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FOR IMMEDIATE RELEASE

Genome-editing of Human Embryos Must Be Strictly Regulated

We are a group of professionals involved in every aspect of developing new medicine for advancing human health, from bench to bedside. We are appalled and deeply troubled by the report from Dr. Jiankui He of Shenzhen, China, who claimed that he and his team have disabled the CCR5 gene in human embryos using CRISPR/Cas9 technology, and twin girls have been born carrying such edited genome with a claimed purpose of defying future possibility of infection by human immunodeficiency virus (HIV). CRISPR/Cas9 genome-editing technology has been widely studied since 2012. While many laboratories throughout the world have utilized the technology, it is not yet ready to be applied to human reproduction due to significant scientific (e.g., mosaicism and off target effects) and ethical concerns. Although the details of He's experimentation have not yet been fully disclosed, the process of deploying this genome-editing tool from laboratory experiment to live birth of human infants, equivalent to a first-in-human clinical trial of a new drug/technology, is deeply disturbing. The preclinical studies were done in secrecy; the validity of the clinical trial design was concerning; the process of informed consent was questionable; the conducting of the first-in-human embryo trial appeared to have evaded the proper regulatory oversight; and the trial was registered retroactively. Finally, the claimed benefits of the twin infants in preventing HIV infection are not practically verifiable other than via in vitro testing. We as a group of biomedical and clinical professionals strongly condemn the irresponsible and unethical behavior manifested in the conducting of this first-in-human embryo gene-editing clinical trial. We call for an immediate and independent investigation of He's operation and data by an international panel of experts (stem cell biologists, reproductive physicians, bioethicists, etc.). We demand for mechanisms to be put in place to protect the CRISPR twins and their family, and other victims in He's clinical trials. We believe that strict regulation and transparent oversight in safeguarding human research are of utmost importance, in addition to having clear and unequivocal scientific rationale. Such standards apply to all human studies, most especially and urgently in human embryo gene editing in China and beyond.

Chinese American Hematologist and Oncologist Network (CAHON)

www.cahon.org

The Sino-American Network for Therapeutic Radiology and Oncology (SANTRO)

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