Ethical Issues in Gene Editing

Genome editing is a molecular technique by which targeted mutations are introduced into the genetic material of living organisms. The technology was initially used in research to answer fundamental questions about gene function. It is now starting to be applied more broadly and has the potential to move into clinical healthcare in the coming years.

Genome editing tools such as CRISPR-Cas9 are revolutionizing life science research and have the potential to prevent and treat many diseases. Among the promising near-term applications under investigation are therapeutic uses of CRISPR to correct somatic mutations, which are changes that arise in genes during a patient's life and can cause cancer and other diseases. However, making clinical changes in germline DNA, which involve genetic material that can be inherited or multiplied in future generations, carries risks that most scientists consider unacceptable at this stage.

QIAGEN's solutions are used in almost every laboratory conducting CRISPR and other gene modification technologies– as such, we would like to make clear QIAGEN's position on the ethical use of genome editing technologies.

We at QIAGEN endorse the principles and proposals of scientific organizations and advisory groups – such as the American Society of Human Genetics (ASHG) and the European Society of Human Genetics (ESHG) - that have issued cautionary guidelines.

Among the concerns raised about the clinical editing of germline DNA is the danger that a mistake in use of CRISPR for medical purposes could pass along adverse effects to future generations or introduce a new heritable disease. CRISPR and other genome editing techniques are still evolving at a rapid and unpredictable pace, and experiments carry with them significant uncertainties about longer-term outcomes. Another ethical risk is opening the door to nonmedical "enhancement" or attempts to create "designer babies" – such as modifying embryos to produce taller, stronger or smarter individuals or of a certain appearance.

Tight regulations and ethical rules about the use of genome editing are necessary to prevent misconduct and avoid harm to people and the ecosystem in which we live. At QIAGEN, we fully support the careful development of guidelines by scientific and societal leaders, with involvement and transparency for diverse elements of society with a stake in the issue.

In March 2019, 18 of the world's most recognized life scientists and ethicists published a call in Nature magazine (Nature 567, 165-168 (2019), https://www.nature.com/articles/d41586-019-00726-5.) for a global moratorium on all clinical uses of human germline editing to produce genetically modified children. These leaders are asking for a fixed-period ban on changing heritable human DNA (in sperm, eggs or embryos) to make genetically modified offspring. This measure is designed to establish restraint until the orderly development of an international framework can be completed to guide gene editing. These scientists work at top institutions in seven

countries (the United States, China, Germany, France, Italy, Canada and New Zealand).

We have called upon all QIAGEN employees to endorse the current moratorium on clinical germline editing and to notify QIAGEN's Head of Legal and Compliance about any suspicions of customers using our products in a non-compliant manner in this field. If the suspicion of unethical conduct is confirmed, such reports will be passed to the Food and Drug Administration (FDA, https://www.fda.gov/aboutfda/contactfda/default.htm) or relevant regional regulatory authority. We will continue to work with our stakeholders to develop policies for the long term – guided by QIAGEN's vision of making improvements in life possible as well as a commitment to the highest ethical standards.