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Submission to the Senate Community Affairs Legislation Committee on Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021

July 12th, 2021

Murdoch Children's Research Institute (MCRI) is the largest child health research institute in Australia and is dedicated to making discoveries to prevent and treat childhood conditions. The field of human genetics is one of MCRI's longstanding strengths and we are proud of the role our subsidiary, Victorian Clinical Genetics Services (VCGS), plays in providing not-for-profit clinical and laboratory pathology genetic services to thousands of Australian families. Mitochondrial disease is an area in which MCRI has a prominent international profile, thanks to over 30 years of experience in mitochondrial disease diagnosis, prevention and research led by Professors David Thorburn and John Christodoulou plus our clinical and VCGS laboratory teams. David and John have been closely engaged in providing expert input to the 2018 Senate Inquiry, the NHMRC Expert Review Committee and public engagement efforts that resulted in drafting of Maeve's Law. Professor Julian Savulescu and Dr Chris Gyngell from our Biomedical Ethics Research Group have also provided expert input on ethical aspects of Mitochondrial donation. Given that background, I am delighted to now provide specific comment on the proposed legislation.

In previous submissions, I provided strong support for mitochondrial donation to be made legal in Australia, subject to it being introduced in a cautious and carefully regulated way for prevention of severe mitochondrial DNA (mtDNA) disease, similar to the process in the United Kingdom. The proposed legislation addresses the significant community support for legalising mitochondrial donation identified in previous rounds of consultation. It appropriately restricts the use of this approach only to women who are at risk for having a child with severe mtDNA disease. It provides a mechanism to ensure that the prospective parents will receive counselling about potential alternatives and about uncertainties associated with introduction of new medical technologies. The stage 1 clinical trial approach will enable access to the technology as quickly as possible while encouraging ongoing collection of data about its safety and efficacy and ensuring strong regulatory oversight. Sensibly, it largely follows the UK process, with some modifications to ensure compatibility with differences in the Australian healthcare system. The proposed legislation thus provides a strong balance of maximising the potential benefits for families with mtDNA disease while having safeguards that take into account concerns raised by some sectors of the community about ethical, legal, religious or other social issues.

I am impressed by the thoughtful consideration that has gone into the Bill, particularly in terms of the two-stage approach, the development of distinct research/training licenses versus clinical licenses and oversight by the NHMRC Embryo Research Licensing Committee. I am also heartened by the Federal budget making financial plans for introduction of mitochondrial donation.

The only section of legislation I wish to comment on specifically Is Paragraph 28P(4-5) of Part 1—Main amendments to Prohibition of Human Cloning for Reproduction Act 2002 (p.24-25 of document 21043b01) and referred to as Note 120 (p.33) of the Explanatory Memorandum. This section relates to "*Committee approval before creation or placement of embryo*", i.e., consideration by the NHMRC Licensing Committee

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of whether a specific woman is eligible to access mitochondrial donation. Explanatory Note 120 states "*To address this criterion, the intention is that the ERLC would need to be satisfied that there was an appropriate level of clinical evidence to be able to make this determination. It is therefore intended that each individual application for approval by the ERLC would need to be accompanied by an acceptable level of clinical and diagnostic information, in a form approved by the ERLC, to enable the ERLC to make this decision.*"

The following comments are perhaps more relevant to the implementation and regulatory process, rather than the legislation itself, but warrant mention. Two key aspects of determining eligibility are assessing whether a woman is at high risk of having a child with severe mitochondrial disease and whether other reproductive options may be more suitable than mitochondrial donation for that woman. These factors depend on the specific mutation in the family and the likely distribution of the mutation in the woman's eggs. Hence, their assessment requires specific expertise in the clinical aspects of mitochondrial disease and in the genetics and reproductive biology of human mitochondrial disease.

In the UK, the HFEA process was to seek input from two external referees from a panel of International experts on whether each case fulfilled the eligibility criteria prior to issuing a licence to the couple. That mechanism had potential for different levels of expertise among reviewers to result in inconsistent responses and I believe it has now been modified to minimise that prospect. The proposal for the NHMRC Embryo Research Licensing Committee (ERLC) to review applications is a sensible one that should lead to fair and consistent outcomes. It is worth noting that the current membership of the ERLC lacks specific expertise in the clinical and genetic aspects of human mitochondrial disease. Hence, the ERLC (or a sub-committee of the ERLC) would presumably need to be supplemented or advised by additional individuals to provide expert input on the risk of a woman having a child with severe disease and whether other reproductive options may be more suitable than mitochondrial donation. There may be multiple ways in which that process could be structured but I suggest that in order to provide consistency, it would be desirable to have a small expert group advising the ERLC on a consistent basis rather than the initial HFEA approach described above.

I wish to emphasise that these comments are not a criticism of the HFEA, who have provided an international masterclass in introducing and overseeing mitochondrial donation. The proposed legislation on mitochondrial donation draws heavily on the UK experience and my comments reflect a desire that we incorporate the learnings that have occurred in the UK over the last 4 years. Thank you for the opportunity to comment on this well crafted piece of legislation. I look forward to MCRI researchers continuing to play key roles in prevention of mitochondrial disease in Australia in coming years.

Yours sincerely,

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