ALLIANCE for Regenerative Medicine

The Alliance for Regenerative Medicine's (ARM) Position Statement Regarding Human Embryo or Germline Genome Modification

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Genome editing technologies (including zinc finger nucleases, CRISPR/Cas9 and TALEN-based methods) represent a powerful new approach for targeting and changing DNA sequences.

Genome editing has been successfully applied to the improvement of plants, the generation of transgenic animal models and the development of potential therapeutics for human patients. Across a variety of academic and commercial settings, numerous efforts are currently underway to apply genome editing approaches to treat and potentially cure many human diseases, including HIV/AIDS, hemophilia, sickle cell disease and several forms of cancer.

These efforts focus on genomic repair of somatic (non-reproductive) cells and do not involve the genetic modification or manipulation of human embryos or reproductive cells (germline cells).

The potential of somatic cell genome editing for research and therapeutic product development purposes is extremely promising and progressing rapidly; however, the field of research involving genome editing of human embryos or human reproductive cells is highly premature.

The scientific and ethical issues related to germline modification in human embryos have been rigorously debated in the context of many other technologies, and this type of intervention has been largely rejected, even prohibited, in many nations.

It is ARM's position that it is not acceptable to pursue this kind of research at this time – in ARM's March 2015 commentary piece in Nature, we call for a voluntary moratorium to allow time for dialogue within the scientific community and all stakeholders.[1] Going forward, we encourage rigorous and transparent legal and policy discussions, as well as continued public debate about the science, safety and ethics of modifying human embryos or germline cells.

Subsequently, a number of agencies and organizations released their own statements, largely consistent with ARM's position and desired next steps, including the following:

- On April 29, 2015, Director of the U.S. National Institutes of Health (NIH) Francis S. Collins published a statement that "NIH will not fund any use of gene-editing technologies in human embryos," noting the many safety and ethical concerns that

[1] "Don't edit the human germ line," March 12, 2015, Nature. Available: http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111

exist, and also citing a "current lack of compelling medical applications" that would justify such research. [2]

- On May 18, 2015, the National Academy of Sciences (NAS) and the National Academy of Medicine (NAM) announced its initiative on human gene editing, including plans for an international summit later this year to "explore the scientific, ethical and policy issues associated with human gene-editing research." [3]
- On May 26, 2015, Dr. John Holden, Assistant to the President for Science and Technology and Director of the White House Office of Science and Technology Policy, released a statement echoing the importance of the scientific community's continued discussion on this topic, noting the "serious and urgent questions about the potential implications for clinical applications that could lead to genetically altered humans." [4]

We stress that, given the potential to reduce human suffering and the cost of care, non-controversial genome editing approaches to treat and potentially cure human disease that involve genetic modification of somatic cells rather than germline cells should be promoted and encouraged, not hindered or delayed.

ARM's membership is committed to improving the lives of patients by developing and bringing to market advanced therapies that prioritize safety and efficacy. As an organization, we value and respect the perspectives that patients, their families, physicians, caregivers and other medical professionals bring to this issue.

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[2] "Statement on NIH funding of research using gene-editing technologies in human embryos," April 29, 2015, National Institutes of Health. Available: http://www.nih.gov/about/director/04292015_statement_gene_editing_technologies.htm

[3] "National Academy of Sciences and National Academy of Medicine Announce Initiative on Human Gene Editing," May 18, 2015. Available: http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=05182015&utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+nationalacademies%2Fna+%28News+from+the+National+Academies%29

[4] "A Note on Genome Editing," May 26, 2015, White House Office of Science and Technology Policy. Available: https://www.whitehouse.gov/blog/2015/05/26/note-genome-editing