Rt Hon Dr John Reid MP
Secretary for State for Health

12 June 2004

Dear Dr Reid,

Re: Human Fertilisation and Embryology Authority

The British Fertility Society understands that the HFEA is included in the 'arms length' review that you are undertaking. We feel that you should be aware of the views of our Society which represents all the professionals working in this specialty as well as the patient representatives.

The existence of a strong legislative framework for Reproductive Medicine is strongly supported by the BFS. It ensures that the services we provide are acceptable to society as well as those giving and receiving treatment. The benefits are acknowledged not only by those in the UK but also in many other countries in Europe and beyond. Nonetheless we have concerns about the implementation of the Act by the Authority and we recommend that legislative changes are needed to enable improvement. The BFS have given written and oral evidence to the Science and Technology Select Committee which is reviewing the HFEAct. I have identified below those issues which relate more specifically to the implementation of legislation by the HFEAuthority which is pertinent to your review.

It is important to remember that IVF began in the UK in 1978 is no longer regarded as a new or experimental treatment. Most adults know of someone who has had IVF. Thousands of healthy young adults in the UK were conceived with medical help. NICE has made recommendations which will bring these treatments into main stream NHS practice. Regulation of Assisted Conception is still needed and the BFS support this strongly. However it is now the time to bring the regulatory processes back into the mainstream as well.

The Authority has 3 principal functions.

1. **The Register.**
   The Act requires that a Register be maintained of all parents having treatment (whether or not successful) and of any children born. The continuation of this register is no longer defensible morally or clinically desirable. About 10,000 babies are born following assisted conception treatment each year in the UK compared with total birth number of about 600,000 (~1.6%). IVF conceived babies are not freaks and should not be stigmatised by the government. The

State keeps no record of the genetic origin of children conceived naturally. To keep records of assisted conceptions discriminates against the infertile and their children. Normal clinical records and Routine Birth Registration is all that should be required. It is however desirable for safety reasons that we monitor these children through adulthood and into the second generation. This can be achieved through the existing health monitoring procedures and does not need the HFEA register.
We would recommend that the requirement to maintain a register be removed from the Act. Identifying medical records should be kept by clinics according to procedures of Good Medical Practice. Removal of the requirement to maintain a register should be a considerable cost saving for the HFEA.

2. **Inspection and licensing.**
The BFS have repeatedly warned against duplication of regulation in our field. Your current review and the implementation of the EU Directive on Tissue Banking in 2006 gives an opportunity to ensure that we have robust, consistent and effective regulation which the BFS would support. The accreditation process is very different from the existing HFEA inspection process and we believe will be a major improvement. The BFS has already worked with the HFEA and DH to prepare a set of Standards against which clinics can be accredited. This incorporates and should replace the current HFEA Code of Practice.
Other regulatory bodies (e.g. CHAI) must recognise the Accreditation status of the service so that repeat inspections are not needed.
We recommend that the current Code of Practice and Inspection process be replaced by an Accreditation process similar to that provided by the MHRA. This should be carried out by a professional inspection team. We anticipate that this should be a significantly less expensive process than the current HFEA procedures.

3. **Policy Making.**
The BFS perceives a conflict of interest between the regulatory function of the Authority and their policy making role. Whilst accepting that the Authority must make decisions based on individual licence applications, it is not appropriate that the same body is responsible for the long term decisions. They are the 'policy makers' as well as the 'police' 'judge' and 'jury'.
We recommend that long term policies are made by a body which is separate from the regulation.

4. **Research Licensing.**
The BFS welcomes the government support in legislation for research into reproductive technologies and associated science. All such research is subject to local Ethical Committee approval (COREC procedures) and scientific scrutiny by funding bodies. This includes the evaluation of the consent procedures, the investigators, the facilities, the scientific design, the funding as well as ethical issues. It should not be necessary for the HFEA to duplicate this and incur additional expense and delay in the award of a licence. Compliance with the law is all that should be needed.
We recommend that research proposals be subject only to the standard COREC procedures as apply to all other medical studies. The additional need

to scrutiny by the HFEA is not needed although we recognise that it may be necessary to provide legal advice in some cases.

5. **Funding.**
   Currently the HFEA is funded mainly by private patient fees or by the PCTs for NHS funded contacts. An average Centre providing about 600 treatments per year must pay over £60,000 in fees to the HFEA. An MHRA annual Inspection to a similar sized pharmaceutical company might pay only £6000. The BFS believe that the interests of the infertile patients are best served by directing these addition funds to treatment not unjustified regulation.
   We would urge that any reduction in the activity of the HFEA and hence revenue savings, be directed towards the implementation of the NICE recommendations for the provision of IVF treatment.

The BFS urges you to consider the points made above and hopes that the conclusions reached will ensure that the high standards of practice in this field continue and that when possible funds are directed towards treatment not unjustified expensive regulation.

Yours sincerely

Professor Alison Murdoch
Chair of the British Fertility Society.