Joint Committee on the Human Tissues and Embryos Draft Bill

British Fertility Society Evidence: 9th June 2007

The British Fertility Society (BFS) comprises a membership of over 800 healthcare professionals (doctors, scientists, nurses, counsellors and others) with involvement in fertility care provision and reproductive medicine research in the United Kingdom. The Society has the following aims and objectives:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for, and equity of access to, fertility treatments.

INTRODUCTION

The BFS has already responded in detail to the 25 proposals outlined in the preliminary White Paper published in December 2006, and the committee's attention is drawn to the detailed comments within that response *(http://www.fertility.org.uk/news/pressrelease/07_05-WhitepaperResponse.html.)*. The principal themes relevant to the fertility sector emphasised within our response were:

1. The need to re-evaluate the **costs of regulation** to the fertility sector which are high compared to those incurred in other areas of health care.
2. A concern with respect to the role and accountability of the Regulator in the **determination of policy i**n this sector.
3. A concern with respect to the current framework of **research regulation**, specifically the time taken to process applications and doubts with respect to the competence of the current regulatory structure to deliver an efficient public and professional service.
4. A view that the regulator currently acquires more information than necessary about individual **routine treatment** cycles.

The response has been collated after consultation with the membership and ratified by the Executive Committee of the Society.

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THE COMMITTEE'S CALL FOR EVIDENCE FOLLOWS A STRUCTURED FORMAT. USING THIS TEMPLATE THE BFS WOULD WISH TO SUBMIT THE FOLLOWING REMARKS.

A. THE DRAFT BILL OVERALL

The BFS agrees that the review of the Act is timely. The principle underlying the Arms Length Review process was, as we understand it, the intention to facilitate "cost savings and benefits to be passed on to the regulated sector and free up more resources for the delivery of services to patients" (Ref. page 124). Naturally, this would be greeted enthusiastically by those within the clinical sector, particularly against a background of the clear national failure to implement NICE guidance on the management of the infertile.

The BFS would strongly suggest that revised legislation must allow for sufficient flexibility to permit clinicians and researchers to operate within a supportive regulated framework which does not inhibit innovation.

There continues to be vigorous public and political debate about human reproductive technologies. Recent examples include donor anonymity, screening for adult onset disorders, egg donation for research and sex selection. The BFS believes that there should be a clear separation between this necessary open debate and the regulatory process. The debates should involve all relevant stakeholders, but should also afford the articulation of views by those with particular subjective interest in matters of controversy e.g. patients and providers, as well as those with wider interests e.g. in ethics, social policy, politics, religion, philosophy. Consideration could be given to the establishment of a National Bioethics commission in parallel with the new Authority, based within and accountable to Parliament, and which could facilitate recommendations in respect of policy.

B. RATE AND THE NEW REGULATORY ARCHITECTURE

The BFS wishes to express reservations about the need for the RATE and its proposed constitution, and doubt that as proposed it will be capable of delivering on its statutory responsibilities. The suggestion that the membership of the RATE, majority lay, would be less than that of the current HFEA give us concern that the capability of the Authority to reach informed and acceptably accountable decision making would be compromised. The proposal for the establishment of expert advisory panels (EAP's), with responsibility for guiding the RATE, would require such panels to be filled with individuals with expertise in science and clinical practice. How these panels would be appointed and accountable is unclear, and their constitution would seem to reduce the role of Authority members to merely rubber-stamp EAP recommendations. This additional layer of bureaucracy would seem to be little different from the present roles of the HFEA and the HTA and hardly likely to result in cost savings. The RATE would in the view of the BFS be unable to deliver on this exceptionally complex range of responsibilities.

The constitution and appointment process of EAP's needs careful consideration if such panels are to be competent to deliver on their responsibilities and to have the confidence of the sector. We believe that professional bodies such as the BFS, the Association of Clinical Embryologists, the

RCOG and counselling associations should have ex-officio advisory roles in the new regulatory structures. It is important therefore that there is a clear mechanism to allow the views of those regulated to be recognised and taken into account.

C. FUNDING RATE

The BFS understands that the treasury requires that those being regulated pay the costs of regulation. At present, there is no accountability for the actual fees being levied on clinics, patients and Primary Care Trusts. The BFS also has concerns that the RATE may have the power to levy additional unspecified fees. That infertile patients are singled out for a "tax" in having treatment when the same does not apply in other regulated health sectors is perceived as discriminatory.

The RIA as outlined (Ref p. 128) is misleading and fails to elaborate the real costs overall to clinics providing licensed treatment. These might better be set out as follows (comparative figures for other regulated areas falling within the scope of the RATE are shown):

	RIA Presentation	**Actual annual fee per clinic/lab**
HFEA Treatment Licences	Licence fee £500 Treatment fees: per IVF £105.50 per DI £52	Range: £6,000-£110,000 Average: £45,000
HFEA Research licence	£500-750	£500-750
HTA Service Note this usually covers several labs in one establishment	£3,600-7,600	£3,600-7,600
HTA Research Note this usually covers several labs in one establishment	£5,200	£5,200
MHRA Accreditation of Hospital **Blood Banks**	£310,000 total in UK per annum £775 per lab.	£775
MHRA Accreditation of **Pharmaceutical** labs	£20,000-£40,000	£10,000-£20,000

- A person unfamiliar with the IVF process may not realise the significance of the fee per treatment charged. They would assume from Section 4.30 that the fee charged by the HFEA is modest compared to the HTA fee given in 4.32.
- The fees given in 4.33 in relation to MHRA inspections under The Medicine for Human Use and Medical Devices Regulations (i.e. drug companies) is given for a 2 year period compared to the annual cost for the HFEA and HTA fees.
- The Blood Bank inspection costs are given as the total cost for all Banks together

The RIA presentation gives the impression that the current fees by the different agencies are comparable and thus acceptable. The Heath Care Commission fees are not shown despite the great overlap in function between the HCC and the HFEA. The reality is that the HFEA fees are up to 5 times more than those charged to drug companies and around 58 times more than those charged to a Blood Bank. It is to be noted that most IVF centres are within NHS Trusts (about 67/85 licensed centres) and the income going towards the HFEA fees is income that cannot be spent on developing patient services.

The BFS also has anxieties that in an amalgamated authority there may be potential for one sector underwriting the regulatory activities of another. The numbers of Blood Banks (400) and Licensed Tissue Establishments (600 + 284 satellite centres) compare with 124 expected licensed infertility treatment centres.

D. DEFINITIONS (Gametes, Embryos, Sperm, Egg, Nucleus)

We feel strongly that the proposed definitions are not helpful in ensuring clear and appropriate regulation of research and clinical practice. There will always be a difficulty in defining separate entities in biology that are in reality part of a continuum of development, in this case from primordial germ cells, formed even before the gonad, through blastocyst and fetus to the child. The definitions go much further than previously and are at wide divergence from accepted scientific and clinical usage. It appears to us that the appropriate definition of an embryo for clinical practice is 'cells placed in the uterus of a women with the intention of producing a pregnancy', i.e. what is defined as a 'permitted embryo'.

There are practical problems with the proposed definition of egg, sperm and gamete. The proposed definition includes cells of the male or female germ line at any stage of maturity. Thus in addition to including mature sperm and eggs (i.e. those capable of fertilisation), this definition stretches back to include primordial germ cells. These are formed in the fetus in the first few weeks of development, and are indeed not located in the gonad which has not yet formed at that stage and is generally regarded as 'sexually indifferent'. Nonetheless these cells are clearly male/female germ line cells.

This new definition would also encompass much important research during the various stages of follicle development in the ovary, and the early stages of spermatogenesis in the testis. This research is adequately regulated by Research Ethics Committees, and any storage of such tissues for subsequent reproductive use is covered by the human tissue regulations. Further regulation, in particular licensing, serves no interest and will jeopardise the UK's position in this field.

E. INTERSPECIES EMBRYOS

The BFS supports this research avenue which will have important relevance for critical advances in stem cell science. The BFS is anxious that regulation of this and other areas of primary research suggested to be sited in Primary Legislation are positioned elsewhere within the legislative framework. We are concerned that primary legislation is not an appropriate way to determine what may or may not be allowable in the future. It seems an unwieldy way to regulate the unknown, and leaves the possibility that either legislation cannot prevent developments that were unforeseen, or that unforeseen and acceptable benefits cannot be introduced because they are blocked in Primary Legislation.

F. RESEARCH LICENSING

The BFS absolutely recognises the need for robust regulation of research in this as in any field of practice. The BFS notes that adequate mechanisms exist already for research regulation using human tissues. Embryo research should absolutely be conducted within legislative boundaries with input to existing research ethics processes as required by the Authority. Involvement of the Authority

in research applications must not impede this process by introducing delay, duplication, or most importantly not allowing research that has otherwise met the standards of ethical and scientific review. Mechanisms to streamline the approval process, perhaps using existing research ethics structures, should be explored.

G. EMBRYO TESTING AND SEX SELECTION PRACTICES

The BFS is pleased to see the clarification in paragraph 1ZA(1) (a) to (e) concerning the situations in which embryo testing can be performed. However, the BFS does not support the suggestion in sub-paragraphs (2) and (3) that the regulator should have the final say as to whether a specific genetic condition can be screened. In pre-natal screening, a regulator has no role in the decision of whether to terminate a pregnancy on genetic grounds and the responsibility for such decisions remains with the parents and their clinical team who have to work within the law. The BFS is of the view that the decisions surrounding embryo selection through PGD are not so dissimilar from those related to pre-natal screening of the developing fetus to justify the involvement of a regulator in the former but not the latter. Clearly, clinics that undertake PGD would need to be licensed to carry out that activity and their records need to be available for scrutiny to confirm their compliance, but to suggest that there be an obligation for the regulator to issue licences on a case-by-case basis is unwarranted.

Similarly, with regard to sex selection for non-medical reasons (Paragraph 1ZB), the BFS is of the view that this should not be banned in primary legislation. We have seen no convincing evidence of harm from sex selection in the UK, and do not believe that there is likely to be an enormous uptake of this kind of service. We believe that the Code of Practice should be permissive for the present and allow sex selection in exceptional circumstances, subject to monitoring.

H. CONSENT TO STORAGE AND USE OF GAMETES AND EMBRYOS

On the whole the BFS supports the proposed amendments in this section. The only area of concern is the proposal in paragraphs 9 and 10 of Schedule 3 to allow gametes to be removed from individuals who lack the capacity to consent providing a clinician certifies that they meet the conditions set out. BFS members feel that this exposes clinical teams to potential accusations of assault. It is essential that a person's gametes obtained in this way cannot be kept in storage in the event of their death (paragraph 12) and that the gametes cannot be used until the gamete provider regains the capacity to give consent to do so.

I. TREATMENT CONDITIONS (Need for a Father)

The BFS supports the removal of the "need for a father" clause. It is much more important to ensure that a child's "need for a family" is met. Research shows that children do better when there is a supportive social network within which they can flourish.

J. STORAGE LIMITS

The 10 year limit seems to be entirely arbitrary and based on a premise of convenience rather than pragmatism. There are situations where embryos potentially suitable for donation or research become available only within a very short time frame before the statutory requirement to remove them

from storage. The BFS would suggest some flexibility to take account of these circumstances. There is no evidence of harm to embryos at any specific time-point relevant to duration of storage.

K. REGISTER OF INFORMATION AND ACCESS TO THE REGISTER

The BFS understands the arguments in favour of retention of a register of children conceived through IVF, specifically those derived from gamete or embryo donation. A register however of all patients who have undergone IVF seems to many members within the BFS not to be justifiable.

A case to support the need for a central database of laboratory data relating to all embryos created has not been made. Presently this generates an unnecessary administrative burden of doubtful value. It is however the view of the BFS that it would be essential that the regulator have access to clinic records to validate reported treatment outcomes. This should be facilitated through the inspection process. This would represent a significant potential opportunity for cost savings.

Uniformity across the UK of age of access to the register (16 years), whether or not one intends to conceive a child, should be facilitated within the revised legislation. It is imperative that appropriately resourced counselling services are made available to support individuals obtaining information from the register. Rights to access the register should be extended to the children of donors, and to the descendants of both groups.

L. PARENTHOOD AND THE USE OF SPERM OR TRANSFER OF EMBRYO AFTER DEATH

We would support the proposed legislation.

M. LEGISLATING FOR FUTURE SCIENTIFIC DEVELOPMENT

The BFS is concerned that primary legislation is not an appropriate way to determine what may or may not be allowable in the future. It is an unwieldy way to regulate the unknown, and leaves the legislation open to being unable to prevent developments that were unforeseen, or if foreseen are no longer unacceptable. Sex selection by sperm sorting may be an example of this. It is not unlikely that kits (even for home use) will become available and purchasable over the internet. It will then be impossible to prohibit their use in the UK, even if public opinion remains against this for non-medical grounds. We consider that it may be more appropriate if the regulator, were able to decide on the suitability of new areas of treatment, in some instances following public consultation and the involvement of an accountable parliamentary bioethics structure.

N. EMBRYO TRANSFER IN TREATMENT

Good clinical practice should be encouraged subject to guidance from appropriate professional bodies. As an example of this, the BFS earlier this year led a consensus initiative around embryo transfer practice relevant to multiple pregnancies after IVF. *(http://www.fertility.org.uk/news/pressrelease/07_04-MultipleBirths.html)* If outcome data suggest to the regulator through the inspection process that clinical or laboratory practice is suboptimal then those providing services should be called to account.

The Society remains committed to providing guidance on this and other standards in fertility care and has issued wide ranging guidance in collaboration with the RCOG. *(http://www.fertility.org.uk/news/pressrelease/07_05-BFS-RCOG.html)*

CONCLUSION

We believe the main roles of the regulator are:

- To protect patients and offspring by monitoring safety and efficiency of procedures/clinics.
- To reassure the public with respect to concerns about the creation and manipulation of human embryos.
- To protect those working in the field from public criticism through rigorous monitoring and controls.

The Society looks forward positively to working within the new regulatory framework when established, and with an appropriate regulator, and hopes the comments and suggestions included within this submission are of help to the Scrutiny Committee.

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