Thank you for asking me to provide further commentary on the proposed new legislation (Maeve's Law). I was very pleased to hear that this is to be debated in the House of Representatives, with the expectation that the proposed law will be put to a conscience vote. If passed, this legislation will give families who previously had limited reproductive options an opportunity to restore their reproductive confidence, with the express aim of avoiding severe mitochondrial disease in their offspring.

I think that the adoption of a clinical trial model is a very pragmatic one. It will give families immediate access to the technology, and provide a mechanism to build further clinical evidence of efficacy and safety of the technology. In addition, this approach will give state jurisdictions time to consider changes that might need to be made their relevant state legislation to align it with the federal legislation if they deem that appropriate.

Licensing of one or more organisations that are recognized to have the capacity to develop and provide the expert clinical support and the necessary IVF expertise is very appropriate, but 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.

Careful consideration needs to be given as to the appropriate criteria for identification of families for who mitochondrial donation might be appropriate. I would suggest that an expert clinical panel (including clinical subspecialists with expertise in the diagnosis and management of paediatric-onset or adult-onset mitochondrial disease, clinical geneticists, IVF experts and ethicists) should be convened. I anticipate that in a number of clinical/genetic scenarios it will be possible to reach very clear consensus that mitochondrial donation is an appropriate option, without having to have an independent expert assessment every time such a scenario is presented for consideration. There will be other scenarios where the evidence is not so clear cut, and where such an expert clinical panel could be regularly convened (and also on an ad hoc basis as necessary) to review referrals the family's managing clinician on a case-by-case basis. Implementation of such processes will ensure timely access to and consistent application of the technology to the families who would benefit most from mitochondrial donation.

Should you require any further clarification or wish to discuss any of my comments, please do not hesitate to contact me.

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