Opening Statement by Dr John Waterstone Irish Fertility Society

Oireachtas Joint Committee on Health regarding the General Scheme of the Assisted Human Reproduction Bill 2017

28th February 2018

I am a medical doctor who has been working in Assisted Reproduction for 30 years. My specialist training took place in the NHS in London and I currently work in the HSE as a Consultant Obstetrician, as well as being the Medical Director of Waterstone Clinic.

I am here today to represent the interests of the patients I care for. As President of the Irish Fertility Society (IFS), I have contributed to the submission to this Joint Committee made by the Society and the majority of the views I express today are shared by the majority of its members.

I am very concerned that some elements of the Children and Family Relationships Act (although not implemented) and of the legislation which is now before the Joint Committee are insensitive to patients' needs and unreasonably coercive.

I want to thank the committee for the opportunity to present my views today. I cannot overemphasise the vital role you play if legislation is to result which is fit for purpose. A full list of specific issues is included in the more detailed submissions which supplement this opening statement. I will only address key issues here.

Statutory Legislation VS Guidelines

Many clinical issues (i.e. the number of embryos which can be transferred at a time, and age limits for accessing treatment), should be the subject of practice guidelines formulated by the Assisted Human Reproduction Regulatory Authority (AHRRA) rather than statutory legislation. The latter mechanism is too inflexible to allow evidence based alteration of practice to take place as new techniques develop and attitudes change.

Composition and function of Assisted Human Reproduction Regulatory Authority

The AHRRA must be effective. Its exact composition is vital if it is to function effectively and requires scrutiny by the Joint Committee. The Joint Committee should know that all IVF units in the country are already strictly regulated, licenced and inspected by the Health Products Regulatory Authority (HPRA) under the EU Tissues and Cells Directive (EUTCD). After a decade of regulatory activity, the HPRA has accumulated valuable practical experience with regard to inspecting IVF units. It is vital that the functions currently carried out by the HPRA are not duplicated by the AHRRA and that a single regulatory body results. Duplication will generate unnecessary costs which are likely to be passed on to patients. A way must be found to merge HPRA activities with those of the proposed new AHRRA, developing a single regulatory body which implements both the EUTCD and proposed Assisted Human Reproduction Legislation.

Protection against financial exploitation

IVF treatment is only modestly successful and is expensive. Patients deserve safeguards which promote success and protect against financial exploitation. These functions have not been specifically proposed for the AHRRA but should be.

Restrictive AR Legislation and Conscientious Objection

Laws governing AR in Northern and Western Europe have tended to be restrictive, particularly with regard to financial compensation of egg donors and of surrogates and also with regard to anonymity (as opposed to identifiability) of donors. This has given rise to reproductive tourism where patients travel to other jurisdictions to escape restrictions in their own countries. The Joint Committee needs to be aware that this legislation cannot ignore reproductive tourism and also to be aware that an increasing number of European scholars and policy makers are arguing for more lenient national policies towards AR (Ref. 1). This draft legislation, although in the main progressive, is restrictive with regard to egg and sperm donation and to surrogacy and is in danger of looking backwards rather than forwards. Restrictive legislation will give rise to ethical dilemmas for AR clinicians who may have conscientious objections to unreasonable restrictions of patients' reproductive autonomy. Clinicians insist on their rights to such conscientious objection.

Parts 2 and 3 of the Children and Family Relationships Act (CFRA)

This dysfunctional attempt at piecemeal AR legislation on the part of the Department of Justice is, in retrospect, regrettable. Grave concerns voiced by the Institute of Obstetrics and Gynaecology (IOG) were completely ignored and the legislation was rushed through the Dail without sufficient debate. Parts 2 and 3 of the CFRA are unacceptably coercive with regard to the State forcing information regarding donor origin on 18 year olds, often against the wishes of parents. The Nuffield Council on Bioethics in the UK has concluded that *"it is not the role of State authorities, whether through direct contact with donor-conceived people, as they reach adulthood, or through the use of official documentation such as birth certificates, to intervene to ensure that all donor-conceived people know of the circumstances of their conception".* Ref. 2. Parts 2 and 3 of the CFRA threaten the rights of Irish citizens to privacy and reproductive autonomy. They would, if implemented, be open to constitutional challenge and I personally, on conscientious grounds, will be unable to comply with the measures involved. The DOH has already conceded that patients (more than 1000 per year) can continue to travel to Spain, Czech Republic and the USA for anonymous egg donation so that the National Donor Conceived Persons Register, should it ever materialise, would be hopelessly incomplete.

Points 2 and 3 of the CFRA are also dogmatic rather than pragmatic with regard to financial compensation of egg donors. Egg donation is for many couples a marvellous application of IVF technology which turns failure into success and the fulfilment of parenthood. Points 2 and 3 of the CFRA suggest ignorance of the fact that even the UK (initially a vociferous opponent of any compensation for donors) has relaxed its stance and now allows a payment of €750.00 to egg donors. It would be foolish for Irish legislation to copy legislation in other jurisdictions which has proved a failure. If altruistic egg donation is to be promoted a modest amount of financial compensation should be allowable for donors.

My clinic carries out altruistic egg and embryo donation and we are already finding that some potential donors are not prepared to donate unless the process is anonymous; an absolute ban on donor anonymity (as in Parts 2 and 3 of the CFRA) would, for these patients, prevent an altruistic act taking place. I believe couples should have a choice of using anonymous or identifiable donors.

The Joint Committee should take this opportunity to recommend the replacement of Parts 2 and 3 of the CFRA by acceptable and workable legislation.

Specific Issues - see separate submission for details

Many issues require further discussion, some of the most important are the following:

1. ***IUI treatment must be covered by the proposed legislation***

2. ***Age limits for treatment***

3. ***Mandatory counselling for all patients***

4. ***Maximum number of embryos transferrable***

5. ***Time limits for cryopreservation of gametes and embryos***

6. ***Posthumous conception – 3-year limit unreasonable***

7. ***Egg and sperm donation – anonymity and financial compensation of donors***

8. ***Surrogacy – conditions proposed are so restrictive as to amount to an effective ban***

9. ***PGS - omitted from general scheme***

10. ***Composition of AHRRA***

11. ***Suggested additional functions for AHRRA***

    a. ***Regulation of ovulation induction and IUI***

    b. ***Follow up of pregnancies and children after AR***

    c. ***Measures to prevent financial exploitation of patients***

Alterations to the General Scheme and Resolution of issues

The Joint Committee on Health must devise mechanisms for bringing representatives of the DOH together with representatives of the IFS and the IOG (i.e. those who have put considerable time and effort into formulating the legislative scheme and those who – together with their patients – will spend many years living with the consequences of the legislation). Above all, it is imperative that this legislative process is not rushed through with undue haste. The joint committee needs to ensure that the issues concerned are given the consideration they deserve in order to bring about a better future for patients, families and children.

Considering the complexity of the subject matter briefing documents accompany this opening statement. These include IFS communications to the Department of Health, IFS practice guidelines and IFS submissions to this Joint Health Committee.

References

1. ESHRE Task Force on Ethics and Law 2008: Cross Border Reproductive Care

2. "Donor Conception; ethical aspects of information sharing". Nuffield Council on Bioethics
   2013