Opening Statement by Dr. John Kennedy, Group Medical Director, Virtus Health Ireland

28th February 2017

Representing Virtus Health Ireland, including Sims IVF, Sims IVF Cork, and Rotunda IVF, collectively the largest provider of Assisted Human Reproduction services in Ireland

Introduction

Our submission is the work of a multi-disciplinary team, comprised of doctors, embryologists, nurses and compliance specialists, all actively working in fertility.

As a group we welcome the introduction of legislation that extends beyond the technical regulations for the laboratory set out in the EU Tissue and Cell Directive. We recognise the importance of the legislation and look forward to establishing a relationship with the future regulating body.

We are confident that the storage requirements for gametes and embryos, the guidelines for genetic testing, the Welfare of the Child provision and other parts of the Bill will greatly improve patient experience, and are in keeping with the aim of the act; to safeguard "the health and wellbeing of children born as a result of such treatments and to women who receive such treatments."

We do however have a duty of care to our patients, and believe that certain aspects of the legislation may have consequences for their treatment and their future families. We have outlined the points in the following document and ask that they be taken into consideration prior to approval of this Bill.

We have also included a number of points where we would like clarification, to ensure not only our compliance with the legislation, but also that the best and most appropriate treatment options are available to patients.

Our response is presented in accordance with the sections of the Bill, and headings and subsections have been included accordingly.

Part 1 Preliminary & Part 2 General

A service provider is referenced as a "person" rather than a clinic. We would request clarification of who exactly will be licenced.

Head 6

This provision excludes potential candidates from non-medical (social) egg freezing as there is no reasonable expectation of subfertility in this group.

Subsection 2(b)
We would request clarification of the national standards in relation to disproportionate risk of health of the woman or child. We would be supportive of a multi-disciplinary case by case review of high risk patients to determine and counsel them regarding the risks of AHR and pregnancy so they can make an informed decision regarding their care.

Subsection 2(c)
We are supportive of the welfare of the child provisions and welcome the planned guidelines and instructions.

Subsection 3
We would strongly advise that the age for treatment is reduced to 18, the legal age of adulthood in Ireland.

Subsection 4
It is our belief that limiting treatment to patients 47 years or younger is discriminatory. In keeping with international practice and UK guidelines we would suggest that the age limit is determined by the age of natural menopause, which is 50.6 years. It is worth noting that 153 patients over the age of 47 years in the last 5 years have attended Sims for egg donation treatment. 50% of those patients achieved a pregnancy as a result of treatment. Notwithstanding the children who would not have been born had this legislation been in place at that time, even the unsuccessful couples would have been denied their constitutional right to attempt to have a family. We feel strongly that this is the most punitive aspect of the proposed legislation.

Subsection 5
The restrictions on treatment for men are unclear and may prove difficult to enforce. Without clear guidelines for approving or refusing treatment the intention of this statement may not be enacted. This restriction will significantly impact on oncology patients and their potential treatment.

Head 7 Welfare of the Child
We are in agreement with the approach put forward in the general scheme

Head 8 Counselling

We understand and accept the guidelines established for counselling and will work to facilitate the requirements in the near future.

We do have some concerns over the mandatory nature of counselling which many patients do not wish to undertake. We are very supportive of the role counselling plays in the provision of AHR but feel that this should be encouraged and patient directed, not mandatory.

Head 9 Consent
We would like to request clarification regarding the use of embryos for training purposes as opposed to research. Does the term research as used in the bill include the use of gametes and embryos for training?

It is stipulated that written request is required to revoke consent; we would like to confirm that treatment may be delayed on receipt of a verbal request.

Head 10
We are very supportive of the move towards single embryo transfer but are happy that there is scope for individual assessment for each patient depending on their circumstances and needs.

Part 3 Gamete & Embryo Donation

Head 12
Embryo Donation: for surplus embryo donation the embryo donors would not have undergone the level of screening required for donation under the statutory instruments.

Subsection 1(b)
This section provides a minimum age of 18 to be a donor. We are requesting clarification as previous sections required the patient to be 21 to engage in any AHR treatment.

Subsection 3
We would like to request clarification regarding the use of embryos for training purposes as opposed to research. Does the term research as used in the bill include the use of gametes and embryos for training?

Head 13 Embryo Donation for the use of AHR or Research

We would like to seek clarification regarding the creation of embryos solely for donation. Is this prohibited? We understand that supernumerary embryos may be used for the treatment of infertile couples where both donor egg and sperm are needed and can also be used for same sex female couples where there is also a need for an egg donor. Given that there is provision for double donation in these circumstances then we would propose that "double donation" (both egg and sperm donation) be facilitated for those couples who would remain childless without such a resource.

Head 16 Limits on the Use of Donated gametes and embryos

Subsection 4(a)

This section stated it is prohibited to use sperm provided by more than one man per treatment cycle. Does this apply if oocytes are separated at retrieval and fertilised in separate dishes, with only embryos from one dish transferred per cycle? In this instance traceability is fully maintained throughout the cycle and intending parents would be aware if a child was conceived using partner or donor sperm.

Subsection 5(b)

Embryos created can no longer be used in the event of the death of the donor. We feel strongly that as donors can't withdraw consent once embryos have been created, embryos created should be suitable for use following the death of the donor.

Head 17 Access to Gamete & Embryo Donation

Subsection 3(a)

We believe that this subsection is discriminatory to men as it does not provide for the use of a surrogate, restricting their treatment options.

Head 19 Non-commercial Gamete & Embryo Donation

We would suggest that reasonable expenses for the donor be extended to include compensation for loss of working hours where appropriate.

Head 21 Disclosing Medical Information

We feel this section provides clear guidelines for all medical practitioners, and will be beneficial in ensuring appropriate care is provided.

Head 22 Storage of Gametes & Embryos
We are supportive of this provision, and agree that storage limits are a necessity. We would like clarification regarding the application of this provision; will it be applied retrospectively? If these limits are applied to existing embryos and gametes will the time frame begin from the date of freeze/creation or from the date the provision becomes law?

Subsection 9
We would like a definition of reasonable efforts to contact a patient; the number of attempts and the methods required to be considered reasonable.

We are also requesting clarification of the extension period. Will it be a standard length, e.g. 5 years? Can patients apply for more than one extension or will extensions be limited?

Will the same timelines apply to oncology patients or will an extended storage period be available to them without application?

Part 4 PAR

Head 24

Subsection 1(b)
We are concerned that this may be discriminatory towards male patients seeking treatment as it states the surviving partner must carry the pregnancy. This does not allow for surrogacy in the event the surviving partner is male.

Subsection 1(d)
We would suggest that the automatic one year delay to treatment is overly prescriptive. We would prefer to see treatment available to the patient once they have received appropriate counselling and clearance from a qualified counsellor**.**

Head 27
This provision states the surviving partner must carry the pregnancy. It does not make provisions for surrogacy in the event the surviving partner is male.

Part 5 PGD

We are accepting of the guidelines provided and believe the matter has been addressed sensitively and thoroughly.

Part 6 Surrogacy

Head 36
We would like to confirm that clinics will not be able to facilitate patients who request the shipment of their embryos abroad for the purposes of surrogacy. Does this mean that the only option available to patients is domestic surrogacy?

Does this also prohibit the routine fertility testing of couples thinking of travelling abroad for surrogacy if such an option is not available to them in Ireland, e.g semen analysis, or blood tests?

Does this also prohibit AHR providers from giving information to couples about surrogacy options abroad?

We would ask if there is any exceptions considered for oncology patients where a domestic surrogate is not available. Will this provision be replied retrospectively to oncology patients who have created embryos and plan to travel abroad for the purposes of surrogacy?

Head 42 Advertisements for Surrogacy
Given the other requirements set out in the legislation such as the prohibition of commercial surrogacy we do not understand the restrictions on advertising for surrogates.

We would propose the establishment of a state agency, similar to existing organisations within the UK and other countries that help identify surrogates for patients. This service will be essential for Irish patients in light of the prohibition on international surrogacy.

Part 8 Assisted Human Reproduction Regulatory Authority

We welcome the establishment of the AHRRA.

Current oversight is provided from a cell and tissue perspective by the HPRA. We are concerned that having 2 separate regulators will result in work duplication for both the organisations and providers. We would propose putting all regulatory oversight under one organisation such as in the UK with the HFEA.

We would also suggest that the board membership include a member who is currently actively working within the area of AHR.

How will AHRRA be funded? Our concern is that there will be an additional cost to patients.