

governance in the EU, realize the subsidiarity principle as strengthened by the Lisbon Treatyⁱⁱ, and focus on regulating issues where there is consensus across the EU. Therefore, we propose that the EC initiates an investigation of this model. The approach towards co-existence policies in the EU may serve as an example.

In the third of our articles [14], we present certain reform details regarding the postauthorization requirements as well as discuss the current political landscape in the EU and whether any regulatory reform is currently feasible.

Author Contributions

D.E. took the initiative and prepared the first draft of the manuscript. All other co-authors each contributed a section to the manuscript and were involved in finalizing the manuscript.

Acknowledgments

This work was supported by the Swedish Foundation for Strategic Environmental Research (Mistra) through the Mistra Biotech research program; and the German Federal Ministry of Education and Research through the project 'Ethical, Legal and Socio-economic Aspects of Genome Editing in Agriculture' (grant reference number: 01GP1613C).

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<https://doi.org/10.1016/j.tibtech.2019.12.016>

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Science & Society

Geneva Statement on Heritable Human Genome Editing: The Need for Course Correction

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As public interest advocates, policy experts, bioethicists, and scientists, we call for a course correction in public discussions about heritable human genome editing. Clarifying misrepresentations, centering societal consequences and concerns, and fostering public empowerment will support robust, global public engagement and meaningful deliberation about altering the genes of future generations.

Heritable Human Genome Editing: Nearing a Critical Juncture

The impending decision about whether to develop and use heritable human genome

Box 1. Why Another Statement?

We write as a group of public interest advocates, social science and humanities scholars, ethicists, policy experts, and life scientists who share a commitment to social justice, human rights, and democratic governance of science and technology. In January 2019, we met at the Brocher Foundation near Geneva, Switzerland to assess and discuss public engagement and the governance of heritable human genome editing. As an international group including both academic experts and civil society representatives, we necessarily produced a different kind of statement.

Nearly all previous statements on heritable human genome editing have been authored by groups dominated by scientists and bioethics professionals and based in scientific and medical perspectives. By contrast, this statement foregrounds social justice, human rights, and civil society perspectives. Its aim is to reorient the conversation around heritable human genome editing by identifying misrepresentations and misunderstandings that muddy the discourse and by encouraging a robust consideration of the social, historical, and commercial contexts that would influence the development of heritable human genome editing and shape its societal effects.

modification carries high stakes for our shared future. Deciding to proceed with altering the genes of future children and generations would mean abandoning the restraint urged by the United Nations (UN) General Assembly's formal endorsement of the Universal Declaration on the Human Genome and Human Rights [1] and required by the laws and regulations of more than 50 nations (F. Baylis *et al.*, in preparation), including 29 that have ratified the Oviedo Convention, a binding international treaty [2]. Policymakers put these prohibitions in place to protect human rights and the fundamental equality of all people; to safeguard the physical, psychological, and social wellbeing of children; and to avert the emergence of a new eugenics.

Despite the persistence of these fundamental and widely shared concerns, a small but vocal group of scientists and bioethicists now endorse moving forward with heritable human genome editing^{i,ii} [3]. They have taken it as their task to decide how we might proceed toward altering the genes of future children and generations. In fact, the question at hand is whether to proceed at all. Neither the responsibility for answering that question nor the authority to answer it can be theirs alone (Box 1).

We contest moves toward reproductive use of human genome modification and affirm the need for broad societal

consensus before any decision about whether to proceed is made. We insist on the need for genuine public engagement that is inclusive, global, transparent, informed, open in scope, supported by resources, and given adequate time.

Toward that end, we call for an urgently needed course correction (Box 2) along three dimensions.

First, we need to address and clarify several misrepresentations that have distorted public understanding of heritable human genome modification.

Second, we must reorient the conversation by foregrounding societal consequences and undertaking a thorough analysis of threats to equality.

Third, we need criteria for 'public empowerment': robust public engagement that promotes democratic governance through shared decision-making [4].

Clarifying Misconceptions

Informed deliberations will require setting the record straight on key points about heritable human genome editing that have repeatedly been presented in a confusing or inaccurate way, distorting understanding and creating barriers to meaningful public engagement.

Perhaps the most fundamental and widespread misrepresentation is that heritable

human genome editing is needed to treat or prevent serious genetic diseases. Deliberations about heritable human genome editing should hence acknowledge these basic points:

- Heritable human genome editing would not treat, cure, or prevent disease in any existing person. Instead, it would modify the genes of future children and generations through the intentional creation of embryos with altered genomes. This fact makes it categorically distinct from somatic gene therapies. Heritable human genome editing should be understood not as a medical intervention, but as a way to satisfy parental desires for genetically related children or for children with specific genetic traits.
- Modifying genes in early embryos, gametes, or gamete precursor cells could produce unanticipated biological effects in resulting children and in their offspring, creating harm rather than preventing it. Heritable human genome editing would also require and normalize the use of *in vitro* fertilization (IVF), exposing healthy women to significant health burdens [4].
- Prospective parents at risk of transmitting a genetic condition already have several options to avoid doing so, should they find them acceptable. For example, prospective parents may seek to have unaffected children via third-party gametes or adoption.
- In nearly every case, prospective parents at risk of transmitting a genetic condition who wish to avoid doing so and to have genetically related children can accomplish this with the existing embryo screening technique preimplantation genetic diagnosis (PGD) [5]. While PGD also raises troubling ethical questions about what kind of lives we welcome into the world, modifying or introducing traits through genome editing would vastly intensify these concerns. Genome editing cannot be considered an

Box 2. The Need for Course Correction

The organizing committee of the 2015 International Summit on Human Gene Editing asserted that clinical use of germline editing should not proceed without 'broad societal consensus'^{iv}. Instead of sustained commitment and the allocation of significant resources toward this prerequisite, we have seen steady efforts to weaken it. Perhaps the clearest example came from the organizing committee of the 2018 International Summit on Human Genome Editing. Meeting in the shadow of He Jiankui's utterly unethical experiments, this group issued a call for a 'translational pathway to germline editing', with only a cursory mention of 'attention to societal effects'^{vi}.

More recently, the need for broad societal consensus was reaffirmed in the call for a global moratorium on heritable human genome editing by an international group of scientists and ethicists, including two of the three scientists most often recognized as CRISPR pioneers [5]. Subsequent endorsements of their statement^{vii–ix} [10] and additional calls for a moratorium from scientists, bioethicists, and biotechnology executives^x [11] provide a welcome reminder that enthusiasm for heritable human genome editing is far from universally shared in scientific and industry circles. The proposed moratorium would allow time to develop the more substantive, inclusive, and empowering forms of public engagement needed in deliberations about heritable human genome editing.

alternative to PGD, because PGD would remain a necessary step in any embryo editing procedure.

Centering Societal Consequences and Concerns

To date, most conversations about heritable human genome editing have neither adequately analyzed its societal context nor meaningfully explored its social justice and human rights implications, despite their seriousness.

We share widespread concerns that the accumulation of individual choices shaped by cultural and market forces could result in heritable human genome modification ushering in a new form of eugenics. Particularly troubling is the prospect that heritable human genome editing would be used in efforts to alter a wide range of human traits. Although several recent proposals would limit it to genes associated with medical conditions, none adequately grapples with how the tenuous distinction between 'therapy' and 'enhancement' uses would be defined or enforced. Even well-intentioned efforts to restrict its use to specified conditions would be unlikely to hold, especially under the self-regulatory arrangements often envisioned.

Some dismiss such concerns, saying that it will not be possible to genetically enhance traits like intelligence or appearance

because their genetic underpinnings are too complexⁱⁱⁱ. This point is important but not decisive. Some prospective parents are likely to find fertility clinics' marketing appeals compelling even when the genetic modifications offered are dubious. It is clear that social inequality and discrimination can be spurred by the mere perception that some humans are biologically 'better' than others.

Deliberations about heritable human genome modification must seriously investigate the implications of social and historical dynamics such as these:

- Competitive pressures to 'get ahead', coupled with commercial incentives in the fertility industry (especially where it operates in the private sector), could foster the adoption of heritable human genome editing by those able to afford it. Unequal access to perceived genetic 'upgrades' could then exacerbate the recent dramatic rise in socioeconomic inequality.
- Racism and xenophobia are resurgent around the world, fueled by discredited scientific and popular assumptions about biological differences among racially categorized populations. Eugenic thinking, which aims to 'improve' humanity through genetic and reproductive technologies and practices, persists in popular discourse and could be

reinvigorated by the availability of heritable human genome editing^{iv} [6,7]. These pernicious ideas increase stigma and discrimination against those considered genetically disadvantaged, including disabled people and communities, and undermine the fundamental equality of all people.

- Outcomes in related biotechnological spheres provide examples of the likely trajectory of heritable human genome editing if commercialized. These include the promotion of social sex selection by fertility clinics and of unproven and risky 'treatments' by commercial stem cell clinics.

Public engagement and empowerment are likely to reveal additional concerns that have not yet surfaced, particularly if we commit to including and listening to a broad range of voices and perspectives.

Fostering Public Empowerment

Despite widespread recognition that decisions about this powerful technology cannot be made by scientists alone, public involvement is often devalued, undermined, or limited to predetermined issues (e.g., selecting conditions for which germline editing should be available). What is often proposed in lieu of genuine public engagement is a top-down project of educating the uninformed public with the explicit goal of engineering acceptance. A related approach sidelines public engagement by framing heritable human genome modification as inevitable while ignoring social and medical alternatives, as well as the numerous policies prohibiting it.

Public empowerment requires that participants set the scope and framework of assessment. All facets of the question – especially whether heritable human genome modification should be pursued at all – must remain open to debate. Deliberations must proceed with a clear, shared understanding of what is in

question and at stake and with transparency about financial or other interests shaping the conversations. Further, the outcomes of public deliberations need to be taken into account by policymakers and integrated into formal decision-making processes.

Robust public engagement must also be global and inclusive, involving a range of publics whose voices have, to date, been overlooked or minimized [8]. While scientists' contributions are important, their voices should not dominate; social values and implications must be at the center. Thus, in addition to scholars in the social sciences and humanities, legal and policy specialists, and other experts, deliberations must include a broad swath of organized civil society, with special attention to public interest organizations focused on women's health, reproductive rights and justice, racial justice, environmental justice, gender equality, disability rights, and human rights.

Concluding Remarks

No decision about whether to pursue heritable human genome modification can be legitimate without broadly inclusive and substantively meaningful public engagement and empowerment. Such deliberations may be challenging and messy. They will take time and organizing them will necessitate creativity, hard work, and significant human and financial resources [9]. The course correction proposed here is essential to these efforts.

We must in the meantime respect the predominant policy position against pursuing heritable human genome modification, if we are to prevent individual scientists or small committees from making this momentous decision for us all. This will preserve time to cultivate an informed and engaged public that can consider and discuss the societal consequences of altering the genes of future generations and make

wise, democratic decisions about the shared future we aspire to build.

Acknowledgments

The authors gratefully acknowledge the Brocher Foundation (www.brocher.ch), Geneva, Switzerland, for hosting the workshop that initiated this statement and for generously providing financial support for Open Access publication. We also thank Kathrin Martin for her assistance.

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<https://doi.org/10.1016/j.tibtech.2019.12.022>

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Forum

Synthetic Rewiring of Plant CO₂ Sequestration Galvanizes Plant Biomass Production

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