



gene ethics
working for a GM-free future

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January 14, 2022

Hon Greg Hunt MP
Minister for Health and Aged Care
PO Box 6022,
Parliament House,
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E: Minister.Hunt@health.gov.au

Re: The Mitochondrial Donation Law Reform Bill 2021 (Mito Bill)

Dear Minister,

GeneEthics considers mtDNA transfer and heritable human germline genome editing should continue to be illegal. We have therefore asked all Senators to vote No to the Mito Bill when it is debated in the Senate.

As the Revised Explanatory Memorandum to the Mito Bill admits: “the risks for children born using these techniques are not yet fully understood and the available scientific evidence to support this procedure is limited.”¹ The Government’s Consultation Paper on the Bill also concedes: “immediate and long-term risks for the child and longer term implications for subsequent generations are not yet fully understood.”²

Of course, we deeply sympathise with people suffering one of the 300 Mito diseases but the proposed Mito laws would also legalise heritable human genome editing experiments and the clinical use of new, untried and very risky mtDNA techniques and procedures. Changes to the genetic makeup of any children born and their descendants would be permanent and irreversible.

The proposed high-risk mtDNA techniques may satisfy the desire of a woman suffering a Mito disease to have a child genetically related to her. But her aspiration should not trump the risks of disease in her child and future generations, which are unacceptably high. She already has many options available to start a family, which are much safer for her child and its descendants.

Amendments to the Bill are essential if it is enacted

That said, if the Bill is to pass despite our well-founded objections, we ask you to make several amendments that are crucial to helping ensure the more robust governance, regulation and conduct of Mito experiments and clinical use. They would make the law more precautionary, open and transparent than the Bill is now.

We ask you to make the following changes.

¹ Mitochondrial Donation Law Reform Bill 2021, Revised Explanatory Memorandum, P75.

https://www.aph.gov.au/Parliamentary_Business/Bills_LEGislation/Bills_Search_Results/Result?bld=r6697

² Australian Department of Health, Legalising mitochondrial donation in Australia: Public consultation paper, 2021, P3.

1. OGTR and GTTAC engagement

We commend you for amending the Bill in the House to ensure the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (ERLC) can seek expert technical advice. It is a big responsibility for a non-expert committee.

However, it is also essential that the Office of Gene Technology Regulator (OGTR) and its expert Gene Technology Technical Advisory Committee (GTTAC) also review experimental and clinical Mito applications, as they do for all other medical genetics proposals.

There is no sound policy rationale for the Bill to expressly preclude the OGTR from assessing applications to deploy Mito techniques and processes, and from offering its objective expert advice to the ERLC. Such assessments would provide the licensing committee with a greater diversity of expert opinion. OGTR engagement may also help to ameliorate the trenchant problem of conflicts of interest, which must also be remedied.

2. Minimise conflicts of interest

The Bill needs amendments to minimise, manage and resolve the very real problem of conflicts of personal, professional or commercial interest that would inevitably arise among ERLC members, expert technical advisors, and other persons with powers under the Mito law.

At the very least, all conflicts of competing interests must be declared. These people must also recuse themselves from offering Mito-related advice or making Mito licensing decisions.

Professor John Christodoulou of the Murdoch Children's Research Institute rightly warned in his submission to the Senate Community Affairs Committee Inquiry into the Mito Bill that:

“Careful thought will need to be given as to the governance of the licensing body to minimize any perceptions or indeed actual conflicts of interest.”³

And Ms Wallbank from the Australian Government Department of Health acknowledged that conflicts of interest would be an important potential issue when she told the Senate Community Affairs hearings on August 6, 2021 that:

“... the Bill allows for the ERLC to request and have regard to advice from any person having appropriate expertise, ... to assist with ensuring that there's no conflict of interest, given the small pool of experts in this area.”

Ms Wallbank's concerns will not be properly addressed while OGTR and GTTAC experts are precluded from assessing Mito applications, as they do for all other genetics-related medical research projects. The Bill is not an antidote to present and future conflicts of interest affecting crucial decisions.

Some members of the ERLC already have conflicts of interest and it will be an opportunity missed if the Bill is not amended.

Conflicts 1

For instance, Professor Dianne Nicol, Director of the Centre for Law and Genetics at the University of Tasmania, is also Chair of the NHMRC's ERLC⁴ until 2024. As she is also a member of the Genomics Health Futures Mission⁵ (GHFM) Expert Advisory Committee, the

³ Prof. John Christodoulou, Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021, Submission 13.

⁴ Membership of the ERLC, 2021-24. <https://www.nhmrc.gov.au/embryo-research-licensing-committee-2021-2024>

⁵ Genomics Health Futures Mission. <https://www.health.gov.au/initiatives-and-programs/genomics-health-futures-mission>

Professor already has unacceptable conflicts when she advises the Minister for Health on strategic priorities for research investment through the GHFM.⁶

For example, Monash University received \$500,000 for 'Preventing mitochondrial disease using genomics' and Murdoch Children's Research Institute was granted \$3 million to fund a 'Mitochondrial Diagnostic Network for Genomics and Omics',⁷ most likely with the GHFM's Expert Advisory Committee's advice.

The Mission's Expert Advisory Committee may also have recommended that the Minister approve the funding of a Monash University Research Project,⁸ "Preventing Mitochondrial Disease Using Genomics - Ethical, Social and Legal Aspects", which runs from July 1, 2020 to June 30, 2023. The project received a \$250,000 Commonwealth Department of Health grant to:

"increase public trust in genomic technologies used to diagnose and prevent mitochondrial disease."

Having the Chair of the ERLC engage in such a recommendation already poses a conflict. If the researchers, scientists or entrepreneurs conducting these projects were ever to apply to the ERLC for Mito-related licences, the conflicts would be greatly compounded.

Conflicts 2

The Medical Research Futures Fund, with Professor Nicol as a member, also funded the Australian Citizens Jury (AusCJ) that convened a deliberative process from June 17 to 20 2021, in Old Parliament House, Canberra. Twenty-three people, handpicked from among one hundred and thirty two volunteers, discussed human genome editing and also mitochondrial donation.

Professor Nicol was AusCJ Project Co-Leader, expert presenter, rapporteur, media spokesperson, and co-author of the AusCJ Preliminary Report.⁹ Her central role and influential interventions are clear in the forum video, especially at 12'15" and 21'35".¹⁰

In a media advisory she said:

"It has been demonstrated on numerous occasions that lay citizens are perfectly capable of understanding complex technological, ethical, legal and social issues and providing meaningful guidance to policymakers."

But after the four-day meeting, jury members judged the information that the AusCJ had provided as biased in favour of human genome editing and Mito donation. For example, in an ABC interview one citizen participant said: "it just seemed to be a little bit one-sided."¹¹ The Interim Report of the event also notes that, when surveyed, half of the participants did not agree that: "The information I have received has been fair and balanced between different viewpoints" and that many: "felt that a more critical perspective ... was missing."

Though Human Genome Editing was the main topic of discussion, the Preliminary Report also says that:

⁶ Genomics Health Futures Mission, Expert Advisory Committee Members. <https://www.health.gov.au/committees-and-groups/genomics-health-futures-mission-expert-advisory-committee>

⁷ <https://www.australiangenomics.org.au/research/mitochondrial-diagnostic-network/>

⁸ Preventing Mitochondrial Disease Using Genomics - Ethical, Social and Legal Aspects, Monash University research project. <https://research.monash.edu/en/projects/preventing-mitochondrial-disease-using-genomics-ethical-social-an>

⁹ Participant Recommendations and Preliminary Report, AusCJ <https://www.australiancitizensjury.org/interim-report>

¹⁰ Mutant <https://www.youtube.com/watch?v=OskSspvORII>

¹¹ Stephen Merrett, AusCJ Research Forum, September 8, 2021, from 20'40". <https://www.youtube.com/watch?v=xcRtAYsOjCM>

"Mitochondrial donation was included in the task due to the pending debate on legislation concerning its regulation in the Federal Parliament around the time of the AusCJ."

The organisers clearly intended that AusCJ recommendations would be made available to inform and influence the House of Representatives debate and conscience vote on the Mito Bill. However, the validity of the three recommendations in favour of Mito experiments and clinical use are in serious question as:

"Recommendations for mitochondrial donation were developed by a subset of participants, without inclusion and direct consent of the full citizen's jury."

Despite their questionable validity, the AusCJ recommendations may have unfairly influenced the vote in favour of the Bill, which finally occurred on December 1, 2021.

Professor Nicol's roles as the AusCJ Project Co-Leader and ERLC Chair are clearly at odds.

The Mito Bill should at least provide a robust decision procedure for preventing and resolving such conflicts of interest over the ERLC committee issuing experimental and clinical Mito licenses.

3. The Bill now exonerates Mito experimenters, members of the ERLC, other officials, politicians, and advisors, and the IVF industry from accountability for all impacts of their decisions and actions. Such a free pass is against the public interest and the human rights of those affected.

Such exclusionary provisions confirm the Mito techniques and procedures pose unacceptably high risks and unpredictable hazards, with potentially devastating consequences for many people, far into the future. The Bill ignores the human rights of future generations and the increasingly strong case for intergenerational equity. Degrading and contaminating the human gene pool is a serious threat to intergenerational equity.

The Bill should therefore be further amended to remove the provisions that pre-emptively exonerate all those people who should remain responsible for any negative impacts of Mito experiments and clinical use. Everyone involved will be jostling to claim the kudos for any benefits so should also be responsible for any harm.

4. We concur with your amendment to the Bill, to require the ERLC to publish an annual report.

However, the Bill also imposes unreasonable constraints on the ERLC fully reporting. The number of Mito licences issued, the number of live births of Mito-altered children, and any adverse events and accidents should be in the public domain as part of the report. Such information would not infringe the privacy provisions of the law and would provide information critical to public knowledge and understanding of the proposed Mito transfer techniques and reproductive processes.

5. The Bill should require a minimum of twenty Mito experiments to be successfully and safely concluded, with the positive outcomes published, before any Mito donation techniques or processes are considered for clinical licensing.
6. The Senate Scrutiny of Bills Committee raised significant unresolved concerns about some aspects of the Bill, which have not been remedied. Reliance on delegated legislation and other documentation is just one example, where:

"the committee's view is that significant matters, such as provisions defining the scope of key terms as well as requirements relating to the withdrawal of consent, should be included in primary legislation ...".

Conclusion

GeneEthics rejects the Mito Bill and urges that it not be enacted. Additional research is needed, prior to human experimentation and clinical use.

But, if the Bill is to be enacted, we request that you make the vital amendments to the Mito Bill that we have advocated in this letter, to reduce the risks to future generations.

Yours sincerely,

A handwritten signature in black ink that reads "Bob Phelps". The signature is written in a cursive style with a long horizontal stroke extending to the right from the end of the name.

Bob Phelps
Executive Director