Welcome and Discussion of the **Commission's Statement of Task**

Victor J Dzau, MD

President, National Academy of Medicine

International Commission on the Clinical Use of **Human Germline Genome Editing** August 13, 2019



Statement of Task

An international commission will be convened with the participation of National Academies of Sciences and Medicine throughout the world to develop a framework for considering technical, scientific, medical, regulatory, and ethical requirements for germline genome editing, should society conclude such applications are acceptable.

Specifically, the commission will:

- 1. identify the scientific issues (as well as societal and ethical issues, where inextricably linked to research and clinical practice) that must be evaluated for various classes of possible applications. Potential applications considered should range from genetic correction of severe, highly penetrant monogenic diseases to various forms of genetic enhancement;
- 2. identify appropriate protocols and pre-clinical validation for assessing and evaluating ontarget and off-target events and any potential developmental and long-term side effects;
- 3. identify appropriate protocols for assessing and evaluating potential mosaicism and longterm implications;
- 4. identify ways to assess the balance between potential benefits and harms to a child produced by genome editing and to subsequent generations;
- 5. design appropriate protocols for obtaining consent from patients, for obtaining ethical approval from knowledgeable review committees, and for satisfying regulatory authorities;
- 6. identify and assess possible mechanisms for the long term monitoring of children born with edited genomes; and
- 7. outline the research and clinical characteristics developed in tasks 1-6 that would form part of an oversight structure, including defining scientific criteria for establishing where heritable genome editing might be appropriate, overseeing any human clinical use, and bringing forward concerns about human experiments.

Timeline

- May 2019: Commission members appointed.
 Public announcement of task, IOB members, and commission slate
- August 2019: Commission Meeting #1
- November 2019: Commission Meeting #2 and International Workshop
- January 2020: Commission Meeting #3
- March 2020: Report Review Process
- Spring 2020: Report Release and Public Dissemination

Thank you

Find Us Online



@theNAMedicine



www.facebook.com/NAMedicine

www.nam.edu

