Parliamentary Assembly
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COUNCIL OF EUROPE
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Recommendation 2115 (2017)[1]
Provisional version

The use of new genetic technologies in human beings

Parliamentary Assembly

1. Genetic engineering techniques have been applied in the medical field for several decades now. However, new technologies are developing very rapidly: recent discoveries related to the human genome have opened the door to new opportunities and unprecedented ethical concerns. On the one hand, this improved knowledge of our make-up as human beings brings with it welcome potential to diagnose, prevent and eventually cure diseases in the future. On the other hand, it raises complex ethical and human rights questions, including – but not limited to – unintended harm which may result from the techniques used, access and consent to such techniques, and their potential abuse for enhancement or eugenic purposes.

2. In particular, recent advances in genome editing are bound to result in germline interventions in human beings quite soon, for example with the birth of children whose genome has been altered with some unforeseeable consequences in such a way that their descendants are also affected. The scientific consensus is that these techniques are not "safe", leading to a *de facto* moratorium. However, other techniques, such as pronuclear transfer technology (the "three-parent" technique), which is used to avoid maternal inheritance of mitochondrial disease, have been used and resulted in the birth of two babies (one of them for reasons other than the treatment of mitochondrial disease), despite considerable ethical controversy and scientific uncertainty about the long-term effects.

3. Deliberate germline editing in human beings would cross a line viewed as ethically inviolable. Indeed, the 1997 Council of Europe 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 29 member States which have ratified it, posits in its Article 13 that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of any descendants". The convention does, however, also establish a specific procedure for its amendment (Article 32), which should be read in conjunction with Article 28, which imposes on States Parties to see to it that "the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation".

4. Numerous scientific and ethical bodies are starting to make recommendations to establish an appropriate regulatory framework for genome editing and germline interventions in human beings, including most recently the United States National Academy of Sciences and National Academy of Medicine, and the European Academies Science Advisory Council (EASAC). There is currently a prohibition on interventions aimed at modifying the germline in human beings in all European Union and many Council of Europe member States.

1. *Assembly debate* on 12 October 2017 (35th Sitting) (see Doc. 14328, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Ms Petra De Sutter). *Text adopted by the Assembly* on 12 October 2017 (35th Sitting).

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5. The Parliamentary Assembly thus recommends that the Committee of Ministers:

5.1. urge member States which have not yet ratified the Oviedo Convention to do so without further delay, or, as a minimum, to put in place a national ban on establishing a pregnancy with germline cells or human embryos having undergone intentional genome editing;

5.2. and, in addition, develop a common regulatory and legal framework which is able to balance the potential benefits and risks of these technologies aiming to treat serious diseases, while preventing abuse or adverse effects of genetic technology on human beings;

5.3. foster a broad and informed public debate on the medical potential and possible ethical and human rights consequences of the use of new genetic technologies in human beings;

5.4. instruct the Council of Europe Committee on Bioethics (DH-BIO) to assess the ethical and legal challenges raised by emerging genome editing technologies, in the light of the principles laid down in the Oviedo Convention and the precautionary principle;

5.5. recommend that member States, on the basis of the public debate, the DH-BIO assessment and the common regulatory and legal framework devised, develop a clear national position on the practical use of new genetic technologies, setting the limits and promoting good practices.