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April 15, 2025

Dear Ombudsman,

Re: Request for Ombudsman Inquiry into official conduct relating to Gene Technology Regulatory Reform.

The Physicians and Scientists for Global Responsibility (PSGR) are writing to request that the Ombudsman convene an Inquiry into conduct of the Ministry of Business, Innovation, and Employment (MBIE) and the Hon. Judith Collins, Kings Counsel and Attorney-General, in regard to their work on gene technology regulatory reform over the period 2023-2025. That the Ombudsman consider evidence that this body of persons acted improperly in their duties, directly undermining public law conventions, in order to expedite policies and laws in favour of the deregulation of gene editing technology.

PSGR rationale for this request is detailed in the April 2025 white paper which accompanies this letter:

PSGR (2025) When powerful agencies hijack democratic systems. Part I: The case of gene technology regulatory reform. Bruning, J.R., Dommisse, E., Physicians & Scientists for Global Responsibility New Zealand. ISBN 978-1-0670678-0-9

The case of gene technology regulatory reform paper reviews information provided in official documents. This information suggests that officials have set aside and undermined important issues and conventions in their pursuit of a new statute, that are essential to sustaining a robust, healthy, accountable democratic nation-state.

MBIE has effectively secured oversight and control of the development of policy and legislation for the Gene Technology Bill which would regulate the very technologies that it funds as the agency with responsibility for science funding, which MBIE and the Hon Judith Collins believe will promote economic growth. Cabinet documents and official reports indicate that policy and consultation processes activities have been short-circuited and corrupted, undermining administrative and constitutional conventions and principles.

For example, it can be demonstrated that there is no scientifically defensible reason for the public to trust that the proposed Bill can assure that the human and the environment will be safe. No scientifically appropriate enquiry of risk was ever conducted. It can be shown that consultation was pre-arranged to favour scientists and organisations with financial interests in biotechnology research. It appears that subpart 5, clause 50, was inserted at the 'last minute'. There is no discussion of this clause in policy papers, despite its draconian and unacceptable consequences.

PSGR request that the Ombudsman's terms of reference pay particular attention to the benefits of observing the principle of open justice, and require that the inquiry follows independent, impartial and fair processes. The Appendix below outlines our recommendations for the Ombudsman, which are detailed in pages 50-51 of the attached <u>Part I: The case of gene technology regulatory reform</u> white paper.

We look forward to your response.

Yours sincerely,

on behalf of the Physicians and Scientists for Global Responsibility New Zealand Charitable Trust.



Providing scientific & medical information & analysis in the service of the public's right to be independently informed on issues relating to human & environmental health.

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Appendix

Recommendation: That the Chief Ombudsman convene an Inquiry.

That the Gene Technology Bill be placed on hold. That the Ombudsman convene an inquiry to establish whether the actions and processes undertaken by the Ministry of Business, Innovation, and Employment (MBIE) and the Hon. Judith Collins, Kings Counsel and Attorney-General over the period 2016-2025, directly undermined public law conventions and processes to pursue policies and laws in favour of the deregulation of gene editing technology. That the terms of reference of an inquiry by the Office of the Ombudsman pay particular attention to the benefits of observing the principle of open justice, and require that the inquiry follows independent, impartial and fair processes to evaluate:

- Whether the MBIE funded Royal Society Te Apārangi adhered to the spirit of the Royal Society's professional code. The Royal Society did not evaluate the risks of gene technologies, but made recommendations for legislative reform, using language which implied that risks were understood.
 MBIE, the National Party and the Hon Judith Collins then drew on Royal Society information as a formal justification for the deregulation of gene technology legislation.
- That the Royal Commission on Genetic Modification 2001 (RCGM) recommendations produced a path for the stewardship of techniques of genetic modification (which includes gene editing technologies) that remains relevant in 2025. The extent to which RCGM recommendations have been implemented, reversed or undermined in the two decades hence. The precedent that is established if government agencies, such as MBIE, undertake a policy process but fail to take into account the findings of a Royal Commission, and take meaningful steps to ensure that the recommendations are adhered to.
- iii. Contract scientists with expertise in gene-editing techniques and regulatory risk assessment to undertake a methodological evaluation of the scientific claim that gene-editing techniques and organisms may be exempted based on the outcome being indistinguishable from conventional breeding or nature. Ensure that these scientists are free of conflicts of interests, and that they are not working in departments or agencies who are conducting research which is intended to have a commercial outcome. Assess the practical reasoning behind why the biotechnology industry and MBIE would desire that specific gene editing techniques and organisms would be completely excluded from regulation and why. Factors could include: difficulties in removing contaminants during the reagent process, errors, non-target and off-target risks from multiplex reactions.
- iv. Why MBIE officials did not follow accepted administrative law conventions. Cost benefit and economic analyses were not undertaken. MBIE did not contract independent scientific researchers to undertake a methods-based, scientifically rigorous risk assessment to confirm that the proposed regulatory changes would be appropriate and not present an undue risk to human or environmental health and safety. A biosecurity risk assessment (for native and non-native species) was not undertaken.
- v. Evidence of bias. Investigate whether gene technology regulatory reform processes inappropriately commandeered policy by selecting stakeholders for consultation and advisory committees to favour the advice of industries and particular institutions who had financial investments in gene technology.
- vi. Whether it was fair and reasonable that MBIE and Judith Collins would exclude the option of retaining and amending the Hazardous Substances and New Organisms Act 1996, i.e., the status quo, from any consultation process.
- vii. The extent to which the Attorney-General, Judith Collins steered the policy and consultation process.
- viii. Use an independent contractor to run an artificial-intelligence based assessment of the submissions to the Gene Technology Bill, and evaluate the basis for public concerns regarding:
 - a. Trade and economic risks.
 - b. Environmental and human health risks.
 - c. Exclusion of the precautionary principle and other bioethics-based issues.
 - d. Medical clauses.

- e. Deference to offshore jurisdictions.
- f. Extent of support for the Bill, versus extent of support for the HSNO Act.
- g. Concerns expressed by individuals/organisations with scientific expertise.
- h. Food safety risks and food transparency concerns.
- i. Outdoors risks and risks from use outside containment facilities.
- j. The capacity of the regulator to assess new and future risks.

