procedure in human reproduction, the fact that it's safety and efficacy is far from reality and that basic research on human embryo's is already highly controversial , the first three genome edited children were born in 2018 as a consequence of He Jiankui's experiment.

Somatic Genome Editing Is the editing of DNA in adult cells. It can be done ex-vivo or in-vivo. In the former case, the edits on cells are done in a laboratory and after they have been extracted from a living person. In the latter case, DNA is changed inside the body through blood transfusions. The procedure is allowed and routinely used for therapeutic purposes against a multitude of hereditary diseases (Meister 2020). Because somatic cells are non-reproductive cells, any changes made to their DNA are not inherited. Somatic genome editing, unlike heritable genome editing, does not attempt to control future outcomes of subsequent generations. Although controversial and risky in its own right, the ethical deliberation and governance of somatic genome editing is not the focus of this literature review.

Preimplantation Genetic Diagnosis (PGD) A procedure used in assisted reproduction clinics that aim to select healthy embryos for an IVF cycle by screening for inherited diseases.

Phenotype The observed characteristics in humans and animals which are influenced by either the environment or inheritance.

3.2 Policy Debate: An Overview of Major Position Statements

The ability to make direct changes to the human germline has spurred on efforts to establish ethical and regulatory frameworks for the technology enabling it. The policy debate on genome editing has been led by institutional review boards, influential and respected scientific organizations and public bodies for bioethical deliberations. Position statements which have had major influence on the deliberations of heritable genome editing specifically, have come from the United States' National Academies of Science (NAS), the United Kingdom's Nuffield Council on Bioethics, and the German Ethics Council (Mills 2019). Most notably, the NAS can be credited for calling into action the current policy debate by organizing the first international summit on

human gene editing in 2015. A major report was also published in 2017 and another summit followed in 2018. The NAS is a non-profit organization that independently advises the U.S. government on developing policy on scientific research and emerging technologies. For heritable genome editing, the 2017 NAS report developed specific criteria for a permissible use of heritable genome editing. It states that an application would be permissible "in the absence of reasonable [reproductive] alternatives" which do not provide full genetic kinship and further only for a "serious disease or condition" which is fatal or debilitating (NAS 2017; Padden and Humphries 2020, 62). In issuing these criteria, the 2017 NAS report assumed instances of ethically permissible use of heritable genome editing for the sake of reproduction, provided that the CRISPR tool fulfills safety and efficacy requirements. Building on these criteria and in the immediate aftermath of He Jiankui's experiment , the 2018 international summit recommended to define "rigorous, responsible translational pathway toward [clinical trials]" (Baer 2020). This statement condemned He's use of the CRISPR tool for a disease and condition that was not "serious" enough according to the criteria set by the NAS report.

The Nuffield Council is an independent scientific organization and one of the most influential bioethics bodies for public deliberation in the United Kingdom (Henderson 2008; Hurlbut, Jasanoff and Saha 2020). Its 2018 report recommends two guiding principles for a future use of heritable genome editing: welfare of the future person and prevention of social injustice (Arguedas 2020; Nuffield Council on Bioethics, 2018). It too, envisions a permissible use of heritable genome editing by concluding it is not "morally unacceptable in itself" (Drabiak 2020, 223). It does however not explicitly restrict its use to "serious" diseases or conditions like the 2017 NAS report. In fact, it recommends "there are moral reasons to continue with present lines of research and to secure the conditions under which heritable genome editing would be permissible" (Zhang et al., 2020, 1657) A conclusion which arguably invokes a kind of moral imperative for heritable genome editing, according to some critiques (Baylis 2019a, 138). Finally, the (national) German Ethics Council, which functions independently, also concludes that heritable genome editing is not against human dignity. In its 2019 report, the German Ethics Council supports further research on human embryos through a notion similar to that of the 2017 NAS report, in that the CRISPR tool could prevent deleterious genetic disorders, but admits technical obstacles would need to be overcome to manage risks (Deutscher Ethikrat 2019; Begley 2019; Mills 2019).

In general, the dominant discourse of scientists and bioethics involved has been defined by an active search for moral reasons that permit a clinical application. Modes of governance, as proposed by the NAS, Nuffield Council and the German Ethics Council, have all envisioned instances in which heritable genome editing can be permissible and in which basic research should be pursued. Crucially, this is the bottom line of the position statements discussed in this section: although the policy debate deliberates the bioethics, and acknowledges potential harms and wrongs of heritable genome editing, implicitly, there is an agreement that clinical application is permissible and arguably, commendable in some cases. All three reports published have been influential since their publication, becoming some of the most common reference points about the social and ethical implications of heritable genome editing (Arguedas 2020; Baylis 2019a, 143; Mills 2019). Yet, the position statements are frequently cited as treating these risks "briefly and lightly [and making] no apparent connection between them and their recommendations to move ahead" (Darnovsky and Hasson 2020). A wide variety of critics from the social sciences and humanities have condemned this policy debate for drawing up recommendations in the absence of a broad societal consensus on heritable genome editing and its purposes. The following literature review is dedicated to some of these perspectives, which analyse the nature of the policy debate and the manner in which the recommended guidelines for heritable genome editing were developed

4.0 Review of Recurring Critical Perspectives

What are the broader implications and incentives raised by the policy debate on heritable genome editing? Does the medical and scientific nature of this discussion jeopardize an honest and inclusive debate? Does it achieve morally informed consent by human study participants and lay people more generally? Or, does it imply a preference for particular conceptions of human variation and functioning? These are some of the challenging questions, raised by researchers in the humanities and social science about heritable genome editing and its proponents. Their concerns go beyond the predominant utilitarian reasoning adopted by the 2017 NAS and 2018 Nuffield Council reports, in which the ends of heritable genome editing are envisioned, rather than the means it would take to get there. Almost all researchers reviewed, urge for the inclusion of a wider range of perspectives and stakeholders into the discourse. Such perspectives are perhaps fundamental for the discussion insofar that heritable genome editing touches upon issues outside the realm of science, medicine and technology: issues that require consensus and trust from a broad and diverse society. After all, the prospect of changing the human genome, something widely considered to be a common heritage of mankind, is widely conceivable according to the major position statements. As such, it comes without question that critics from the humanities and social scientists are doubtful about the envisioned future of a permissive scientific community and the biomedical hubris that surrounds the prospects of genome editing. Broadly speaking, their concern is that much of policy debate is failing to meaningfully and inclusively deliberate about social and ethical issues of heritable genome editing. The major concerns about the pitfalls of the policy debate are outlined in the following sections.

4.1 Regarding the Medical Model and its Lines of Inquiry

A recurring theme among the criticism is that advocates of heritable genome editing make convoluting claims about patient centered goals of the technology. Josephine Johnston (2020) notes, the 2017 NAS report for instance come to conclusions about a permissible use by "placing normative weight on the treatment-enhancement distinction" (146). So too, did the second international summit held in 2018, which proposed the development of a translational pathway

for germline gene editing (Johnston 2020, 147). For the organizing committee of the summit, as well as the report, the moral boundaries for genome editing are its enhancement capabilities. As Josephine Johnston (2020) notes, the NAS understands an appropriate use as strictly limited to "a compelling medical need" for which there are [no] "reasonable alternatives" (147). On the other hand, any application for enhancement purposes would count as "inappropriate or abusive" (149). In reference to the 2017 NAS report, Johnston clarifies her skepticism about adopting the treatment-enhancement distinction to provide moral clarity. The distinction is a "fuzzy" concept and has its limitations, yet is adopted without reservation by the scientific community to develop and recommend guidelines and answer complex ethical questions (Johnston 2020, 144). To make her point, she draws on the examples of vaccines and contraceptive technologies. Neither intervention, Johnston argues, can be distinguished as either a treatment or enhancement in a clear-cut matter. Both interventions have a medical benefit, but alternatively appear to provide advantages otherwise not found in nature. Therefore, Johnston argues, it would be ill advised to distinguish moral and immoral applications of heritable genome editing along the same treatment-enhancement distinctions. The distinctions are merely useful heuristics or "lines in the sand" and as such, they are simply too unreliable to make "nuanced, context-specific analyses" (Johnston, 2020, 151).

Johnston is not alone to make this observation about the pitfalls of a medical line of inquiry. No proposals (such as the ones by the NAS or other review boards) which envision a clinical application as limited to specific medical conditions have "adequately [grappled] with how the tenuous distinction between 'therapy' and 'enhancement' uses would be defined or enforced" (Andorno, R., et al. 2020, 353). Also, Françoise Baylis maintains that all treatments are enhancements, as they all aim to improve a "species-typical functioning" perceived to be deficient or unhealthy, but that not all enhancements are necessarily treatments, given that not all aim to treat an underlying health condition (Baylis 2019a, 61). In this view, heritable genome editing is always a form of enhancement for Baylis. Instead of referring to the treatment-enhancement distinction, heritable genome editing, she maintains, either aims to improve health or non-health related conditions. A distinction which fails in its own right, to provide moral clarity. She explains this by giving an example of a hypothetical intervention aimed to improve short stature in children. Baylis states that, regardless of whether the cause of below average height is an identifiable underlying health condition or biologically short, but perfectly normal

and healthy parents, the attempt to increase a child's height would be done in the intent of improving health and well-being. This is because the associated social stigmas of short stature would be reduced in a scenario of an application. Despite this same goal of reducing suffering and discrimination, a treatment-enhancement distinction only regards the former case as an ethically permissible intervention as it is caused by a health-related condition. However, in the perspective that all treatments are enhancements, "both cases are ethically acceptable or unacceptable in equal measure" (Baylis 2019b, para. 21). As such, the treatment-enhancement distinction obscures any policy-making procedure that aims to develop formal guidelines for heritable genome editing, because "it frustrates our ability to properly grapple [the surrounding] ethical issues" (Baylis 2019a, 65). Johnston and Baylis show that not only does the treatment-enhancement distinction fail as a categorical decision tool, but also as an ethical one, when deliberating heritable genome editing. As the distinction cannot practically rule out the permissible use for non-health related enhancement, it further cannot be held accountable to rule out ethically questionable, eugenic applications either. Yet, the treatment-enhancement distinction creates strong presumptions about the value and appraisal of medical goals in biomedicine and in the current policy debate.

In a similar line of thought to Johnston, other perspectives, such as those of Peter Mills (2020), scrutinize the policy debate for making therapeutic misconceptions. He explains that, advocates for further research and a clinical application will often argue that the technology can address an *unmet, medical, need.* Empirically, these advocates propose that there are genuine candidates for which heritable genome editing would provide a medical benefit; a benefit urgently needed for conditions currently *unmet* by the existing reproductive options like IVF or PGT. The presumed genuine candidates in the discussion are couples at risk of passing on a serious genetic disorder (especially single gene disorder) and additionally have the independent desire to have healthy children, genetically related to both of them. Although these "most unusual cases" are exceedingly rare, they provide research advocates with best argument for a morally permissible use of heritable genome editing (Mills 2020, 127). According to Mills however, the claim unnecessarily obscures the urgency of a clinical application because the genuine candidates for which the technology is presumed to be for, are so exceedingly rare that efforts and resources would be misplaced in development and implementation of heritable genome editing. As Carol Padden and Jacqueline Humphries (2020) note, couples homozygous for cystic fibrosis (which

are often referred to as genuine candidates by advocates), are so rare that they would not amount to “a readily available population [...] for clinical studies” (58). Likewise, Benjamin Hurlbut (2020) notes, a number of genetic counselors consulted by the Nuffield Council have stated to have not “encountered such [genuine candidates] in what amounted to hundreds of years of combined clinical experience” (190). A presumed urgency therefore has the further implication that it shifts scientific focus on further developing heritable genome editing technologies so that they become safe reproductive alternatives, where the risks can be calculated. Inadvertently, this focus encourages attention towards technical competence [and away from] moral competence within the policy debate according to Mills. Put differently, the attention unnecessarily moves towards *when* the technology is ready for application and away from the complex questions of *whether* it should be applied in the first place, and *who* it may actually be used for in reality.

He notes further that the claim that such rare cases constitute a *medical* need is a categorical mistake: a therapeutic misconception that unjustly places heritable genome editing into a medical context as well as proclaiming that the genuine candidates in question are deserving of objective medical attention. His challenge thereby goes against arguments in favor of heritable genome editing, as found in reports by the NAS (2017) and the German Ethics Council (2019). He posits that therapeutic misconceptions occur under commonly held assumptions that an application of heritable genome editing in fertility clinics would have a “therapeutic purpose”" simply because it “involves a medical procedure” (Mills 2020, 129). Like Johnston, Mills remembers that a medical intervention can also be applied against nonmedical conditions. But he goes further to raise the argument that heritable genome editing is perhaps always a nonmedical procedure, regardless if it is applied for the presumed “genuine candidates" or in a wider range of applications, as currently in question. For instance, Mills (2020) notes that reproductive technologies are not responsible for treating clinical infertility per se, but rather “characteristically circumvent” the underlying condition (131). Praising heritable genome editing for its probable medical benefits to prospective parents who are unable to conceive a child that is genetically healthy and related to them, would thus be unwarranted. A clinical application would not be treating a medical condition, in this case clinical infertility, but would merely address the procreative liberties of prospective parents; a scenario that would implicitly “cast the child in the [...] role of a “therapeutic agent, a means rather than an end in itself” (Mills 2020, 131). Like prospective parents, prospective children, regardless of the conditions they may or may not

inherit, would also lack the profound *medical* need which research advocates frequently refer to. The reason being, that their pre-existence implies that no serious medical condition can be treated or managed for. When speaking of heritable genome editing, the moral responsibility, Mills argues, lies not within the expectations of applying clinical therapy to a child, but within planning the characteristics of its existence. Any moral decision to apply heritable genome editing, for the purpose of preventing a genetic disorder, should then be evaluated as relative to the "reasonable good faith" of prospective parents, and their procreative liberties (Mills 2020, 11); essentially needs and values that are inherently non-medical in addition to being socially constructed and modulated through "discourse and social experience" (Hacking 1999 as cited by Mills 2020, 134).

The final element of Mills' discussion of the clinical trial model, is the line of inquiry which specifies that the development and implementation of heritable genome editing is a *need* for prospective parents and children. He draws on the prominent idea that the innovation, when applied in a clinical setting, will be in accordance with the prospective child's well-fare. Researchers advocating in favor of innovation often argue that ameliorating genetic conditions that risk jeopardizing a fulfilling life are in "need" of medical scrutiny, because the prospective child's need for a "good enough" life demands it (Mills 2020, 132). Heritable genome editing then, would be seen as a necessary intervention and a precondition for tolerable parenting ambitions, especially in cases where they pose a risk passing on genetic disorders. At this point, Mills reminds of the flipside of this argument. Which is that heritable genome editing is still an unproven and risky procedure and could cause adverse iatrogenic effects (such as off-target and on-target or mosaicism) that worsen the very functioning of people it attempts to improve. His main focus is to specify that the lines of inquiry anticipating the medical needs and interests of the prospective child are irrelevant considerations. Arguments that underline the child's "need" for a good life, only apply to children already in existence: "if the child does not exist, then it can, a fortiori, have no further needs" (Mills 2020, 131). This is to say, that the existence of a child with a genetically engineered genome is in essence not necessary. Prospective parents, especially the genuine candidates in question, may have a real desire to have healthy and genetically related children. Mills (2020) acknowledges that their health may be suffering as a result of not being able to attain these reproductive desires. However, he points out that their procreative liberties are merely a "relation of interests" (133). Heritable genome editing then, would not be implemented

to treat a *need*, but rather to meet the interests of prospective parents to have genome edited children. According to Mills a clinical application is not necessary when argued for on grounds of its medical objectives because, it is difficult to argue for the medical needs of prospective children, and because prospective parents cannot have medical needs of procreation.

Notably, the 2018 Nuffield Council report, unlike that of the NAS (2017), does not place normative weight on the treatment-enhancement distinction. It does not acknowledge heritable genome editing as a therapeutic response but plainly as a desirable parental right, with beneficial enhancement capabilities (Hurlbut 2020, 190: Darnovsky and Hasson 2020, 161). But it does envision a permissible use for disease resistance and tolerance: essentially for enhancement purposes. By anticipating a potential to increase population health and wellbeing then, the Nuffield Council nevertheless presumes a "therapeutic efficacy" in heritable genome editing (Katherine Drabiak 2020, 224). Although the report does not endorse heritable genome editing through a medical model like the 2017 NAS report, for Katherine Drabiak (2020) it is not exempt from relying on a therapeutic misconception: running the risk of misrepresenting the technology as either constituting "a nearly proven avenue to address an unmet medical need" or alternatively, a "beneficial preventative measures to enhance future children's health" (227). In reference to the Nuffield Council's positive stance on enhancement purposes, which according to it may enable a nation to meet its "obligation to create conditions of health", Drabiak argues that the report invokes eugenic thinking by not consequently distinguishing unethical enhancement purposes from unethical ones. The ethical transgression therein lies that the 2018 Nuffield Council report implicitly states that heritable genome editing, when applied for enhancement is not necessarily ethically questionable or always opposed to human dignity. A conclusion which is not only misleading, but trivializes the obvious link between the endorsement of the parental liberty to choose "specific beneficial enhanced characteristics for their reproductive projects" and eugenics (Drabiak 2020, 227). It is also questionable, as to whether the "therapeutic efficacy" presumed by the Nuffield Council is meant to benefit the collective welfare interests of all citizens (i.e. for the common good) or only whether it is reserved for the public interests to uphold procreative autonomy and liberty of privileged parents (Baylis 2019a, 185). Once more, this shows that the line of inquiry adopted by the Nuffield Council is ambiguous, as it demonstrates a rather narrow moral imagination and engagement about values and concerns of a broader sociocultural context.

The discussions of both Josephine Johnston and Peter Mills regarding the policy debate are complex. Yet, both critical theorists make a very important analysis about which ethical stakes and moral languages dominate the policy debate. In part, they draw attention at the fact that researchers advocating for the development and implementation are very much caught up in a patient centered salvation narrative. This type of discourse has its pitfalls however, because it is true that heritable genome editing has no real therapeutic objective because prospective children cannot be cured. Furthermore, the highly unusual but genuine candidates in question, have in fact no medical conditions in need of treatment, but instead have specific human desires of reproduction. Hence, it would be a misconception to stipulate that heritable genome editing is "needed to treat or prevent serious genetic diseases [or be understood] as a medical intervention" (Andorno, R, et al. 2020, 352). The trajectory of respected scientific organizations like the NAS and the Nuffield Council towards devising translational pathways is therefore questionable, if the objectives of heritable genome editing are really met, non-medical, and unnecessary. The medical reasons proposed by a prominent scientific community advocating for development and implementation, are thus not helpful, because of the simple reason that they are not medical and that a clinical intervention is not categorically (gene) therapy. To be clear, heritable genome editing unlike IVF or PGD is not about selecting embryo's or persons. Neither is it about helping a living and existing person by reducing suffering through therapy, which is the case for somatic genome editing. It is about creating and designing persons in a laboratory that do not yet exist in the world, in the hope of fixing them according to available knowledge about a genetic predisposition. Yet, proponents of heritable genome editing and prominent scientists routinely use a moral language that puts normative weight on therapy and reduced suffering.

The analyses of these categorical judgements made by the major position statements provide further clarity of the misaligned incentives at play within the policy debate. Mainly, that proponents' lines of inquiry mostly concern technical and private matters and thereby confuse collective welfare interests with values of individual procreative liberties. By having shown the pitfalls of viewing and contextualizing heritable genome editing inside a medical model, Johnston and Mills imply a crucial consideration: circumstances and appropriate reasons for a clinical application lie not within medical reasons, but within reasons that stem from a social and historical context. Normative and socially constructed values about reproduction, genetic disorders, family relations, identity, or human evolution are major determinants of whether or not

guidelines about the use of heritable genome editing are seen as favorable or not. Different societies will deliberate differently about reproductive technologies and take precedence over a variety of broader issues at stake. Medical necessity, as Benjamin Hurlbut indicates, "is a value-laden judgement" (Hurlbut 2020, 190). Placing priority on the procreative liberty of having able and genetically related children then is also a value-laden judgement. A judgement which inadvertently risks describing the absence of complete genetic relatedness as inferior or less valuable, and one which is neither neutral in regards to various normative understandings of disease and disability. Moreover, a value-judgement to have genome edited children is undeniably not universally shared in different sociocultural contexts or by local and minority groups. As such it represents an unwillingness to consider and engage with broader stakeholders involved, on the part of scientists and bioethicists deliberating heritable genome editing (Baylis 2019a, 201).

This goes to show that Johnston and Mills' analyses underscore the importance of public empowerment and sustained efforts for inclusive deliberations. Regrettably, a treatment-enhancement distinction, or a medical model for that matter, sidelines these meaningful deliberations from happening in the first place. This intuition implies that decisions for or against innovation are subject to medical governance and not democratic governance, or any forms of respectful and integrative decision making processes, for that matter. Once more, it shows that efforts to deliberate heritable genome editing by scientific organizations and leading bodies for bioethical deliberation like the NAS, Nuffield Council, or the German Ethics Council have been too narrowly focused, for they would otherwise consider a more socially and anthropologically oriented approach in their efforts to develop and recommend formal guidelines.

4.2 Regarding the Exclusive Nature of the Policy Debate

The common misconceptions identified by Johnston and Mills are representative of a broader trajectory seemingly at work within the policy debate of heritable genome editing; one which places the task of deciding upon moving forward with basic research into the hands of scientists and bioethicists. This section will elaborate on perspectives critical of this particular trajectory of

scientific self-regulation, and which take to heart the underappreciated need to consider human rights and social justice implications when deliberating the ethics and governance of heritable genome editing.

4.2.1 An Overview of Concerns

Many critical perspectives draw attention to the exclusive nature of the policy debate, the forces of power at play and the types of questions being asked and receiving precedence about heritable genome editing. The "*Geneva Statement on Heritable Human Genome Editing: The Need for Course Correction*", co-authored by a large and international group of social scientists, human rights advocates, and civil society representatives, acknowledges that much of the policy debate is dominated by narrow scientific and medical perspectives, which for-ground only the limited medical purposes of the technology (Andorno, R, et al. 2020. The statement parallels and builds on the same misconceptions raised by Johnston and Mills, but goes further to stipulate how these lines of inquiry are implicated in silencing certain concerns and perspectives about social controversies involved. According to the "Geneva Statement", the leading scientific organizations have not only been persistently negligent of centering societal consequences and concerns, but also downplayed existing legal frameworks prohibiting or strongly discouraging the alteration of the human genome. The co-authors elaborate on this position in a roundtable discussion of the statement: Roberto Androno recalls the legitimacy of the 1997 UNESCO Declaration on the Human Genome and Human Rights, and 1999 Oviedo Convention (which is legally binding in 29 nations) while Hille Baker refers to the 1990 UN Convention on the Rights of the Child (geneticsandsociety 2020). All prohibitions are longstanding, international consensuses that have identified the value of protecting certain dimensions of human life, such as the integrity and basic freedoms of future generations. The agenda of the current policy debate however ignores these consensus, further sidelining meaningful public engagement (Andorno, R, et al. 2020, 353).

In a different article, "Geneva Statement" co-author Katherine Drabiak (2020) argues that the 2018 report by Britain's Nuffield Council is guilty of systematically extricating "proposed practices from international human rights law, distorting [its] key definitions" (224). She also

indicates that the report regards earlier prohibitions, notably from the Oviedo Convention and the EU Charter of Fundamental Rights (CFREU), as outdated and inapplicable because of their "contingency" to the state of technology at the time of their approval. Thereby, the Nuffield Council report justifies and advocates for an amendment of the prohibitions by "asserting that scientific knowledge and moral norms have progressed" in such a way that render heritable genome editing as favorable while accepting its good for society. Justification which, "fundamentally mistake the principled reasons grounded in human rights and respect for human dignity" (Drabiak 2020, 226). While the UNESCO declaration is not legally binding and the Oviedo Convention is not signed by the United Kingdom, the Nuffield Council report nevertheless goes against the "powerful moral legitimacy" of these instruments while, its suggestions exemplify a kind of "technological determinism" (Dickenson and Darnovsky 2019, 356). Benjamin Hurlbut (2020) echoes this criticism with reference to the 2017 NAS report. He argues that by having treated previous prohibitions as irrelevant, the NAS commits a significant ethical reversal and as such spreads the assumption that legal frameworks devised to prohibit a technology that is not yet conceivable (which was the case in the late 90's) are ethically premature and pointless. Furthermore, he argues that the framing adopted by the NAS is responsible for asserting and manufacturing the "inevitability" of widespread implementation of heritable genome editing and thus affirms "an imperative of governance" that embraces a supposedly unavoidable technology. (Hurlbut 2020, 187). Such assertions of inevitability are regrettable however, as they create further urgency to permit heritable genome editing and as Hurlbut argues, prompts a search to justify its application rather than an engagement for an inclusive public inquiry about its actual purpose.

The consequence of this manufactured inevitability is evidenced by an opinion piece by Peter Sykora & Arthur Caplan. In reference to the permissible pathways laid out in the 2017 NAS report, the paper concludes with a call to abandon and amend the "outdated ban" imposed by the Oviedo Convention, in order to "recognize, permit and regulate new techniques to allow safe human germline genome editing for therapeutic and preventive aims" (Sykora and Caplan 2017, 1872). Not only do Sykora and Caplan falsely contextualize heritable genome editing within a medical model, but also fall for the idea that its application is inevitable and essential. Their opinion piece further exemplifies the legitimacy of concerns raised by the "Geneva Statement" about how popular false imperatives about technology undermine meaningful deliberation about

ethics. Setting aside that heritable genome editing is at the very least highly ethically controversial in practice, its physical safety risks rather underline the significance of a strict regulation of the technology, instead of rendering it "outdated" (Dickenson and Darnovsky 2019, 356).

Assertions of inevitability as proposed by Sykora and Caplan, but also major position statements by the bodies for public bioethical deliberation, are difficult to disregard as they deem the prudential and moral standards set by international law nearly 40 years ago "irrelevant" or "outdated". While it is always necessary to call into question legal frameworks, amending those that permit research practices from altering the human germline however, requires very strong reasons. That the proposed (medical and therapeutic) reasons in the dominant discourse are implausible and ignorant of wider sociocultural contexts, has already been demonstrated earlier in paper through the perspective of Peter Mills (2020), Josaphine Johnston (2020).

The roundtable discussion about the "Geneva Statement" also addressed the recurring dismissal of broader stakeholders in the policy debate. Co-authors Katherine Drabiak and David King, indicate that much of the policy debate has been driven by a technological imperative and the assumptions that scientists and biomedical experts represent the best interests of society, in particular about health related outcomes of prospective parents or children (geneticsandsociety 2020). The "Geneva Statement" sets out to correct this course by remembering the shared responsibility of scientists to perform research in accordance with the common good. As reported by its authors, the current policy debate however implies an ignorance towards this prerequisite. Rather, scientists are engaged in an active search for moral reasons that permit further development and implementation. The implication being that public engagement "is often devalued, undermined, or limited to predetermined issues [because of the discussions] explicit goal of engineering acceptance" for biomedical interests (Andorno, R, et al. 2020, 353). Drabiak further notes that the medical framing, often employed to produce this acceptance is "not only disingenuous, but disempowering to the public" (geneticsandsociety 2020).

In a similar vein, Gabriela Arguedas-Ramírez voices that because the policy debate has predominantly been led by institutions from the northern hemisphere, like the NAS or the Nuffield Council, it has excluded the countries from the Global South as well as their input. She

argues that in this way, the policy debate has been shaped by the concept of techno-scientific colonial paternalism. The concept explains a scientific culture that limits personal autonomy through epistemological, social and technological frameworks. However, due to imperialist-modern history and its power relations, these limitations are also tacitly exerted internationally, mainly onto the countries of the Global South. The moral consequence being that "interpretations, and ethical notions [are imposed] onto the rest of the world," even though public engagement has not yet deliberated any ethical quandaries that exist in these very countries (Arguedas 2020). Because of the underrepresentation of the Global South in policy debate, but also in research participation in genetic studies, scientists who exercise this concept of paternalism are undervaluing foreign experiences and values. Furthermore, the power relations between the Global North and South, Arguedas argues, ethical and political positions about heritable genome editing are set and pre-determined by western scientists: narrowing the aspects that deserve attention for the populations in the south. In other words, not only are ethical concerns, values and regulations of the Global South ignored by the policy debate, but also changed through the societal and global authority of western science and technology. Arguedas (2020) underlines, "it is naive to think that Global South nations could simply follow their own path [about the governance of heritable genome editing]" (para. 16). Techno-scientific paternalism in this way sidelines and hinders a necessary cosmopolitan enquiry about social justice concerns and about the purpose of heritable genome editing.

Indeed, this observation points out a recurring and notable criticism in the literature about the exclusivity of the policy debate. It pertains to the notion of broad societal consensus, or rather the lack thereof, in recent efforts to deliberate heritable genome editing. Françoise Baylis, understands decision making by consensus as entailing the explicit acknowledgement of the value of every participant's concerns that may surface throughout a discussion; rather than setting the "impossible standard of unanimity [or] reduce consensus to majority rule", broad societal consensus is about unity (Baylis 2016, 22). As she elaborates in her book "*Altered Inheritance",* this decision making process entails the "epitome of flexible resilience" on the part of participants, who despite having strong value commitments, are unopposed to deliberate seriously conflicting parties and amend their own convictions when appropriate (Baylis 2019a, 208). Broad societal consensus thus, entails a commitment to uphold respect and trust when discussing policy. In particular, it preconditions "considerable interpersonal, communication, and listening skills" if

participating experts are to remain honorable and transparent about their personal or professional biases (Baylis 2019a, 174). In this sense, knowledge that guides a decision's trajectory is produced through deliberative acceptance of minority views. Baylis' understanding of broad societal consensus puts forth a prerequisite for the policy debate on heritable genome editing; an explicit effort that enables, "public education, engagement, and empowerment": a bidirectional agreement between science and society that goes beyond and is distinct from the merely unidirectional "recognition of public involvement" as proposed by the major position statements by the 2017 NAS and 2018 Nuffield Council reports (Baylis 2019a, 195).

While it is true that the concluding statement by the 2015 International Summit, organized by the NAS, recommended broad societal consensus as a required standard to move forwards with a development and implementation of heritable genome editing, this commitment has since been abandoned by subsequent position statements and modes of deliberation and governance (Hurlbut 2020, 13; Darnovsky and Hasson 2020, 158; Baylis 2019a, 142). Baylis elaborates on this subtle but consequential ethical reversal amidst the policy debate, by clarifying four recurring strategies employed in major position statements and by prominent endorsements for innovation that aim to detract from the notion of broad societal consensus: The first, involves the explicit ignorance of "broad societal consensus" as a prerequisite to advance basic research, as evidenced by some "some reports and articles advocating for heritable human genome editing that summarize the 2015 Summit statement" (Baylis 2019a, 210). Secondly, some statements, such as the 2018 Nuffield Council report and the 2019 German Ethics Council report contest "the merits of broad societal *consensus* while endorsing the idea of broad societal *debate [or discourse]",* respectively (Baylis 2019a, 210, emphasis added). The third tactic "bait-and-switch tactics", involves appropriation of scientific governance, for instance by substituting "broad *societal* consensus" with "broad *scientific* consensus (Baylis 2019a, 210; Hurlbut 2020, 188, emphasis added). Here, Baylis references an editorial to the 2018 international summit, published by the leaders of the organizing international academies (see Dzau, McNutt, and Bai 2018). Finally, considerable efforts have been made to dismiss "broad societal consensus" by "weaponizing" it, or through "disregarding the relevant literature, pejorative rhetorical questions, [and suggesting that] whatever consensus might mean it is unachievable and thus irrelevant." (Baylis 2019a, 210). A notable example of this is the popular held assertion of the inevitability of widespread clinical heritable genome editing, and that a global moratorium (a temporary prohibition) is impossible to

implement. To give an example, futurist Jamie Metzl for instance, argues “it would be folly to suggest that our species needs to wait for perfect knowledge [and widespread acceptance] to move forward [with heritable genome editing]” (Metzl 2019, 07:06:04). He elaborates, that humans by their very nature, cannot and will not wait for consensus in regards to gene editing technologies” because “optimism and hubris [is built into the human] operating system” (Metzl 2019, 07:06:16:). Baylis criticises that these distraction tactics exemplify the questionable policy strategies by prominent advocates for heritable genome editing. Principally, because a rejection of “broad societal consensus” implies an explicit aversion by bioethicists and scientists to fulfill the true responsibilities of their professions: the effective and respectful engagement of the widest possible range of values and concerns of the public. In her view, the relationship between experts and society in the policy debate is defined by a top-down stream of information. Rather than enquiring about what the public deems worthy of investigating, technical knowledge about genetics is distributed to lay people in the intent to generate trust and help them overcome their reservations about science and technological innovation. The tacit yet routine abandonment of “broad societal consensus” by prominent scientists is revealing in how they view the public’s judgments as dependable to scientific authority and arbitration.

4.2.2 Investigating the Roles Adopted by Prominent Scientists and Bioethicists

In particular Françoise Baylis argues that prominent scientists that have contributed to the policy debate have been negligent of their role to society in their attempts to communicate their expertise with the public, policy makers and legislators. Here, she draws on the work of Roger Pielke Jr. and his framework of idealized roles of scientists. Most notably Baylis develops the idealized roles of issue advocates and science diplomats to discuss the current policy debate and the scientific and social context shaping its trajectory. The former role, she explains, is when scientists are heavily involved in policy making, albeit they attempt to limit the range of policy options in order to advance their personal interests. In the latter, and in the view of Baylis the more desirable role, scientists are equally involved in policy making, although this time they attempt to facilitate a compromise by means of presenting a range of policy options and their scientific underpinnings (Baylis 2019a, 151).

In the context of the ethics and governance of heritable genome editing, an example of scientists acting in the role of issue advocate would be those who propose that the technology addresses an unmet medical need. Baylis explains that these scientists, although they believe in the potential for alleviated suffering, have a view of ethical permissibility that is guided and informed by libertarian ideals: "they prioritize parental autonomy, procreative liberty, and efficiency" (Baylis 2019a, 158). As such, they use their scientific expertise and authority to guide policy debates in their favor by invoking the case of an unmet medical need as a specific and responsible policy option. Issue advocacy that promotes heritable genome editing through liberal ideals, Baylis argues, is in this context regrettable. In her view, this line of advocacy sets terms of debate that go against the aim of social solidarity: fair and just policies that are committed to the welfare of all of society, including those who are vulnerable or marginalized. Issue advocacy, in regards to the development and implementation of potentially risky technology, should hence pursue policy options that promote the "common good in the service of the commonweal": aspects of life to which "the market, property and individual liberty are subordinate" (Baylis 2019a, 160). In this view, Baylis suggests that heritable genome editing can only serve the interests of hypothetical parents. As such, advocates who promote it "only advance specific scientific, economic, and political benefits over benefits to society" (Baylis 2019a, 160). Baylis is a staunch believer in the idea that the human germline, metaphorically speaking, belongs to all of humanity. As a common heritage of mankind then, the entire human family has a shared responsibility in its protection, so that it may continue to benefit everyone (Baylis 2019a, 116). Conversely, heritable genome editing does not seem to be of collective benefit, nor help improve human health. Therefore, rather than advocating for liberal ideals by searching for responsible uses and hypothetical genuine candidates, issue advocates implicated in governing emerging technology should shift focus on the ways the common good and collective benefits can actually be promoted by it, according to Baylis.

The promotion and focus on libertarian ideals in the policy debate is not only misplaced and unthoughtful about technological application, but according to Baylis has had a profound impact on the interpersonal relationship between science and society. Prominent scientists that have presumed ethical permissibility have also been very vocal about objecting to a formal moratorium on heritable genome editing as a policy option. Here Baylis quotes the likes of Jenifer Doudna, who is credited as one of the main developers of the CRISPR tool and David Baltimor, a Nobel

Laureate and chairman of the first and second international summits. Among other prominent scientists, the two have all routinely contested a temporary prohibition or have deliberately not used the word moratorium in statements: essentially acting as issue advocates by narrowing policy options through their expertise. While all are in agreement that heritable genome editing is unsafe and unethical to apply at this moment in time, their contention to a moratorium implicitly reveals a presumption that heritable genome editing should take place in the future: once responsible ways have been agreed upon and the technology is proven safe. In this way phrases like "irresponsible at this time" or a "prudent path forwards" are used deliberately instead of "moratorium" (Baltimore et al. 2015). Even though both appeal to a temporary prohibition, the two former phrases refer to an implicit agreement amongst scientists, while the latter is an explicit international agreement, reached through the engagement of the public, lay people and legislators about which research practices are desirable.

Clearly these are two opposing views about the value of public engagement within scientific research. Consider for example, Baltimore's line of reasoning against a moratorium:

> "The important point is to be flexible going forward. That's what's wrong with a moratorium. [To make] firm statements about what we don't want to do and for how long we don't want to do it [...] is probably not a good idea" (Baltimore as cited by Baylis 2019a, 166).

In other words, the decision about how and when heritable genome editing is to be used should be answered through scientific expertise, not those of society: a moratoria or "firm statements" are inflexible and only hinder scientific progress and freedom. In this way, Baltimore is implicitly saying that heritable genome editing should happen in the future or is inevitable. In essence, this is also a presumption that the ethical hurdles about the technology's application for reproductive purposes are already overcome. What is left to overcome in policy making according to this statement are the technical matters of making the application safe and reducing the occurrence of adverse effects, through more research on embryo's. In reference to the same quote by Baltimore, Benjamin Hurlbut (2020) interprets him as saying "science should race ahead, and ethics should lag behind" (189). Once again an indication that the notion conveyed here by Baltimore and others is that broad *scientific* consensus is sufficient in governing advancing

technology, while broad *societal* consensus is superfluous, impossible to achieve or destructive to scientific progress and freedom. In this view, Baylis makes her position clear: the narrowing of policy options by means of self-regarding issue advocacy in the context of heritable genome editing is undesirable. No less because all of humanity, metaphorically speaking, has a stake in drawing up guidelines for research practices which go against international standards set up to protect the common heritage of mankind.

Instead of scientists acting as issue advocates, Baylis proposes and develops the idealized role of science diplomats. As stated earlier, science diplomats provide their scientific expertise to policy debates in the aim of increasing policy options under consideration. It is their hope that a collective decision can be reached by consensus. Scientists in this role facilitate "knowledge-based [but also] integrity-preserving compromises" (Baylis 2019a, 160). The aim is that the collective decision that is reached is done so in a way that the public, lay people and legislators have not only accessed the scientific information but have also been empowered to provide alternative and sometimes non-scientific information to the discussion. A compromise is reached by "aligning scientific information with values and interests to make clear which policy options support which policy objectives" (Baylis 2019a, 160). So in effect, a science diplomat would precisely strive towards a moratorium, on heritable genome editing. Another potential compromise could be in the form of a global observatory for genome editing, as advocated by Sheila Jasanoff. According to her, such a forum, if kept international and interdisciplinary, can help promote reflection on "what questions should be asked, whose views must be heard, what imbalances of power should be made visible, and what diversity of views exist globally" (Jasanoff and Hurlbut 2018).

Both a formal moratorium and a global observatory would provide an effort for the knowledge-based integrity preserving compromise which Baylis is advocating for. A compromise between the main acting issue advocates: those who on the one side support a complete prohibition or those such as David Baltimore, who support its eventual permission. In essence, a moratorium or global observatory would be expanding the policy options beyond the binary polorizations by facilitating time for broad social conversations, which in turn can enable broad societal consensus (Arguedas 2020). For science to be socially relevant, Baylis remembers, it must find the time to "consult, to deliberate, to question, to investigate, to interpret, and to respond" to societies actual

priorities and aspirations about research trajectories and advancing technology (Baylis 2019a, 124). Prominent scientists involved in the current policy debate however are very much heading into the opposite direction, at a fast and problematic pace. Once more, the trajectory they are taking is one in which the common good is ignored or confused with libertarian ideals of a few, hypothetical parents to have able and genetically related children.

Françoise Baylis' critique also regards the bioethicists involved in the policy debate. Once again, she contends that the professional bioethics bodies involved have, to a large degree, been incongruous and passive towards critically examining scientific acts of self-appropriation. Instead of being socially relevant and pursuing social justice and the common good, bioethicists, much like prominent scientists, have favored liberal ideals of procreation in their ethical deliberations. This, according to Baylis, has prevented them from contributing practical knowledge about values and opinions of possible stakeholders involved in the ethical quandaries. In the context of the practical clinical setting that is heritable genome editing, Baylis demands a bioethics that is concerned with expanding moral imagination and empowering those at the margins in order to enable a decision-making process that is respectful of difference and harmonious. Like scientists, this process should not entail advocacy for a specific ethical imperative or singular policy option that may be in their interest. Bioethicists should also refrain from standing on the sidelines of policy debate about research trajectories set out by scientists. As experts in practical knowledge Baylis explains, they must serve an important role that goes beyond merely translating and interpreting ethical theory for lay people and legislators. She proposes the idealized role of ethics architect as the most desirable for deliberating ethics and governance. These are bioethicists who in policy debate, anticipate participatory exclusion of vulnerable and historically disadvantaged groups beforehand and work towards preventing its occurrence by allowing ethical deliberation to take place. For this to happen, Baylis argues, the "literal and figurative spaces" of policy debate must be reimagined and reconfigured through bioethical expertise (Baylis 2019, 181).

Baylis' case for a bioethics that is policy oriented rests on three presuppositions; innovation, responsibility and accountability. Practicing bioethicists who are innovative, Baylis explains are those who acknowledge that the social environment in which humans are situated significantly influences their identity and autonomy. She explains, humans "are socially, politically and economically situated beings" (Baylis 2019, 184). An acknowledgement of this, by bioethicists,

facilitates the desired commitment to social justice and provides the moral imagination necessary to envision the implications of particular policy options. Particularly, innovative bioethics "invites us to consider contentious ethical issues outside the dominant frames of individual liberty" (Baylis 2019, 184). In this view humans are not isolated, rational individuals who make well informed decisions about their procreative interests and the future well-fare of their children. This social constructivist perspective which Baylis proposes here suggests that the manner in which prospective parents value reproductive options and liberties must be critically examined according to their social context. Following this argument, it cannot be accepted at face value that all prospective parents who accept heritable genome editing for its medical benefit would do so freely and unencumbered by society or prejudice. Truly innovative bioethical inquiry about heritable genome editing would thus involve questioning the dominant social intolerances facing prospective parents who have a high chance of passing on deleterious conditions to their children. Instead, Baylis notes "mainstream bioethics will sometimes blindly advance the liberty interests of privileged individuals" (Baylis 2019, 185)

In a discussion of the He Jiankui case, Benjamin Hurlbut addresses this very issue and argues that the policy debate lacks an engagement with the manner in which social environments significantly construct a person's vulnerability. He's attempt to produce HIV resistant babies was not for a justified medical need, but done in order to "provide a genetic fix to a social problem" and "cure prejudice -of whatever sort the market will sustain" (Hurlbut 2020, 191). Hurlbut explains that HIV/AIDS carries a great stigma in Chinese society and contends that the motivation behind the experiment was to offer the parents a necessary way out of society's intolerances. According to Baylis and Hurlbut, it is precisely this engagement, of embedding science and technology into the broader sociocultural context which has been lacking in deliberations. The value in engaging with the social environment is that it reveals the true purposes for which heritable genome editing may be used in practice. The manner in which people will want to use it and for whom is telling about how ethically permissible or impermissible heritable genome editing would become. Human conditions and appearances of all kinds face social intolerances. In the case of He Jiankui, these tolerances were simply accepted as they were. As a consequence, attitudes towards diversity were seen as enough cause to use heritable genome editing to change the features of appearance (Kristie Lu Stout 2018). A decision which, if one follows Baylis' argument, could not have been reached through morally informed

consent on part of the parents, but instead would have been done in significant degree, through personal dialogue with the social environment, and the limited options it offered them. Marcy Darnovsky and Katie Hasson (2020) have also stated that the fundamental questions in the policy debate ought to be about "social and historical context, commercial dynamics and pressures, of systemic inequalities and discrimination" (168). As such, He's experiment, but also more broadly the policy debate on heritable genome editing cannot be described as instances in which the integrity preserving science or an attempt to deliberate the values and concerns of the vulnerable was the end goal of ethical inquiry.

Additionally, bioethicists involved in the policy debate have not been responsible in their engagement with ethical dissent, according to Baylis. Irresponsible engagement on their part included for instance an absent focus on "what kind of people we are, and what kind of people we want to be" (Baylis 2019, 186). This refers to a commitment to interpersonal integrity towards stakeholders and a sensitive approach to how policy making may have real world impact, and who in particular would be impacted. In other words, for bioethicists to be responsible, they must examine if legislators have the same commitments and understandings of progress as the public does. According to this understanding of Baylis, a responsible bioethicist would for instance have acknowledged that the policy debate and its permissive scientific community was compromising a large group of stakeholders by deciding not to commit to a moratorium or to broad societal consensus.

Baylis also argues that an accountable bioethics, or the commitment to be accountable about the level of expertise and transparency in which policy options and outcomes are shared amongst the public, has also been lacking in the policy debate. This is in part because the evidence about public beliefs and values that was provided to policy deliberation has been limited to public surveys, simple opinion polls or as Darnovsky and Hasson describe (2020) has relied on "pre-packaged panels [..] where laypeople are convened to learn about and discuss controversial topics (167). In this way deliberation has not been representative enough and has constrained the scope of ethical inquiry and modes of debate in advance. In reference to the 2017 NAS report, Darnovsky and Hasson detail that public engagement treated the question of *whether* to proceed at all with heritable genome editing as settled. Instead, they "reduced public deliberation to a limited set of questions about *how* and *when*" (Darnovsky and Hasson 2020, 167, emphasis

added). Their critique also notes that engagement, particularly in the case of opinion polls have often not adequately mentioned the existence of alternative reproductive options, such as pre-implantation genetic diagnosis (PGD) or adoption, and as such have framed the policy discussion and options worth considering. In this way, serious questions about the use of heritable genome editing are not given consideration because the "endpoints are determined in advance" (Darnovsky and Hasson 2020, 167).

Danovsky and Hasson further show that bioethicists have not been accountable to vulnerable groups as well as for the level of bioethical expertise they have provided. An engagement that seeks out meaningful public consultation and change guide policy debate in the interest of social justice would not rely solely on panels consisting of clinicians and scientists. Instead, it would have accounted for an inclusion of experts uniquely suited in matters of social inequality. For instance by including the narratives of "women's health advocates, disabled people and communities, and those working to reduce economic and racial inequalities (Darnovsky and Hasson 2020, 167)." Darnovsky and Hasson elaborate this point by stressing that the welfare of women has largely been ignored in the policy debate on heritable genome editing. They note that heritable genome editing for reproductive purposes requires the application of IVF, while any basic research on human embryo's in general requires large quantities of donor eggs. Both procedures are not without risks to women's health. For instance, egg retrieval for IVF research usually involves drug induced hormonal stimulation. Many side effects can be the cause of this, including ovarian hyperstimulation syndrome, which is sometimes fatal. (Center for Genetics and Society 2006). The exploitation of women donors for their labor (to produce eggs) in embryo research is also a major ethically controversy. A lack of informed moral consent by fertility patients has already been brought up as a concern in connection to the He Jiankui case and research involving heritable genome editing conducted by Shoukhrat Mitalipov (Baylis 2019; geneticsandsociety 2017b, 36:39).

This goes to show that, if included, narrative accounts of fertility patients and women egg donors participating in research would contribute to a more valuable and different policy debate. Essentially, one with a focus on ethical quandaries outside the predominant medical model of inquiry placing normative weight onto the treatment-enhancement distinction. Darnovsky and Hasson show the significance of how a narrow bioethical inquiry and underrepresentation of

particular ethical dissent can skew the opinion of the public and legislators by framing the narrative. In this case, the implication is that heritable genome editing, as well as the basic research involving human embryos (which is ultimately necessary to develop heritable genome editing) is trivialized. A false impression may thus arise about the desirability of an adopted child that lacks full genetic kinship. Reproductive options, such as adoption or the use of third-party eggs and sperm are readily available and have much more potential to provide healthy children for prospective parents, than does heritable genome editing. Yet as Carol Padden and Jacquelen Humphries (2020) point out, these alternatives have not received the attention they deserve by the likes of the NAS. Once more, this underlines the importance of accountable bioethics (or remaining accountable to the levels of expertise that are invited into the policy debate).

To conclude, Francouise Baylis has offered a very profound insight into the roles adopted by much of the professional community that is involved in the policy debate on heritable genome editing. Furthermore, her account has laid out how professional scientific and bioethics communities such as the Nuffield Council and NAS have skewed the debate towards technical competence over moral competence and that a slow, cosmopolitan deliberation of ethics and governance is very much not part of the scientific habitus. Instead the policy debate has been in the mode of "fast science, [enjoined] by fast ethics" where heritable genome editing is already presumed to be integrity preserving, progressive and in the interest of health and well-being (Baylis 2019a 138). Baylis has also revealed which roles of scientists and bioethicists are instead desirable and necessary for a policy debate that remains knowledge-based, integrity preserving compromises and socially relevant. Finally, Baylis' account is revealing about an intolerance towards the role that society plays within the governance of emerging technologies and in guiding research trajectories. Others have explained that such norms and expectations about the governance of advancing technologies are a continuation of false imperatives that have been deeply embedded within the history of biotechnology. The following section will be dedicated to perspectives which have critically examined how the current policy debate on heritable genome editing is influenced by tacit constitutional commitments towards the ownership of making sense and governing human life itself. Both now and in the future.

4.2.3 The Tacit Social Contract between Science and Society

It was stated earlier that the reports by the NAS (2017) and the Nuffield Council (2018) advocated for heritable genome editing in ways that treated international legal framework that prohibit or discourage the alteration of the human genome (such as the 1997 UNESCO Declaration or the 1999 Oviedo Convention) as obsolete in their argumentation (Andorno, R, et al. 2020). Critical perspectives have eluded that this line of reasoning came on the basis of a kind of technological imperative (geneticsandsociety 2020). In the same line of thought, others have noted that the leading bodies for public bioethical deliberation and prominent scientists have routinely asserted that the moral norms which have guided international standards about the human genome are incoherent in the face of technological progress and new scientific knowledge (Dickenson and Darnovsky 2019; Drabiak 2020). Implicit commitments by scientists like David Baltimore to ignore broad societal consensus and a moratorium as a prerequisite to advance the development and implementation of heritable genome editing is further indicative that the policy debate prefers a science that is free to self-regulate, sovereign and unhampered by ethical inquiry (Baylis 2019a).

These perspectives elude to a particular narrative that Sheila Jasanoff (2018) has dubbed the law lag (68). According to her the idea of the law lag has featured prominently in modern biotechnology, especially in the post-genetic era. It describes a false imperative of the governance of emerging technology in which science, its experts and its types of sense making, should not be interfered with by the law or other social institutions. In this view, science achieves new knowledge and thus benefits society only if it is entitled to independently set its own pace and research agenda; “progress indisputably lodges with science, while law must constantly extricate itself from outdated principles to give science its due respect (Jasanoff 2018, 68). In this same view, Benjamin Hurlbut (2020) has described the current policy debate on heritable genome editing as committed to this very lag narrative in debating policy. The debate, he argues not only delays ethical inquiry but also legal inquiry into technological innovation and adaptation. Rather than allowing sociocultural values about diverse dimensions of human life to guide research practices, the narrative adopted by respected scientific organizations render ethics and law as merely reactive to, or as lagging behind science and its technological innovations; In reference to the opening statement of the 2015 international summit, Hurlbut (2020) argues, “[Scientific

experts] decide when “the unthinkable has become conceivable,” such that it is now time to react to its ethical implications" (179).

The social contract described here between science and society is one in which legal institutions are disenfranchised from their own role of governing the trajectory of science and technology through whichever norms exist about life. In effect, allowing and delegating scientific experts to take responsibility and ownership of the terms of debate and the types of questions that warrant ethical deliberation or not. It originates from the tacit commitment to allow scientists to take responsibility for innovation and act as its gatekeeper. The contract is based on the theory that their objective fact-finding and ability to read genetic code makes them best suited to govern the human germline. Indeed, Jasanoff (2018) describes the law lag as a commitment between both sides to demarcate science and law, especially when it comes to governing and monetizing lab created biological entities such as embryo’s: “what does remain constant [today, is] a mutual dependence between knowledge and norms, that is, between the discoveries of science and the dictates of law” (67). What results is a contract in which legislators and bioethicists are implicated in incrementally helping scientists claim sovereignty. In truth however, ethics and law are not incapable of keeping up with innovation, as reports by the NAS (2017) and the Nuffield Council (2018) might make them out to be (Hurlbut 2020). But by buying into a linear model of innovation (from science to innovation to society) actively endorsed by prominent scientists, a new agenda of governance comes into play.

Far from true, this commitment and the law lag rests on a presumption and imaginary. In reality “law, norms and cultural environments shape the preconditions within which science progresses (Hurlbut 2020, 184). Instead, the lag narrative constructs ethics and law as the burden or the “handmaiden” to progress and which effectively sees them depreciated as “discrete field(s) of research inquiry” (Baylis 2019a, 139). In effect, the narrative deliberately reinforces itself, but only through an *idea* of progress and scientific sovereignty. As such, it remains dishonest towards the sociocultural norms and values already governing life in the real world. Fundamentally, the contract is also a threat to democratic and inclusive policy making because it devalues the expertise of lay people as arbitrary and emotional.

Jasanoff names the 1975 Asilomar conference on recombinant DNA (rDNA) as a key event in which the law lag, this tacit social contract, embedded itself into the field of genetic engineering. Much like the policy debate on heritable genome editing today, the Asilomar conference was regarded and celebrated by its organizing committee as an act of responsible scientific inquiry and self-restraint towards an advancing technology which promised great benefit to social health and well-being. In fact, the conference ended by drawing up an informal moratorium for certain potentially risky experiments with rDNA due safety concerns. Yet, the conference ended up as an act of appropriated governance, over resource allocation regarding further research and development (de Nicola Center 2016). Because the moratorium was not binding, it left no controlling mechanism for scientific research. This prompted the National Institutes of Health, (the agency responsible for providing research funding for biomedicine in the United States) to issue binding guidelines about research practices in order to manage risks. In the end, the biomedical community was self-regulating itself through their own established virtual monopoly. In the end, the biomedical community was responsible for "framing the issues to be debated, the terms in which the debate would be conducted, and even to a large extent the legitimate objectives of governance" (Jasanoff 2018, 62).

In effect and in parallel to today's policy debate about heritable genome editing, moral deliberation was limited to what the biomedical experts deemed as realistic and plausible to concern: physical safety risks. Social concerns about ethics and law did not warrant scrutiny according to Jasanoff. In fact, the dominant narrative was that an incapacity to read genetic information was also an incapacity to deliberate ethics and governance of lab-created biological entities. Put differently, the narrative proposed by the biomedical community was that experts in the fields of law or ethics could not realistically make a risk assessment about rDNA or allocate funding for research, without an understanding of genetics. Scientists who adopted this role of gatekeeper, even demanded that lawyers and judges be educated in basic biology and science, "to correct [apparent] absurd judicial ruling" (Jasanoff 2018, 77). This focus on managing physical risks in ethical deliberation largely remained in place within biomedical research and the current policy debate. For example, Chris Gyngell, Hilary Bowman-Smart and Julian Savulescu (2018), who have argued that heritable genome editing is a moral imperative in some cases, state that "truly informed decisions about complex scientific matters requires people to understand science (522). Put differently, public re-education programs about scientific underpinnings are necessary

for detailed understanding of moral implications and ultimately come to conclusions that fit those of scientists. In effect, this narrative developed after the Asilomer conference, ultimately led to a public that was kept at bay in subsequent decades: "[struggling] to meet the ethical and political challenges of advances in genetics and genomics" (Jasanoff 2018, 62). Essentially, the law lag, this hierarchical relationship between scientists and members of society, was tacitly established within the field. But, as Jasanoff notes, the Asilomer conference also set the beginning of a scientific claim to the right to define life and its future purpose through objective sense making and genetic knowledge.

Benjamin Hurlbut (2020) has argued that it was precisely this tacit social contract which led He Jiankui to conduct his experiment and bring to term the first three genome-editing human babies in 2018. He's motivations were a consequence of the prominent scientific community taking the responsibility to set the terms of debate and disregard externally imposed norms. The world's first CRISPR babies, Hurlbut (2020) argues, were not inevitable but a "self-fulfilling prophecy" (182). It became true as a result of the manner in which scientific deliberations about ethics and governance took place prior to the experiment. For instance, Hurlbut maintains that He consulted prominent scientists before proceeding with his plans. After having found that the majority opinion and the 2017 NAS report did not formally endorse a need for broad societal consensus about genome-edited humans, He took it upon himself to conduct the experiment (Baylis 2018). Essentially, He internalized the false imperative of governance (as explained by Jasanoff) as well as the belief that scientific progress will yield new social and moral norms and that although controversial, his experiment will be in the benefit of society and well-received internationally. In this way, Hurlburt (2020) condemns not only He as rogue for acting alone, but also the professional scientific community he was part of and which was committed to self-governance: [they are rogue because they] appropriated from society the authority to declare what is good" (186). This accusation is directed at prominent scientists who in the aftermath of He's experiment going public at the 2018 international summit, condemned He as practicing biomedicine illegally. For instance, the summits concluding press release stated He's experiment was "irresponsible and failed to conform with international norms" (Baltimore et al. 2018). In another example, the leaders of the international academies published a statement calling for an "urgent need to accelerate efforts" to issue formal guidelines on the use of heritable genome editing (Dzau, McNutt, and Bai 2018). For Hurlbut, these and similar comments reveal that rather than changing

the culture that led to the first "CRISPR babies" and admitting failures, prominent scientists, especially those part of the NAS, were preoccupied with deferring blame to He and his accomplices. All the while, efforts continued, in an "urgent" manner to regulate and embrace the "inevitable" application of heritable genome editing. The narrative which ensued in the aftermath of the He experiment continued to reaffirm the tacit contract with social institutions and an appropriation of governance. It was in effect, a continuation of a reckless commitment of scientists towards "a race of their own making": the race of breaking the legislative barrier on editing the human germline (Hurlbut 2020, 188).

The tacit social contract as explained by Jasanoff and Hurlbut has deep seated consequences for public moral imagination about heritable genome editing and about its future implications for humanity. It puts at stake the value of social institutions in deliberating ethics and governance as well as normative understandings about human integrity and well-being. Questions unasked by respected scientific organizations like the NAS of Nuffield Council, remain unasked because the tacit social contract stays committed to defer and delegate moral imagination to scientific expertise. So too, the social contract might entail that formal guidelines about the use of heritable genome editing are solely developed and issued by scientists and through a process of broad *scientific* consensus and not one of broad *societal* consensus. For instance, the lines of inquiry which Mills mentions in his discussion of the "unmet medical need" may well remain the only lines of inquiry that are deemed acceptable in the policy debate on heritable genome editing going forwards. As a consequence, the only moral issue that would deserve normative weight would may be the treatment-enhancement distinction, which the 2017 NAS report bases its recommendations for the use of heritable genome editing on. Because the commitment between science and society reinforces itself, it could be that the policy debate further denies public forms of reflection and remain in the mode of fast science, and fast ethics as described by Baylis. These are very serious concerns which are also shared by perspectives reviewed in the next section. The perspectives in question discuss the very knowledge systems and types of sense making about the human condition which the tacit contract between science and society risks to displace with objective genetic knowledge. Yet, as will be discussed, these moral languages are valuable in the context of heritable genome editing and may be exactly what the policy debate needs if it is to make formal guidelines that remain integrity-preserving and knowledge-based.

4.3 Regarding Narratives of Cultural, Genetic and Phenotype Diversity

As previously discussed, advocates for heritable genome editing frequently point out that an innovation and implementation of the technology will serve in the interests of procreative, liberal ideals. The enhancement of people, specifically the designing of babies, is hereby defended in that certain human traits are seen as favorable while others are understood to be unfavorable. Rosmarie Garland-Thomson asserts that this line of inquiry, about the means and ends of reproductive technologies, stand in conflict with social justice and the commitment to provide fair and just relations for all members of the social order (geneticsandsociety 2017a). For Garland-Thomson, the best interests of advocates of heritable genome editing are not always in line with the best interests of a majority of people living with the very genetic disorders presumed to be curable or correctable through CRISPR. In her view, heritable genome editing, aggregate by a commercial medical industrial complex, poses a profound threat of a new kind of eugenic science: one that functions "in the name of health and reproductive liberty [but also in that of] a parental and medical obligation to fulfill the best interests of future children" (Garland-Thomson 2020, 34). For Garland-Thomson, the advent of heritable genome editing through advocating "liberal eugenicists and techno-optimists" presents a threat of "medical harm [...] genetic discrimination" and promotes "conditional parental acceptance" (Garland-Thomson 2020, 34). She argues that in the context of commerce driven research, the scientists and bioethicists involved have demonstrated an intolerance of human variation that mimics eugenics practices of the 19th century in pursuit of a narrow ideology of health. Specifically, it is the ideology of categorising people as either ill or healthy, as abnormal or normal, disabled or functioning. It is for Garland-Thomson (2020) a "market-driven growth industry" (31). When this process of standardization of human variation is pursued at the level of biological reproduction, the ideology or "[the enforcement of health] as an unassailable aim takes precedence over ethical interests" (Garland-Thomson 2020, 32). Amidst the biomedical hubris surrounding heritable genome editing, the "complexities of how and who these technologies may harm" go unnoticed and are refused as considerations by its advocates (Garland-Thomson 2020, 35). She asserts that the

permissive scientific community has thus far not properly and carefully pondered on the notions of human variation and biologically based superiority and inferiority. By envisioning therapeutic efficacy in heritable genome editing, biomedical scientists routinely associate particular human traits, such as the absence of disease and disability, with a meaningful and flourishing life. Garland-Thomson worries that this intuition leads to an understanding in which a huge variety of genetic disorders are "taken together as occasions of suffering as we project them onto future life" (geneticsandsociety 2017a). As such, advocates fail to notice that human variations thought of as disease and disability do not equate to a ruined life, while also falsely assuming that all people with genetic disorders will welcome selective reproductive processes aimed to extinguish the very conditions they embody or may pass on to their children.

Garland-Thomson is an advocate of imagining the lived experiences of people with disease and disability to reconceptualize undervalued human variation and the determinants of suffering. As such, she argues for broader explanatory resources about disease and illness in biomedicine: ways of knowing which are situated in a metaphysical foundation of the human genome and existential situations of human emplacement. Unfortunately for her, the reductionist nature of the current policy debate and the proposed deliberations of values and concerns have implied "a deficiency of a much more valuable kind of knowledge—social, cultural, relational" (Garland-Thomson 2020, 35). Genetic information about human traits, she argues, is not as authoritative and reliably predictive as it is laid out to be by biomedicine. Although helpfully "tangible and quantifiable" genetics and "preemptive diagnosis [do not] give us meaningful information about that person's capabilities, relationships, or actual lived life" (Garland-Thomson 2020, 35). Her case rests on the epistemic limitations of present day biomedical and genetic knowledge to conceptualize and imagine the desirable human traits that will guarantee flourishing and well-being for future generations. She reiterates that such a focus on the absence of disease and disability undermines our capacity to appreciate the people living with these conditions for the whole persons that they are and for their distinctive individuality. Technical knowledge systems offered by biomedicine are not just erroneous for an ethical deliberation and suggestive of the limits of human knowledge, but also dangerous. Garland-Thomson elaborates, that the epistemic practices of the current policy debate cannot be accountable for morally informed decisions by prospective parents, let alone society, about what kind of persons should or should not exist in the future, what outcomes they should have and which traits will hypothetically be to their advantage or not.

Although we might know the existence of a deleterious "sick" or "diseased" gene, Garland-Thomson asserts that it would be misguided to think that editing it would determine improved health and well-being and offer beneficial collective outcomes for society. Her argument re-articulates and warns of the common scientific misunderstanding of inheritance and genetic determinism. Although predictive of disease, mental disorders and disabilities, "genes by and large do not programme human behavior and health, but exert an altogether subtler influence" and rarely determine (Henderson 2008, 58).

The epistemological dilemma posed by the scientific underpinnings that guide policy debate is that "they exist outside the limits of human knowledge [and] outside of direct human experience" (Garland-Thomson 2020, 35). Genes, Garland-Thomson articulates, require deduction and representation through epistemological linguistic or visual metaphors because they are invisible to the human eye and exist outside human subjective experience of time. She illustrates this in the example of the international Human Genome Project of 1990. The project was launched in order to sequence the human genome in its entirety and gain understanding about the nature of diseases and lay down a pathway for affordable gene therapies. Published in a public database, the project "became a narrative with substantial authority and truth value that made the information meaningful to the public" (Garland-Thomson 2020, 36). But, the "code of life" was not completely mapped by the time of its publication in 2003 and efforts to fully understand it are still going on today. The human genome, in all its complexity remains a fictional entity: the Human Genome Project provided merely an "average [..] reference point against which all of our individual genetic variation can be compared" and from which clues can be derived (Henderson 2008, 55). Despite the advent of new technologies, it would still be false to assume that the science has come so far as to recognize and safely modify "specific genes with particular functions, in order to cure disease or [...] introduce improvements" (Shanks 2020). As such, Garland-Thomson contends that gene editing, as abstract and hypothetical as it is to human spatial and temporal perception, can only be understood through mediated computer images and linguistic metaphors. This metaphor of a "entwined, brightly colored double helix ribbon with the speedy little Pac-Man symbol pruning and clipping it" does the narrative work of teaching lay people and legislators about the microbiology of CRISPR-cas9 (Garland-Thomson 2020, 37). As a metaphor however, it constraints our understanding of the complexity of human nature as well as the causes and consequences of manipulating its DNA. Metaphors, Garland-Thomson

cautiously reminds, “tell us something true [but] also something false” about phenomena outside human perception (Garland-Thomson 2020, 37). Albeit its limitations, genetic knowledge is nevertheless routinely treated as an authoritative answer about predicting, controlling and understanding gene expression. According to Garland-Thomson however, it is erroneous to accept assumptions that intentional gene edits will always lead to the intentional traits, conditions and health benefits often envisioned by biomedicine. At stake, in the policy debate, is that public and laypeople risk accepting the truth value of genetic knowledge due to the epistemological elegance of metaphors, and in so doing may reason against their best interests. For instance, by buying into the market driven ideology of health which is narrowly confined to normal, abled and standardized bodies by medical professionals or parents . In her view, the narrative work of the scientific underpinnings of heritable genome editing has moral implications as it implicitly shapes the ethical decisions about its use.

Elsewhere and in line with Garland-Thomson thoughts, Sheila Jasanoff (2018) reiterates that “sociotechnical imaginaries,” or futures claimed to be attainable through science and technology, have great power to alter ancient understandings of life and the meaning of life (10). In this particular case however, the human condition is tacitly oversimplified through a predictable and manipulable code of DNA, while the social and relational complexities which give life meaning are ignored in peril. Therein, lies the moral implication according to Garland-Thomson, of deliberating the ethics and governance of heritable genome editing solely through scientific underpinnings. For her, it is necessary to acknowledge that genetic knowledge presents humans with “phenomenological and epistemological limitations” about envisioning the purposes of heritable genome editing and approach policy debate with humility and not hubris (Garland-Thomson 2020, 37-38).

Garland-Thomson concludes that ethical deliberation about heritable genome editing would benefit from an appreciation of human diversity. An appreciation of such would counteract the oversimplified explanations about genetic disorders often offered by biomedicine. Such an appreciation, she describes can only come from identifiable phenomenological and existential aspects of diverse ways of being: “genotype diversity is not only the essence of life, but phenotype diversity, our distinctive human individuality, gives life meaning” (Garland-Thomson 2020, 39). Imagining diverse ways of being then is not only a way to exercise humility towards

people with varying diseases and disabilities, but also an opportunity to metaphorically practice living with a deleterious condition and in turn, generate competencies and tolerance in healthcare's future making endeavours. Features necessary for prospective parents to make informed decisions about whether or not to endorse heritable genome editing or not. In the context of the policy debate, Garland-Thomson pleads for more representational work for disability culture and identity and to refrain from the notion that such ways of inhabiting bodies are undesirable. A permissive scientific community in this context represents a threat towards desegregation and integration policies which pursue the common good and honor the individual distinctiveness of people with chronic conditions. In her view science and medicine should strive to create humane technologies which aim to "accommodate rather than eliminate human diversity" (Garland-Thomson 2020, 40) . For Garland-Thomson, this process is only possible if scientific and medical narratives about biologically based inferiority, bad genes or abnormal bodies, are reconceptualized through the inclusion of social, cultural and relational knowledge.

Ethan Weiss (2020) also invokes why the epistemological burden mentioned by Garland-Thompson is important to be aware of. Weiss, who is a physician and scientist, recounts his experiences of raising a daughter with albinism. Albinism is a congenital disorder which can be diagnosed pre-pregnancy. Weiss admits, he and his family would have never decided on having a child if they would have known that it would be born with a disability. After discovering the condition in her infancy, he remembers feeling panicked at the prospect of having a genetically abnormal and imperfect child. He also states that the birth of his daughter prompted him to change his professional endeavors in research and "go after albinism" while imagining a future in which genome editing could prevent or cure children with albinism (Weiss 2020, 69). Over time however, Weiss and his family learned to fully embrace and cherish their daughter, her albinism and more broadly diverse ways of being human. He admits that he also stopped encouraging his patients to do reflexive genetic testing in order to find out the genetic basis for diagnosed conditions. Instead he now advocates them exercise their moral imagination about the implications of genetic diagnosis for them and their children.

Weiss concludes that having raised a child with albinism his understanding of life itself changed as his values about virtues, attributes and appearances. The experiences confronted his objective sense making abilities which he used as a learned physician to explain health and the normal

human conditions. Yet, these sense making abilities were the ones which prevented him from normalizing his daughter and her genetic condition at the time of her birth. He contends that an informed choice about whether or not to use heritable genome editing in order to prevent a particular disability is impossible to make without the experience of parenting a child with disability.

In the same line of thought, others warn that the policy debate thus far has been an expression of the common sense ableism often driving healthcare allocation. Ableism in the context of healthcare is the problematic presumption that anyone with an illness or disability is weak, fragile or has no control over their life and as such is in need of medical scrutiny. In its mission to ameliorate, cure and eliminate all species-atypical functions, ableism is inherently wrongful towards people with a disability, "irrespective of type and degree are assumed unacceptable" (Campbell 2012, 214). For example, Alice Wong has criticized the 2017 NAS's recommendation of limiting heritable genome editing to "serious diseases and conditions" which are "fatal and debilitating" as unaccountable for preventing harmful clinical trials involving disabled people who regard their conditions as an integral part of their identity and culture and do not want to be their conditions to be "edited out" by healthcare (Stanford Medicine X 2017; Padden and Humpries 2020, 55). The determination by Russian biologist Denis Rebrikovto to prevent the inheritance of deafness with CRISPR, underlines this fear (Cohen 2019b). Even though genetic deafness is not caused by a single mutated gene or considered a pathological condition or debilitating (but instead as another variation of humankind) by many, it is still at risk of being arbitrarily defined as in "need of medical intervention, ranging from sterilization to experimental surgery [or through germline genome editing]" (Padden and Humphries 2020, 58). Padden and Humpries also fear that apart from eliminating deaf-cultures and other self-defining communities, ableist logic also threatens the potential of advantages of mutations for human adaptability by standardizing the human genepool: "variation in the human gene pool is valuable, and the choice to remove [it] must be balanced against the severity of the condition it is intended to prevent" (Padden and Humpries 2020, 57).

The perspectives discussed in this section are notable because they show that amidst the mission to perfect the human, fix its flaws and prevent pain and suffering the policy debate must confront the epistemological shortcoming of genetic knowledge when it comes to answering questions

about the human condition and which lives need fixing or should be removed entirely. Deliberation on the use of CRISPR must also come to terms with the fact that genetic knowledge alone carries with it a moral implication in which life's value is prematurely oversimplified through a metaphor and compared to a particular kind of norm and standard. Prospective parents, as vulnerable as they are, cannot make informed decisions about heritable genome editing if they are only provided with a pre-pregnancy genetic diagnosis showing the presence of a germline mutation. Neither can lay people or legislators make informed decisions on recommended formal guidelines that were only developed by scientists and only contain objective truths about DNA. . Developing formal guidelines on heritable genome editing must therefore involve knowledge and sense making from the subjective, phenomenological experiences of life and the manner in which individuals, in their distinctiveness, encounter society and adapt to their environment. It is crucial that these narratives inform the policy debate and inform the development of guidelines for heritable genome editing because, it seems as though it is impossible to grasp what it means to be human without them.

5.0 Conclusion and Recommendations

The purpose of this paper has been to investigate the broader scientific and societal background shaping the policy debate on heritable genome editing and to critically examine the scope and implications of the ethical inquiry that has happened so far. Two research questions have guided this literature review. First, what is the nature of the interaction between science and society in the policy debate of heritable genome editing? Second, what are the implications of the policy debate for moral imagination about heritable genome editing?

The critical literature on the policy debate of heritable genome editing has been focused on the broader sociocultural context affected by advances in biomedicine: emphasising the important and virtuous role of science to pursue social justice, human rights and the common good. Critiques have articulated that the medical lines of inquiry about ethics and governance have dominated the policy debate and have served as the main arguments for proponents to continue the development and implementation of heritable genome editing. The review of these perspectives has made clear that the medical model however, makes substantial therapeutic misconceptions about the application and purpose of heritable genome editing. Heritable genome editing, when applied even in the interest of health, does not solve medical problems, but rather social problems. Its purposes in an applied clinical setting would be in meeting liberal ideals of reproduction and the desire for children with specific traits who have full genetic kinship. These desires and the value and emphasis they receive, are however socially constructed. As such, ethical permissibility of heritable genome editing lies in normative understandings about human life. The critical literature understands that what is at stake in the policy debate, is that contemporary social constructs and the manner in which they come into being, must be examined critically for traces of prejudice and intolerance for which heritable genome editing may provide presumed solutions or fixes.

Other perspectives have focused on the exclusive nature of the policy debate. The manner in which prominent scientists have appropriated responsibility about deliberating the ethics and governance in the current policy debate has been examined, as well as the historical events and tacit institutional commitments that have paved the way for contemporary power imbalances in

the life sciences. It has been revealed that prominent scientists involved in the policy debate have routinely made efforts to hold on to this responsibility by claiming ownership over defining the properties of life and manners of sense making. In turn moral competencies and expertise outside of genetics and biology have been devalued by the policy debate in terms of relevancy and authority. Observing these alternative and sometimes non-scientific perspectives, which situate life within a complex relational, cultural and social context are in fact relevant and authoritative in their own right as has been demonstrated by the likes of critical disability studies or narratives of parents. Specifically, these perspectives have provided a unique insight into the distinctiveness of various human conditions as well as having diversified an understanding of the worth and value of life itself. Furthermore, they have demonstrated that having knowledge-based and integrity-preserving policy debate in which various meanings of human existence and notions of well-being are brought up, can only be achieved if the ways of knowing and sense making that originate outside biology are engaged with and empowered. For instance, the narrative accounts of the disabled and chronically ill have the potential to reconceptualize the often wrongful definitions in healthcare about health, well-being and ways of being human. Prospective parents and participants in reproductive research may as a result reach a more informed and wise decision about their best interests and whether or not heritable genome editing fits these interests or not.

Regarding the first research question, the combined critical literature has demonstrated that the policy debate has favoured technical expertise of scientists and has unjustly devalued the empowerment of the broader sociocultural context. The adoption of a medical model has hindered efforts to reach broad societal consensus and as such represents an act of appropriated governance on the part of prominent scientists involved. Concerning the second research question, it seems that the policy debate constricts the public in exercising profound moral imagination about research practices and clinical applications of heritable genome editing. Ethical inquiry about heritable genome editing is routinely restricted to technical and medical questions and in turn facilitates prominent scientists to decide themselves upon the terms of debate, what constitutes progress, which research trajectories are worth pursuing and finally how to understand human life itself. It would be naive to assume that the ethical inquiry that has happened so far was anything resemblant of inclusive or cosmopolitan. Realistically then, the policy debate cannot be held accountable to have developed knowledge-based and integrity-

preserving guidelines for heritable genome editing and its ethical permissibility. Put differently, pre-packaged panels of scientists are not capable enough to decide on their own, which human lives are desirable today and which human lives are desirable in the future.

The main challenge facing the policy debate is in reconceptualizing the value and authority of the diverse, socially constructed ways of thinking about the human condition in the present, but also in the future: no matter how value-laden and political they may appear to be. This entails accepting the limits of objective sense making about life, on the parts of not only scientists, but also the broader culture and social institutions involved in developing formal guidelines in biomedicine. Like Gabriela Arguedas-Ramirez (2020) notes, the policy debate, in its efforts to find morally defensible arguments for the use of the CRISPR technology on the human germline, creates forms of epistemic and geopolitical subalternity: in which the privileged speakers, the prominent scientific organizations such as the Nuffield Council or the NAS, sideline social value conflicts and "wrong the [vulnerable and underprivileged] in their capacities as knowers" (para. 27). Until prominent scientists do not slow down their urgent efforts to create formal guidelines for a translational pathway, begin efforts of broad inclusive deliberation and practice epistemic virtue, these subalternate classes will wrongfully remain on the periphery of decision making, and so too will their moral languages. To prevent further wrongful conduct and rogue science, the policy debate on heritable genome editing must remain socially relevant. A formal moratorium or global observatory looks to be crucial and necessary for this to happen. On the other hand, formal translational pathways towards clinical use of heritable genome editing are nothing but reductionist of public moral imagination. It would be a shame if decisions about whose lives are worth living are solely based on objective truths about their genome and the supposed imperfections they may inherit.

6.0 References

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