Written submissions in response to the Call for Evidence on Genome Editing

The responses in these Written Submissions are based on an analysis of (a) policy and regulatory models for genome editing innovations and technologies ("**GETs**") recommended by various scholars; and (b) the existing legal framework in relation to drugs and medical devices. I attempt to address specific questions raised in the Call for Evidence (as set forth in more detail below) and, more generally, to outline controls and safeguards to regulate the possible use of GETs for research, testing and commercial purposes as comprehensively as possible.

(A) Perspectives on genome modification

1. To what extent can the development of genome editing techniques be regarded as distinct from or continuous with existing techniques? In what way are the differences significant? (***Indicative questions —The distinctive significance of genome interventions*** *at page 7 of the Call for Evidence*)

Scholars have argued that GETs are not significantly different from existing interventions insofar as the intended physiological modifications may presently be accomplished via consumer goods and services, practices, pharmacologies, technologies, and medical products and procedures.
The kind of physiological modification introduced by the use of GETs can be said to be internal sustained enhancement.[1] On account of the permanent and hereditary nature of physiological change caused by GETs, they are qualitatively different from drugs and medical devices but may bear similar mechanisms and risk profiles to interventions relating to serious and life-threatening diseases. Accordingly, the legal standard of safety and efficacy applicable to GETs must necessarily be higher than that of pharmacological interventions and medical devices. For this, a new set of regulations may be introduced for GETs or the drug and medical devices laws may be amended appropriately. It is worthwhile, at the outset, to provide a non-exhaustive taxonomy of GETs on the basis of the intended end-points of each intervention. Legal segregation in this regard is imperative to ensure that a different set of regulatory controls apply to different kinds of modification.

2. What obligations do scientists involved in developing and using genome editing technologies owe to society and what freedoms should society allow to these scientists? Do genome scientists have any special obligations to society that are distinct from those of other scientists? (***Indicative questions — Science and society*** *at page 7 of the Call for Evidence*)

Genome scientists are obligated to utilise GETs to their full potential in clinical studies and tests in order to develop possible cures for diseases whilst ensuring safety, efficacy and minimisation of side effects. In conducting such research, scientists are directly accountable to the subjects involved in clinical trials in terms of not only their safety, but also to protect confidentiality, store and transmit personal health data carefully, and respect individual autonomy. The benefactors of such research, i.e. the public, are in turn obligated to facilitate such research endeavours by volunteering to participate in clinical trials.

[1] A novel system or process that augments some core biological capability beyond the range of human capacity, or introduces a capacity which cannot be attained without intervention. *See generally,* Tamara Garcia and Ronald Sandler, *Enhancing Justice* (2008)

3. What obligations do governments have towards society to ensure 'safe' science or otherwise to shape the scientific research and development? (***Indicative questions — Science and society*** *page 7 of the Call for Evidence*)

Municipal governments and legal mechanisms have a significant role to play in providing appropriate safeguards and incentives and enforcing the rights and responsibilities of scientists and participants through a robust national health policy, including (a) clinical trial protocols specific to genome editing research; (b) safe storage of personal health data; and (c) confidentiality of participants. Other measures include (d) counselling; (e) research and educational infrastructure; and (f) measures to increase awareness and participation.

4. To what extent are laws and legal frameworks necessary or desirable in seeking to ensure adherence to the moral principles that should inform genome editing? (***Indicative questions — Science, morality and law*** *at page 8 of the Call for Evidence*)

The legal segregation of GETs on the basis of intended end-points is imperative to ensure that a different set of regulatory controls apply to different kinds of modification. Given the limitless possibilities for precise genome editing offered by existing, emerging and speculative GETs, the law needs to prevent abuse of such technologies by clearly identifying what can and cannot be edited, regardless of how safe it is proven to be. Allowing curative or therapeutic changes – where individuals are given the option of removing inherited disease genes, deformities and disabilities – seems reasonable, but there need to be legal barriers to certain non-therapeutic changes that threaten human rights and dignity. The standard recommended by the scientific community, which includes those who invented the GETs, is that their application must be "philosophically or ethically justifiable". For the purpose of designing a system of reasonable state controls upon an individual's procreative liberty, reference to the philosophy of eugenics and medical jurisprudence is useful.

It is submitted that the most effective way to regulate the use of GETs, in pre-clinical research, clinical trials and for commercial purposes, is by licensing GETs to state-aided and autonomous institutes, as described below, to prevent abuse and ensure fair and equitable access to the benefits GETs have to offer. Accordingly, GETs may be classified and regulated in the following manner:

Classification	**Regulation**
(i) Therapeutic GETs/ medical treatment — to cure diseases and anomalies, respond to genuine medical needs and restore normal physiological functioning	• May be licensed only to government hospitals and research institutes to facilitate ease of access and to ensure affordability of prevention and treatment to low-income groups • A ceiling may be fixed on the price of GET medical treatments to maximise impact • Claims in relation to GET medical treatments may be covered by insurance policies
(ii) Enhancement GETs — to expand human capacities without a curative effect (iii) Cosmetic GETs — to make physiological changes which can be classified as superficial or minor (cosmetic changes such as skin/ eye/ hair colour, height and facial features)	• May be licensed to government hospitals and private institutes • Price of GET enhancement and cosmetic treatments may be fixed by market forces since such modifications are not essential to health and wellbeing
(iv) Controversial GETs — to modify genetic traits in a manner which is unethical,	Must be prohibited and heavily penalised. However, it will be difficult to enforce a legal

	harmful or violates human dignity (sexual orientation, gender selection, personality and behavorial traits, extension of lifespan)	ban on such GETs without the state violating privacy rights of individuals, which may include, among other things, comparison of genomic data by regulatory to detect such abuse.

(B) Biomedical research and treatment

5. The translation from research into treatment and whether genome editing raises any special considerations, either about the assessment or management of risk, or about who should assess the safety and acceptability of therapeutic use? (*page 12 of the Call for Evidence*)

This assessment needs to be carried out by a panel of scientists from various government-aided and autonomous institutes, in exercising a role similar to which ethical advisory boards play in the process of approval of drugs and medical technologies.

6. The fitness and preparedness of regulatory systems and the variation in regulatory provisions among different countries. (*page 12 of the Call for Evidence*)

The existing stratification in current medical devices regulation, in relation to the rigorousness of assessment procedures depending on the design and functioning of devices, may be extrapolated to GETs. However, legislation needs to react to the emergence of GETs by recognising that they require regulatory controls proportionate with the nature and degree of physiological change intended. The current regulatory landscape is inadequate to provide safeguards for the use of GETs for the following reasons:

- The definition of "medical devices" in international conventions and domestic regimes excludes devices that are manufactured for purposes which cannot be classified as either diagnostic or therapeutic. This definition needs to expand to include GETS in order to ensure the safety and regulatory oversight of devices intended for enhancement and cosmetic changes as well.
- Controls under consumer protection laws and general product safety standards do not safety hazards and health risks that could arise from the use of GETs.
- There needs to be a Federal/ Central regulatory body equipped with the expertise to approve GETs for research and commercial use. Current administrative systems and government agencies responsible for drugs, technologies and consumer goods lack the jurisdiction and ability to deal with GETs. Within the existing system, GETs are likely to be approved as "substantially similar" as drugs and medical devices with a minimal level of scrutiny.
- Scholars have also suggested the developing of a "positive list" of enhancement devices in order to keep the purview of positive regulation "appropriately narrow" and to devise a regulatory model encompassing only those devices that warrant at least some monitoring.

7. What are the significant decisions that need to be taken before therapeutic use of genome editing may be contemplated (for non-heritable and heritable genetic changes) and who should have the responsibility for those decisions? (***Indicative questions — Impacts*** *at page 13 of the Call for Evidence*)

Policymakers will need to frame a restrictive legal definition of "therapeutic use" to the exclusion of all interventions that do not perform at least one of these functions: (a) prevent or treat diseases and anomalies; (b) have a curative effect; (c) restore normal physiological function; or (d) respond to a genuine medical condition. This delineation will inform a different set of policies to maximise access to therapeutic GETs as a safe, viable and affordable option for the prevention and treatment of diseases.