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Advisory Committee on Assisted Reproductive Technology (ACART)
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ACART Discussion Paper: Import and Export of Gametes and Embryos

Thank you for the opportunity to comment on the Advisory Committee on Assisted Reproductive Technology's (ACART) discussion paper *Import and Export of Gametes and Embryos*.

The discussion paper presents arguments on six key issues in respect of the import and export of gametes and embryos where there is "potential for a significant clash between New Zealand requirements and those elsewhere", and requests submissions on New Zealand's regulatory framework in relation to those areas. The six areas are: altruistic donation v commercial supply; right to access identifying information about donors v no right to access such information; family size requirements; use of sex selection; scope of informed consent; and the use of gametes and embryos overseas in procedures or research prohibited or precluded in New Zealand.

As Health and Disability Commissioner, I am charged with promoting and protecting the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). One of my functions under the Health and Disability Commissioner Act 1994 is to make public statements in relation to any matter affecting the rights of health or disability services consumers.

While the discussion paper raises a number of social and ethical issues, I have decided to limit my comments in this case to the scope of informed consent, which raises direct issues under the Code. However, I reiterate this Office's previous comment to ACART in relation to the import and export of gametes and embryos[1] that the use of any imported gametes and embryos should be required to meet the same quality and safety standards required for those originating in New Zealand, including standards relating to consent, information provision and the treatment of donors.

[1] See HDC's comments on ACART's consultation on *Advice on Aspects of Assisted Reproductive Technology: A consultation paper on policy issues* (emailed to ACART on 7 September 2007), and ACART's discussion document *Use of Gametes and Embryos in Human Reproductive Research: Determining policy for New Zealand* (emailed to ACART on 1 March 2007).

Consent to export gametes and embryos

You have asked whether consent should be required before gametes or embryos are exported to or from New Zealand. In other words, should export occur only where a gamete provider has given explicit consent to export?

I am surprised that this section of the discussion paper does not refer to Rights 7(9) and 7(10) of the Code. As noted in my letter to you of 7 February 2013 (in relation to the status of embryo donors as consumers), Rights 7(9) and 7(10) of the Code relate to the use, return, and disposal of body parts and bodily substances removed or obtained in the course of a health care procedure. There is no definition in either the Act or Code of "body part" or "bodily substance"; however sperm and eggs would be considered "bodily substances". As such, Rights 7(9) and 7(10) apply to the use, return, and disposal of gametes removed or obtained in the course of fertility treatment.

What this means is that, in accordance with the Code, gamete donors should receive information and make an informed decision about how their gametes will be used, stored, and what will happen to them after treatment is completed, including in relation to the export of gametes and the implications of a decision to export (as set out in paragraph 38 of the discussion document[2]). Any future use of the gametes should only be in accordance with the choice the consumer made.

Any gamete imported into New Zealand should also only be used in accordance with Rights 7(9) and 7(10) of the Code, that is, in accordance with the consent of the gamete donor. In my view, such consent should include consent for the gamete to be imported into New Zealand and for the gamete to be used for the specific purpose proposed. It should not matter that the gamete has been sourced outside of New Zealand. It would be inappropriate for different rules to apply to the use of gametes imported into New Zealand than to those sourced in New Zealand.

The exception to the above is where it is proposed that the gametes be stored, preserved or used for the purposes of research that has received the approval of an ethics committee, or for the purpose of a professionally recognised quality assurance programme, an external audit of services, or an external evaluation of services (see Rights 10(b) and (c) of the Code).

As also noted in my letter to you of 7 February 2013, the legal requirements regarding the use of embryos are less clear under the Code. This is because under the Code an embryo created in a laboratory and outside of a woman's uterus is unlikely to be regarded as a "body part" or "bodily substance" of either the genetic mother or father. Once fertilisation has taken place in the laboratory, a new entity comes into existence which may not qualify as a body part or bodily substance of a consumer for the purposes of Rights 7(9) and 7(10). Accordingly, on a strict legal reading, once an embryo is created the donors do not have the protections of Rights 7(9) and 7(10) of the Code. However, as I noted in that letter, regardless of the legal technicalities it is my view that, at the time gametes are extracted for fertility treatment, each

[2] Those implications include: gamete providers may not be able to withdraw or vary consent after export if gametes and embryos are exported to a country with different rules or practices concerning when a donor can withdraw consent; parties involved in import and export may have different or mistaken assumptions about when they or others may withdraw or vary their consent; conditions attached to consent given in New Zealand may not be upheld after export; and individuals who decide to withdraw consent to the use of their gametes or of embryos formed from their gametes may face difficulties in notifying the appropriate party or body that they have withdrawn consent.

gamete donor should be fully informed and asked about their wishes for the future use of any surplus embryos, and any future use of those surplus embryos should be in accordance with the stated wishes of the gamete donors, including the export of such embryos.

As with the import of gametes, it is my view that any embryo imported into New Zealand should only be used in accordance with the consent of the gamete donors. In my view, it would not be appropriate for embryos to be imported into New Zealand without the informed consent of the gamete donors.

In the section "Arguments in support of requiring explicit consent to gametes and embryos being exported to or from New Zealand", it is noted that in most cases, donors will not have considered the possibility that their donated gametes or embryos created from their donated gamete, might be sent to another country for use in treatment or research. In my view, this is a matter that should be discussed with gamete donors at the time of donation, if it is a real possibility.

In the section "Arguments for not requiring explicit consent to export to or from New Zealand" the discussion document states, "Once a donor has made a donation, he or she no longer has a role in decision making about gametes …" This statement is inconsistent with Rights 7(9) and 7(10) of the Code (as outlined above) and therefore misstates the legal position in New Zealand.

I do not accept the argument that informed consent requirements will become "overly complex" if consent to the export and use of gametes and surplus embryos is required.