ASGCT and JSGT Joint Position Statement on Human Genomic Editing

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The American Society for Gene and Cell Therapy (ASGCT) and the Japan Society of Gene Therapy (JSGT) (collectively, "Our Societies") recognize the great scientific advancement represented by the techniques of genome editing and their vast potential value for an improved understanding and possible treatment of human disease. These techniques provide uniquely powerful tools for generating models of human disease, for characterizing the molecular and biochemical basis for pathogenesis, and for suggesting approaches to definitive correction of genetic defects underlying much of human disease. However, our Societies also recognize that the application of genome editing under some circumstances poses very serious ethical problems for which there is no scientific or general societal consensus and that should be considered as inappropriate human genetic manipulation until and unless serious scientific and ethical concerns can be resolved.

Somatic cell genome editing

Gene editing methods will make great contributions to the study, understanding, and treatment of human disease. At the somatic cell level, certain types of genome editing will have legitimate scientific and medical applications because they have potential advantages over less precise gene transfer technologies. Our Societies consider current scientific methodology to be sufficient to clarify and correct the inevitable issues related to safety and efficacy of somatic cell gene editing. Although the ethical concerns arising from somatic cell gene editing naturally merit broad scientific and societal discussion, our Societies consider it unlikely that somatic cell gene editing will give rise to new or unique ethical concerns substantially different from those associated with other forms of research and therapy that have already been well discussed.

Embryonic cell genome editing and germ-line modification

Our Societies recognize that gene editing in human embryonic cells or in stem cells destined for use in creation of a human being may in the long run have the potential for correcting genetic defects associated with genetic disease, not only in patients, but theoretically in future generations as well.

Our Societies also recognize that this area of research is complicated by a number of major and unresolved ethical concerns associated with germ-line genetic modification. Because research subjects would include not only embryos but also future generations, the difficulties of long-term follow-up raise ethical, practical, and scientific hurdles. The requirement that the results of an experiment be susceptible to analysis and characterization before further applications are undertaken cannot be met with human germ-line modification with current methods, because the results of any such manipulation could not be analyzed or understood for decades or generations—a situation incompatible with ethical imperatives and with the scientific method. Finally, our Societies consider it essential to develop effective social and policy mechanisms for carrying out broad and deep discussions of human germ-line alteration so as effectively to understand and balance the individual, familial, societal, and perhaps even species-level rights, needs, interests, and values affected by this rapidly advancing science.

In addition, our Societies consider the currently available genome editing technologies to be inadequately understood and developed for carrying out gene editing or other forms of genetic manipulation of human reproductive cells, pluripotent stem cells, or embryonic tissues with the potential for incorporation into viable human zygotes for either disease prevention or enhancement. Acceptable technology would require a far greater understanding and control of gene interactions than is currently available, elimination of off-target effects, and absolute prevention of mosaicism in resulting human embryos or zygotes. Our Societies consider that such applications with the current technology would not be adequately controlled and would therefore be ethically unacceptable.

In the meantime, research on gene editing in reproductive cells in various animal model systems, including primates, should be continued. This has the potential to clarify technical problems associated with gene editing and to devise solutions that will strengthen the technology. Such efforts could also lay the groundwork for establishing guidelines for eventual studies with nonviable human embryos.

Summary

Our Societies consider these safety and ethical concerns to be sufficiently serious to support a strong stance against gene editing in, or gene modification of, human cells to generate viable human zygotes with heritable germ-line modifications. Even with technical advances that may eventually solve the safety and mosaicism problems, our Societies conclude that there are not ethically acceptable ways to conduct embryonic gene editing or other germ-line modifications because the results of such experiments are not susceptible to long-term evaluation in a scientifically reasonable time scale. For these reasons, our Societies support a strong ban on human germ-line gene editing or other germ-line genetic modification unless and until these technical and ethical problems can be solved, broadly and deeply discussed, and societal consensus reached.

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