Maine Medical Association

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TO: Joint Standing Committee on Health and Human Services

FM: Dan Morin, Director of Communications and Government Affairs

DATE: April 30, 2021

RE: **Support, LD 1601**, Resolve, To Establish an Advisory Panel To Study the Implications of Genome-editing Technology for the Citizens of the State

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The Maine Medical Association, the state's largest professional physician organization representing more than 4300 physicians, residents, and medical students across all clinical specialties, organizations, and practice settings presents this testimony in strong opposition to LD 1436.

Human genome editing is advancing rapidly, with ongoing clinical trials focused on the prevention and treatment of various human diseases. While genome editing holds great potential to help improve human lives, the technology raises profound safety, ethical, legal, and social concerns. These concerns are compounded by the fact that regulatory and ethical guidance often lag rapid technological developments. The bill before you offers the opportunity for Maine to better prepare.

Ethical issues regarding genome editing include concerns that editing may be used for non-therapeutic and enhancement purposes rather than for therapeutic purposes (i.e. improving health or curing disease). There are also downstream concerns of possibly creating classes of individuals defined by the quality of their engineered genome, which could exacerbate social inequalities or be used coercively.

Attached you will find American Medical Association (AMA) Policies and Code of Medical Ethics' Opinions Related to Human Genome Editing from a 2019 issue of the *AMA Journal of Ethics.*

We urge a vote of Ought to Pass for LD 1601, Resolve, To Establish an Advisory Panel To Study the Implications of Genome-editing Technology for the Citizens of the State. Thank you.

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AMA CODE SAYS

AMA Policies and *Code of Medical Ethics*' Opinions Related to Human Genome Editing

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Abstract

Recent research using gene editing technologies has made such tools more accessible and easier to use, fueling the promise of their therapeutic capacity. However, development of gene editing tools reminds professionals and the public that these technologies' potential use extends beyond treating somatic disease to germline editing, with consequences yet unknown. This article canvasses AMA *Code of Medical Ethics*' opinions and policies relevant to gene editing.

Innovation

According to Opinion 1.2.11 of the American Medical Association (AMA) *Code of Medical Ethics*, "Ethically Sound Innovation in Medical Practice," innovative treatments and technologies incur special responsibilities for the medical professionals who develop or adopt them in practice.[1] Specifically, the AMA *Code* recommends that innovations be designed "so as to minimize risks to individual patients and maximize the likelihood of application and benefit for populations of patients" and with "aware[ness] of influences that may drive the creation and adoption of innovative practices for reasons other than patient or public benefit."[1] This opinion emphasizes the need for foresight with regard to potential consequences of innovation. In the context of gene editing, then, physicians motivating genetic innovations should consider how gene editing might be applied therapeutically while keeping in mind that this technology could be used for purposes other than treating diseases, such as to create "designer babies" or for human enhancement.

Additionally, physicians who use new or changing innovations in their practice should engage in active and transparent conversation with other physicians about both positive and negative outcomes "to promote patient safety and quality."[1] In general, physicians should encourage dialogue within the medical community about new ideas, as other physicians might have valuable insights about outcomes or the resources needed for effective use of therapies.[1]

Research in Gene Editing

Opinion 7.3.6, "Research in Gene Therapy and Genetic Engineering," addresses ethical questions about gene editing directly.[2] The AMA *Code* reaffirms medicine's focus on beneficence in the use of new genetic technologies by stating the following:

In medicine, the goal of gene therapy and genetic engineering is to alleviate human suffering and disease. As with all therapies, this goal should be pursued only within the ethical traditions of the profession, which gives primacy to the welfare of the patient.

In general, genetic manipulation should be reserved for therapeutic purposes. Efforts to enhance "desirable" characteristics or to "improve" complex human traits are contrary to the ethical tradition of medicine. Because of the potential for abuse, genetic manipulation of nondisease traits or the eugenic development of offspring may never be justifiable.[2]

Physicians are limited to using clinical applications that will benefit their patients and are expected to exercise caution in using these technologies.

The AMA *Code* also addresses the extension of gene editing from somatic to germline interventions:

Moreover, genetic manipulation can carry risks to both the individuals into whom modified genetic material is introduced and to future generations. Somatic cell gene therapy targets nongerm cells and thus does not carry risk to future generations. Germ-line therapy, in which a genetic modification is introduced into the genome of human gametes or their precursors, is intended to result in the expression of the modified gene in the recipient's offspring and subsequent generations. Germ-line therapy thus may be associated with increased risk and the possibility of unpredictable and irreversible results that adversely affect the welfare of subsequent generations.

Thus in addition to fundamental ethical requirements for the appropriate conduct of research with human participants, research in gene therapy or genetic engineering must put in place additional safeguards to vigorously protect the safety and well-being of participants and future generations.[2]

This opinion serves as a kind of checkpoint or safeguard by reminding physicians of unique, long-term considerations attached to germline editing, and it details conditions under which gene-based research using human subjects is ethically permissible, including restriction of research to somatic cell interventions.[2]

Personalized Medicine

Other AMA *Code* opinions and House policy complement the guidance outlined in Opinion 7.3.6. In H-460.908, "Genomic-Based Personalized Medicine," the AMA addresses the growth of gene-based interventions and their social, ethical, and legal implications.[3] Furthermore, the AMA notes the importance of genetic discrimination in H-65.969, "Genetic Discrimination and the Genetic Information Nondiscrimination Act."[4] Opinion 4.1.2, "Genetic Testing for Reproductive Decision Making," underscores the importance of informed consent and respecting patients' autonomy in decisions related to interventions, such as genetic screening, and above all aims to protect those choosing to utilize genetic technology.[5]

References

1. American Medical Association. Opinion 1.2.11 Ethically sound innovation in medical practice. *Code of Medical Ethics*. https://www.ama-assn.org/delivering-

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