Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Recommendation 2264 (2023)[1]

Heritable genome editing in human beings

Parliamentary Assembly

1. In November 2018 it was announced that, as a result of unsanctioned work by a Chinese researcher, at least two babies (twin girls) had been born with modified genes with the aim of conferring on them immunity to the HIV/Aids virus. The act was strongly criticised by ethicists and scientists worldwide due to its premature nature and high risk of unwanted side effects. This led to renewed calls for a worldwide moratorium on establishing a pregnancy with germ-line cells or human embryos having undergone intentional genome editing of their nuclear DNA.

2. The Parliamentary Assembly recalls its Recommendation 2115 (2017) "The use of new genetic technologies in human beings", in which it pointed out that deliberate germ-line editing in human beings would cross a line viewed as ethically inviolable. Indeed, the Council of Europe's 1997 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, "Oviedo Convention"), binding on the 30 member States which have ratified it, posits in its Article 13 that "[a]n intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants".

3. The Council of Europe's Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) assesses the ethical and legal challenges raised by emerging genome editing technologies with respect to the Oviedo Convention. The Assembly commends the clarifications agreed by the CDBIO in 2022, according to which Article 13 applies in the research as well as the clinical context, and that any intervention that seeks to modify the human genome may be carried out only for preventive, diagnostic or therapeutic purposes – and that gametes, embryos or their precursors that have been subject to such an intervention may not be used for the purposes of procreation.

4. There is a broad consensus in the scientific community that the current technology is not yet safe and effective enough to establish a pregnancy with germ-line cells or human embryos having undergone intentional genome editing of their nuclear DNA, and no country explicitly permits it. In the last five years, there has, however, been a noticeable push by many scientists for a "translational pathway for heritable human genome editing" to be developed, namely the opening of clinical trials when, in the future, certain minimum standards will be met.

5. The Council of Europe has a mandate that encompasses the promotion and protection of the human rights of all individuals and is thus responsible for carefully weighing the human rights implications of heritable genome editing in human beings. The risks are serious and manifold, and cannot be ethically justified. For the Assembly, even if and when the technology is considered safe and effective enough, the ban on establishing a pregnancy with germ-line cells, their precursors or human embryos having undergone intentional genome editing of their nuclear DNA should thus be upheld.

6. The Assembly thus recommends that the Committee of Ministers:

6.1. urge member States which have not yet ratified the Oviedo Convention to do so without further delay;

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1. *Text adopted by the Standing Committee*, acting on behalf of the Assembly, on 28 November 2023 (see Doc. 15855, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Mr Stefan Schennach).

6.2. remind the States Parties to the Oviedo Convention of their obligation to implement its Article 28 through the promotion of a broad and informed public debate on heritable genome editing in human beings; the protection of the human genome as the heritage of humanity and future generations' human rights also need to be debated;

6.3. call upon Council of Europe member States to embrace a clear and total prohibition on establishing a pregnancy with germ-line cells, their precursors or human embryos having undergone intentional genome editing of their nuclear DNA, by introducing legislation at the national level and opposing permissive regulation at European and international levels.