



House of Commons  
Science and Technology  
Committee

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# Human Reproductive Technologies and the Law

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**Fifth Report of Session 2004–05**

*Volume I*





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***Volume I***

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# 1 Introduction

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1. Louise Brown, born in 1978 in Oldham and District General Hospital, was the first child born in the world as a result of the use of in vitro fertilisation (IVF) techniques. Her birth dramatically expanded the options available to couples unable to conceive naturally and, as a result, a number of centres in the UK started to offer this treatment. The attractiveness of IVF treatments to patients can be observed by the fact that in 1990 a total of 64 licensed centres treated almost 10,000 patients, resulting in the birth of 1,443 children. However, by 2000 the number of centres had increased to 105 with almost 30,000 patients treated and over 8,000 births. Around 1% of births in the UK (8,000 babies) were conceived using IVF and in many European countries the figure is higher.

2. IVF and embryo research are regulated by the Human Fertilisation and Embryology Authority (HFEA), formed as a result of the Human Fertilisation and Embryology Act 1990. While IVF has become commonplace, the pace of medical and scientific advice has been rapid and the public interest and concern has ensured that the HFEA has never been far from controversy. In 24 April 2002, Dame Ruth Deech, outgoing Chair of the Human Fertilisation and Embryology Authority, her successor Ms Suzi Leather, and the Chair of the Human Genetics Commission, Baroness Kennedy of the Shaws, gave evidence to us on some of the issues that faced their organisations. We asked Dame Ruth what areas of the 1990 Human Fertilisation and Embryology Act (HFE Act) needed to be reviewed.<sup>1</sup> She responded that “There is nothing that I would like to see changed or tightened. The procedure for appeals needs looking at from a human rights point of view. I would relax the confidentiality provisions but the structure remains pretty good.”<sup>2</sup> In our view this represented a complacent response to developments in fast-moving field, especially at a time when the HFEA had been at the centre of several legal challenges to its jurisdiction. We concluded that it was necessary to “reconnect the Act with modern science”.<sup>3</sup> The Department of Health’s limp response was that the Government was keeping the Act “under review”.<sup>4</sup> We considered this statement to be inadequate, and on 24 October 2003, we announced our decision to embark on a review of our own.<sup>5</sup> On 30 March 2004, we announced the inquiry’s terms of reference (see Table 1). The Department of Health announced a review of the HFE Act on 21 January 2004 and is looking to this Inquiry to inform the review.<sup>6</sup>

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1 Hereafter, we will refer to the Human Fertilisation and Embryology Act 1990 (c. 37) as the “HFE Act”.

2 Fourth Report of the Science and Technology Committee, Session 2001-02, *Developments in Human Genetics and Embryology*, HC 791, Q 32

3 HC (2001-02) 791, para 20

4 Department of Health, Government Response to the Report from the House of Commons Science and Technology Committee: *Developments in Human Genetics and Embryology*, November 2002, Cm 5693, para 34

5 Press Release No. 45, Session 2002-2003

6 Q 1301

**Table 1: Inquiry into Human Reproduction and the Law: Terms of Reference.**

<p>a) To consider a) the balance between legislation, regulation and reproductive freedom; b) the role of Parliament in the area of human reproductive technologies; and c) the foundation, adequacy and appropriateness of the ethical framework for legislation on reproductive technologies.</p>	
<p>b) To consider the provisions of the Human Fertilisation and Embryology Act 1990 in the context of other national and international legislation and regulation of medical practice and research</p>	<p><i>To include related legislation such as the EU human tissue directive, and law covering human rights, surrogacy, adoption and abortion. To include relevant declarations and statements by international bodies. To compare the safety and welfare provisions of the Human Fertilisation and Embryology Act 1990 with those that cover other areas of medical practice.</i></p>
<p>c) To consider the challenges to the Human Fertilisation and Embryology Act 1990 from a) the development of new technologies for research and treatment, and their ethical and societal implications and b) recent changes in ethical and societal attitudes.</p>	<p><i>To include new areas of research, treatments and interventions, such as cloning, cell nuclear transfer, transplants of ovarian and testicular tissue, embryo splitting, selection of genetic characteristics (including sex selection), stem cell therapy and the use of immature gametes.</i></p>
<p>d) To consider the composition, expertise and approach of the Human Fertilisation and Embryology Authority, its code of practice, licensing arrangements and the provision of information to patients, the profession and the public.</p>	

3. In view of the keen public interest in the many scientific and ethical issues raised by the inquiry, we undertook, as a first step, a public online consultation. The aim of this consultation was to listen to and gauge the public’s views, both to help us frame the inquiry’s terms of reference and to allow new voices to contribute to the debate. We believe that this approach represented a significant innovation in the use of “e-consultations” in the UK.

4. The Human Fertilisation and Embryology Act 1990 contains a revision to the Abortion Act 1967. A key issue for us was to decide how to tackle the abortion issue. In view of the complex arguments to be heard in relation to assisted conception and embryo research in what was likely to be our longest inquiry of the Parliament, we decided to limit our deliberations to these issues. A further section of the HFE Act deals with surrogacy arrangements and we make recommendations as to how this topic should be addressed.

5. This inquiry comprised 12 evidence sessions and two UK visits (to visit the assisted conception unit at Guy’s and St Thomas’ Hospital and the Assisted Reproduction and Gynaecology Centre in London and to discuss stem cell research at the Medical Research Council’s National Institute for Medical Research). A further visit was made to Stockholm and Rome, to learn more of the contrasting approaches taken by Sweden and Italy, and also the Vatican. We also took part in a number of meetings. On 29 April 2004, we met with members of the British Medical Association’s Medical Ethics Committee, chaired by Dr Michael Wilks. Also contributing was Baroness Warnock. The Warnock Report is the



basis for UK regulation of assisted conception and embryo research and is thus the key reference point for our inquiry. Her participation in our discussions was much valued. On 15 July 2004, a seminar was held in Westminster Hall organised by Progress Educational Trust and Epan, a consultancy offering services to those working with genetic and reproductive technologies, in association with our Committee. This proved to be a useful opportunity to discuss the issues with a wide range of interested parties and for them to hear about our inquiry. Our online consultation also proved to be a valuable source of views (see Box 1).

**Box 1: Online consultation**

Our online consultation on Human Reproductive Technologies and the Law ran from 22 January 2004 for eight weeks at [www.tellparliament.net](http://www.tellparliament.net). The aim of the forum was to get the views of a much wider group on the issues involved and to help us shape the terms of reference for the inquiry. The site was designed with a view to encouraging people from all walks of life to take part in the online forum. It provided a glossary and background information about the inquiry with a list of useful resources as well as the main headings with the scenarios in the online forum. Tellparliament.net was publicised through direct mailings, local media coverage, viral emails, web links and word of mouth.

The online discussion was structured around four main headings:

- Screening and Therapy
- Surrogacy and Donation
- Consent and Confidentiality
- New Fertility Treatments

To initiate the debate, the Committee Secretariat provided several scenarios under each of the headings.

A section devoted to Human Cloning was added in the third week of the forum following the news story of research in human cloning in Korea. There was also a section for General Comments for participants to raise any additional points and to comment about the site itself.

333 people registered to take part in the online forum at [tellparliament.net](http://tellparliament.net). 111 individual users logged on to the site and posted a total of 554 messages. Out of those who registered 181 were members of various organisations, including academic institutions and 152 were private individuals. Out of those who actually posted messages on the site 54 were members of organisations, while 52 were members of the public. There was an even split between male and female participants.

6. This has been a long inquiry and we are indebted to our advisers: Dr Gillian Lockwood, Medical Director of Midland Fertility Services; Professor Sheila McLean, Director of the Institute of Law and Ethics in Medicine at Glasgow University; and Professor Derek Morgan, Professor of Health Care Law and Jurisprudence at Cardiff Law School. They have been invaluable in negotiating the many complex technical, legal and ethical issues this inquiry has raised.

7. This report will begin by providing some background to the regulatory framework in the UK (Chapter 2). After that we will discuss the status of the embryo (Chapter 3). Our conclusions on this vital issue will then inform our discussions of the problems with the HFE Act and its implementation by the HFEA (Chapters 4 and 5). Since the HFE Act was passed there have been enormous changes in the provision of assisted reproduction services and the implications for regulation will be discussed in Chapters 6 and 7. We will then discuss some possible approaches to regulation (Chapter 8) and then conclude with

our blueprint for a legislative and regulatory system fit for purpose in the 21<sup>st</sup> century (Chapter 9).

## 2 Regulation of assisted reproduction

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### The Warnock Committee

8. The public's reaction to the birth of Louise Brown has been described as a mixture of "pride in the technological achievement, pleasure at the new-found means to relieve, at least for some, the unhappiness of infertility, and unease at the apparently uncontrolled advance of science, bringing with it new possibilities for manipulating the early stages of human development".<sup>7</sup> In 1982 the Government set up the Committee of Inquiry into Human Fertilisation and Embryology, under the chairmanship of Dame Mary (now Baroness) Warnock.<sup>8</sup> Although Baroness Warnock is a philosopher, the 16-member Committee was dominated by scientists and health professionals, although only Professor Malcolm MacNaughton had professional involvement in assisted reproduction. The Committee's terms of reference were:

"to consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of their developments; and to make recommendations."

The Committee published its report in July 1984. A key conclusion was that the human embryo had a special status, entitling it to "some protection in law".<sup>9</sup> It recommended new legislation setting out legal limits on assisted reproduction and embryo research and the setting up of a licensing authority.

### Voluntary Licensing Authority/Interim Licensing Authority

9. In March 1985, the Medical Research Council (MRC) and Royal College of Obstetricians and Gynaecologists (RCOG), recognising that the introduction of a statutory body would take time, founded the Voluntary Licensing Authority for Human in vitro Fertilisation and Embryology (VLA) under the Chairmanship of Dame Mary Donaldson. The VLA consisted of people drawn from both the scientific and medical professions but was balanced by the inclusion of lay people. The VLA comprised members who carried out the licence inspections and issued licences to centres as appropriate and a secretariat. All potential centres had to make a written application to the VLA describing the particulars of the treatment services or research that they wished to undertake or were already providing.

10. Following a consultation, in 1987 the Government published a White Paper, *Human Fertilisation and Embryology: A Framework for Legislation*, in which it committed itself to legislation.<sup>10</sup> In April 1989 the VLA decided to emphasise the temporary nature of its existence by changing its name to the Interim Licensing Authority for Human in vitro Fertilisation and Embryology.

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7 Department of Health and Social Security, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* ("The Warnock Report"), July 1984, Cmnd 9314, p 4

8 Hereafter, this will be referred to as the Warnock Report.

9 Para 11.17

10 Cm 259, November 1987

## Human Fertilisation and Embryology Act 1990

11. The Human Fertilisation and Embryology Bill was given a second reading in the House of Lords in December 1989. The debates in Parliament focused on three main issues: embryo research; welfare of the child; and abortion. The Bill received Royal Assent on 1 November 1990, with the HFEA taking up its full statutory responsibilities in August 1991. While the Act contains a number of prohibitions on the uses of human embryos, it gives wide powers of interpretation to the HFEA. The Act set out the duties of the HFEA, including the requirement to publish a Code of Practice and maintain a register of those receiving treatment and born as a result of treatment, and also its composition.

12. The HFE Act also makes an amendment to the 1967 Abortion Act, its principal effect being to limit the time limit for abortions to 24 weeks (save in limited specific circumstances), and to the Surrogacy Arrangements Act 1985. The effect of this latter amendment was to make it clear that surrogacy arrangements could not be legally enforced and to extend the Act to include cases where sperm and eggs, rather than an embryo, are placed in a woman.

## Subsequent legislation

13. There have been a number of revisions to the HFE Act and these are shown in Table 2.

Table 2: Relevant legislation since 1990.

Legislation	Principal effects
The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991/1540	Extend the maximum storage period for gametes (as set out in section 14 of the Act) in respect of people “whose fertility since providing them has or is likely to become, in the written opinion of a registered medical practitioner, significantly impaired”.
The Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991/1889	These Regulations prescribe the composition and procedures of HFEA licence committees and the appeals procedure.
The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991/1588	Extended the purposes for which gametes could be stored: during investigations into offences under the HFE Act; and for research, testing of pharmaceutical products and teaching.
The Parental Orders (Human Fertilisation and Embryology) Regulations 1994/2767	Regulations made under the act that gave effect to the scheme set up by s30 of the 1990 Act as an alternative to the adoption procedure in relation to children born following a surrogacy arrangement.
The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996/375	Extends the storage period for frozen embryos in certain cases.
The Human Fertilisation and Embryology (Research Purposes) Regulations 2001/188	Extended the purposes for which licences to include therapeutic research.
The Human Reproductive Cloning Act 2001 c.23	Created an offence of placing a human embryo in a woman other than by fertilisation.
The Human Fertilisation and Embryology (Deceased Fathers) Act 2003 c. 24	Allows a man to be registered as the father of a child conceived after his death using his sperm or using an embryo created with his sperm before his death.
Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004	Removed the right of new donors to remain anonymous once the child has reached 18 years.

## Legal challenges

14. The interpretation of the HFE Act has been at the centre of a number of legal challenges in recent years, all of which have so far been unsuccessful. The key cases are shown in Table 3.

Table 3: Significant cases surrounding the HFE Act.

Case	Significance
R v Secretary of State for Health, ex parte Bruno Quintavalle (on behalf of Pro-Life Alliance [2001].	It was claimed that organisms created by cell nuclear replacement did not fall within the definition of "embryo" in s.1(1) Human Fertilisation & Embryology Act 1990. Successful in the High Court but overturned in Court of Appeal.
Rose v Secretary of State for Health and the HFEA [2002] EWHC 1593	Joanna Rose was born before as a result of donor conception before the HFE Act was passed. The judge ruled that a case could be brought under the Human Rights Act challenging the rights of post-1990 donors to remain anonymous.
R (Quintavalle) v Secretary of State for Health [2003] UKHL 692.	Josephine Quintavalle sought and obtained permission to seek judicial review of the HFEA's decision announced on 13 December 2001 to award a licence to treat the Hashmi family. She challenged that decision on the ground that the HFEA had no power to issue a licence that permitted the use of HLA typing to select between healthy embryos. Her challenge succeeded but was initially lost on appeal on 16 May 2003. Quintavalle has since been given leave to take the case to the House of Lords. The case was heard in March 2005.
Evans v Amicus Healthcare and ors [2003] EWHC 2161.	Natalie Evans wished to use her stored embryos to have a child. However, her former partner withdrew her consent for the procedure. Evans contested this on human rights grounds but lost. She is now taking the case to European Court of Human Rights.
Leeds Teaching Hospitals NHS Trust v A and others [2003] EWHC 259 (QB)	Sperm mistakenly used in IVF implantation resulting in genetic father not being husband of genetic mother. The case resolved the issue of paternity
R. (on the application of Assisted Reproduction and Gynaecology Centre) v Human Fertilisation and Embryology Authority [2002] EWCA Civ 20 [2003] 1 F.C.R. 266	The HFEA's policy of allowing only two embryos to be transferred in most cases was challenged but the HFEA was vindicated.
R. v Human Fertilisation and Embryology Authority Ex p. Blood [1999] Fam. 151 [1997] 2 W.L.R. 807	Diane Blood sought permission from the courts to be inseminated with her dead husband's sperm. HFEA ruled that consent had not been given. Eventually, Mrs Blood won the right under European law to take the sperm abroad.

## International law and treaties

### *European Convention for the Protection of Human Rights*

15. The Council of Europe Convention for the Protection of Human Rights, originally drawn up in 1950, was transposed into UK law by the Human Rights Act 1998. It has three Articles with relevance to the 1990 HFE Act.

#### Article 8—Right to respect for private and family life

“Everyone has the right to respect for his private and family life, his home and his correspondence.”

“There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”

#### Article 12—Right to marry and found a family

“Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.”

#### Article 14—Prohibition of discrimination.<sup>11</sup>

The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

16. These articles do not, according to Sarah Elliston of Glasgow School of Law, “seem to support an absolute right to have children or to be provided with assistance to do so. At most therefore, there seems to be a requirement that states do not place unreasonable obstacles in the path of people who wish to have children”.<sup>12</sup> There have been concerns that elements of the HFE Act may be incompatible with the Human Rights Act. However, until now there has been only one successful challenge when Joanna Rose successfully argued that maintaining the anonymity of gamete donors engaged Article 8 of the Convention but the HFE Act did not contain a provision that directly infringed her human rights; the worst that could be said of it was that it failed to afford them a mechanism whereby their particular human right might best be vindicated.

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11 Article 14 is a so called 'derivative' right and can only be engaged once another substantive right has been engaged although it is not necessary to show that that other right has actually been breached.

12 Ev 365

### **European Convention on Human Rights and Biomedicine**

17. The UK is not a signatory to the 1997 European Convention on Human Rights and Biomedicine, unlike most other European countries.<sup>13</sup> There are several significant articles that conflict with UK legislation. Article 14 on “Non-selection of sex” states:

“The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease is to be avoided.”

18. While the HFEA’s policy is not to license the use of PGD for sex selection for social reasons, it is not illegal. Also, sperm sorting techniques are currently not covered by the HFE Act. However, Article 18 is the most significant in that it states:

“1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.”

It is this second point that makes the Convention popular with some witnesses as it would reduce the number of embryos available for research, and would prohibit therapeutic cloning in particular. CARE, a Christian charity, strongly believes that we ought to sign up to this Convention “Otherwise the UK will continue to be apart internationally and forfeit the chance to influence in this area”.<sup>14</sup> However, the UK is not alone in not signing this Convention. We are joined by Germany, Ireland, Russia, Austria and Belgium, among others and it has still to be ratified by France, Italy, Spain, Netherlands and Sweden.

19. There are several additional protocols, one of which is the 1998 protocol on cloning, which prohibits “Any intervention seeking to create a human being genetically identical to another human being, whether living or dead”.<sup>15</sup> A 2005 protocol on biomedical research expressly excludes in vitro research on embryos.

### **United Nations**

20. The Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, states that practices that are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted (article 11). The UN General Assembly, in resolution 56/93 of 12 December 2001, decided to establish an Ad Hoc Committee for the purpose of considering the elaboration of an international convention against the reproductive cloning of human beings. All countries agree on the need to ban ‘reproductive’ cloning – the cloning of a human to produce another human. One group of more than 40 countries, led by Costa Rica, the United States and the Vatican, wants also to outlaw therapeutic cloning. The other group, led by Belgium and France, proposes that individual nations be left to decide whether or not to allow therapeutic

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13 Of the 44 Member States of the Council of Europe, 30 have signed the Convention and 19 have ratified it. <http://conventions.coe.int/>

14 Ev 272

15 Article 1



cloning. The Costa Rican motion states that “Any person commits an offence within the meaning of this Convention if that person intentionally engages in an action, such as somatic cell nuclear transfer or embryo-splitting, resulting in the creation of a living organism, *at any stage of physical development*, that is genetically virtually identical to an existing or previously existing human organism.”

21. In November 2003 the United Nations postponed its decision on proposals to ban human cloning after nations failed to agree whether such a ban should include cloning for research purposes. At a meeting of the UN General Assembly's legal committee on 6 November 2003, countries voted narrowly, by 80 votes to 79, with 15 abstentions, to defer talks on the proposed ban for two years. However, the issue was discussed at a meeting of the legal committee on 21-22 October 2004 but once again no agreement could be reached. A compromise was reached to issue a non-binding declaration, a draft of which was published on 19 November. This states:

- a) Member States are called upon to prohibit any attempts to create human life through cloning processes and any research intended to achieve that aim;
- b) Member States are called upon to ensure that, in the application of life science, human dignity is respected in all circumstances and, in particular, that women are not exploited;
- c) Member States are also called upon to adopt and implement national legislation to bring into effect paragraphs (a) and (b) above;
- d) Member States are further called upon to adopt the measures necessary to prohibit applications of genetic engineering techniques that may be contrary to human dignity.

The UN's legal committee voted 71 to 35 in favour of this declaration with 43 abstentions on 18 February 2005. The declaration passed to the full 191-nation General Assembly, which voted 84 to 34 in favour, with 37 abstentions on 8 March 2005. The UK voted against the declaration.

### ***EU Charter of Fundamental rights***

22. At the Cologne meeting of the European Council in June 1999, it was decided to establish a Charter of fundamental rights in order to make their overriding importance and relevance more visible to the Union's citizens. The Presidents of the European Parliament, the Council and the Commission signed and proclaimed the Charter on behalf of their institutions on 7 December 2000 in Nice. The Charter contains the fundamental rights and freedoms as well as basic procedural rights guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and derived from the constitutional traditions common to the Member States, as general principles of Community law. Article 3 of the Charter – the Right to the integrity of the person – has particular relevance to our inquiry:

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law,
- the prohibition of eugenic practices, in particular those aiming at the selection of persons,
- the prohibition on making the human body and its parts as such a source of financial gain,
- the prohibition of the reproductive cloning of human beings.

23. There have been concerns over the inclusion of eugenic practices in the EU Charter of Fundamental Rights, which could be interpreted to mean any form of PGD. James Lawford Davies told the Committee said “I think it does present a real issue. On a very basic interpretation of the term “eugenic” being something which improves humanity, usually through some sort of genetic screening, then pre-implantation genetic diagnosis is quite literally eugenic in its nature. I know that the Charter is said to be non-negotiable [...] and quite how eugenic will be interpreted by the courts, if and when it comes to that, I do not know. Certainly some of the public interest groups have expressed their intention to challenge what is allowed at the moment under Article 3 [...] and I think it remains to be seen how the wording in the Charter is interpreted.”<sup>16</sup> The Department of Health dismissed the significance of the Charter, declaring that it “is a political declaration and currently not legally binding. [...] the Charter will be binding on the EU institutions, and on Member States in so far as they are implementing EU law. However, the regulation of medical ethical issues is not regulated under EU law, and as such, the Charter would not apply.”<sup>17</sup>

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16 Q 852

17 Ev 428

## 3 The embryo

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### Status of the embryo

24. At the heart of any review of assisted reproduction legislation is the fundamental question of the status to be accorded to the human embryo. There is a range of positions which can be taken on this. These fall into three principal views:

- a) that the embryo is a human life and therefore is entitled to conferral of full human rights;
- b) that the development of personhood is a gradual process but that the embryo is entitled to some protection; and
- c) that the embryo is no more than a collection of cells, albeit with the potential to develop into a human being.

25. The first of these approaches is often identified with the Catholic Church. It is set out by the Catholic Bishops' Conference of England and Wales and the Linacre Centre for Healthcare Ethics, who wrote in evidence to this Inquiry:

“If the human embryo is the same individual as the older human being, this has immediate moral implications. There is no such thing as a ‘subhuman human’: a human being/organism with subhuman moral status. Human status is not something we have to ‘earn’ by reaching some arbitrary level of functional ability. If fertilisation is, in the normal case, the origin of a new human individual – a life distinct from the parents – that individual will have rights and interests from fertilisation onward in regard to his or her well-being. They have rights and interests of which they are unaware, just as newborn babies do. These rights and interests should not be entirely subordinated to the interests, or perceived interests, or desires or wants, of adult human beings.”<sup>18</sup>

This position dates from 1869 when Pope Pius IX abolished the distinction in between early and late abortions. Previously, St Thomas Aquinas favoured a later ensoulment: at 40 days for the male foetus and 90 days for the female foetus. Advocates of this view are not necessarily associated directly with the Catholic Church. The Rev Dr John Fleming, Consultant to the Society for the Protection of the Unborn Child (SPUC) said his organisation had no theological view of the matter: “Its position is based upon the biological facts, that from the beginning a new human life comes into existence at fertilisation. It takes its position under the universal declaration of human rights, that everyone has a right to be treated as a person.”<sup>19</sup> Such a stance would logically result in the conclusion that IVF should only be undertaken without the destruction of embryos and that embryo research for any purpose should be prohibited.

26. The gradualist approach is favoured, among religious perspectives, by the Church of England and the Jewish faith. Dr Michael Nazir-Ali, the Bishop of Rochester, argued that

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<sup>18</sup> Ev 318

<sup>19</sup> Q 712

the gradual emergence of a person was often the approach in Christian tradition until 1869.<sup>20</sup> It draws on distinctions between the unformed and formed foetus in the definition of homicide.<sup>21</sup> Augustine wrote:

“If what is brought forth is unformed (*informe*) but at this stage some sort of living, shapeless thing (*informiter*), then the law of homicide would not apply, for it could not be said that there was a living soul in that body, for it lacks all sense, if it be such as not yet formed (*nondum formata*) and therefore not yet endowed with its senses”.<sup>22</sup>

27. The Office of the Chief Rabbi told us “The embryo is not a person, but must be treated with the respect due to a form of human life”.<sup>23</sup> This respect is generally based on the potentiality of that embryo to become human life. Thus, while the gradualist approach accepts that the embryo of the human species is morally significant, it does not afford it the rights that would be conferred on it following live birth. As John Polkinghorne from the University of Cambridge expresses it:

“The very early embryo is entitled to a deep moral respect because of its potential humanity, so that it is not just a speck of protoplasm that you can do what you like with and then flush it down the sink, but it is not yet fully a human being”.<sup>24</sup>

28. The third view, that the embryo is no more than a ball of cells, has not been expressed to us in this inquiry. The Warnock Committee articulated it as follows:

“A human embryo cannot be thought of as a person, or even a potential person. It is simply a collection of cells which, unless it implants in a human uterine environment, has no potential for development.”<sup>25</sup>

The Warnock report weighed up these three approaches and adopted the gradualist view, recommending that “the embryo of the human species be afforded some protection in law”.<sup>26</sup> The report considered that it was inappropriate to endow the embryo of the human species with the full panoply of human rights. However, it was also inappropriate simply to consider it as nothing more than a ball of cells. The approach taken by the Warnock committee has in our view provided a firm foundation for legislation. **While it has been argued that there have been many scientific developments and changes in social attitudes, the Warnock Committee’s approach to the status of the embryo remains valuable. While this gradualist approach to the status of the embryo may cause difficulties in the drafting of legislation, we believe that it represents the most ethically sound and pragmatic solution and one which permits in vitro fertilisation and embryo research within certain constraints set out in legislation.**

20 Q 697

21 *Embryo Research: Some Christian Perspectives*, A report from the Mission and Public Affairs Council, Church of England

22 Quaestionum in Hept I II n 80

23 Ev 373

24 JC Polkinghorne, The person, the soul, and genetic engineering, *Journal of Medical Ethics*, 2004;30:593-597

25 para 11.5

26 para 11.17

29. Adopting a gradualist approach, we believe, recognises the special status of the embryo of the human species, while at the same time respects the legitimate interests of intending parents and the wider society. It does not, therefore, exclude other considerations such as seeking to provide treatment for the infertile or discovering the causes of infertility or the genesis of serious illness. However, it does require that embryos should not be used without carefully evaluating the reasons and rationales for their use in a specific manner or for a specific purpose. Since this approach does not preclude the creation of human embryos for legitimate purposes or their use in an approved manner, it is worth considering its implications for the ways in which the embryo might be treated.

## Uses of embryos

### *Alleviating infertility*

30. Arguably, one of the least controversial uses of the human embryo is implantation with the intention of establishing a pregnancy. Despite some (relatively uncommon) residual concerns about assisted reproduction itself, such services seem to be well tolerated in UK society and their aim – the birth of a child – is widely regarded positively. The question here, therefore, revolves not around the status of the embryo, but rather on the ‘rights’ or interests of individuals to have assistance in reproducing. This raises directly the question of reproductive liberty. This concept became of increasing importance in the 20th Century, particularly in the early years when a number of states adopted policies designed to intervene in the reproductive choices of individuals, by, for example, instituting policies of non-consensual sterilisation. Such policies are now widely regarded as objectionable.

31. The philosophical view that individuals should have the right to make private choices – such as reproductive decisions – free from the scrutiny of the state can be traced to John Stuart Mill:

“[...]the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. The only part of the conduct of any one, of which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign”.<sup>27</sup>

Its application to reproduction has been espoused by Professor Emily Jackson from Queen Mary, University of London. She has written that “interfering with a particular individual’s decision to conceive a child would usually involve violating their bodily integrity and sexual privacy. We do not sterilise people who have been convicted of violent offences against children because, however gruesome their crime, their person must remain inviolate. [...] the freedom to decide for oneself whether or not to reproduce is integral to a person’s sense of being the author of their own life plan”.<sup>28</sup> Professor John Harris from Manchester University has argued that “There are many arguments from many sides, which purport to give reasons for limiting access to reproductive technologies and to gene based reproductive procedures. There is one reason to reject them all, and that is that they

27 JS Mill, *Utilitarianism & On Liberty* (ed. M. Warnock), 1962, Fontana Press

28 Emily Jackson, Fertility treatment: abolish the ‘welfare principle’, *Spiked Online*, 11 June 2003

do not point to dangers or harms of sufficient seriousness or sufficient probability or proximity to justify the limitation on human freedom that they require.”<sup>29</sup>

32. This approach emphasises the importance of the individual, specifically the autonomy of the individual and the right to make private choices. It has been challenged by Professor Robin Gill from the University of Kent, who argues that “We live in the “time of the triumph of autonomy in bioethics” in which “the law and ethics of medicine are dominated by one paradigm – the autonomy of the patient”. He argues that “conceptions of individual autonomy cannot provide a sufficient and convincing starting point for ethics within medical practice”.<sup>30</sup> However, it is worth bearing in mind that legal tradition is that decisions which fall into the private domain are generally regarded as not of interest to the state. Certain exceptions to this maxim do, of course, exist but these generally arise in the sphere of criminal law. Thus, when the service to be provided is the implantation of an embryo with the intention of establishing a pregnancy, and in line with Article 8 of the European Convention on Human Rights (incorporated into UK law by the Human Rights Act 1998) reproduction itself would seem to be firmly situated within the private domain. The primary consequence of this is that the right to private and family life espoused in Article 8 can be said to apply to reproductive decisions. Only if one of the possible derogations from that Article can be established (for example where there is a threat to public health or morals) would the terms of this Article be inapplicable.

33. Nonetheless, a number of justifications have been put forward for limiting reproductive freedom in assisted reproduction. The weight given to these issues and the extent to which they are dealt with in other forms of regulation are, we believe, critical in establishing a new framework for regulation. These arguments, which will be dealt with in turn, are as follows:

- a) Protection of the embryo;
- b) The procedures result in the creation of a new life;
- c) The intervention of a third party;
- d) Concerns for the welfare of children who are born using assisted reproduction;
- e) Concerns that, where embryos and gametes are donated, a genetic link should be maintained;
- f) Concerns that it would expose patients to excessive levels of risk;
- g) Concerns that individual reproductive decisions may have wider impacts on society; and
- h) The need to supervise a morally controversial aspect of assisted reproduction.

34. The Chair of the HFEA, Suzi Leather, stated to us that she thought it was the special status of the embryo that justified regulation. However, it is important to draw a distinction between legislation and regulation and it is not clear that protection of the special status of the embryo requires oversight beyond that set out in legislation. It is interesting to note

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29 John Harris, *Reproductive Liberty, Disease and Disability*, unpublished article, 2004

30 Robin Gill and Gordon Stirrat, *Journal of Medical Ethics*, in press

that in the Warnock report, the idea of protecting the embryo in law arose from the discussion of embryo research rather than assisted reproduction. Professor Peter Braude from Guy's Hospital and a former member of the HFEA felt that it was the creation of a new life that justified intervention. He told us that "I do not think there is another area of medical practice that is like assisted conception. There is no other area I know other than drugs in pregnancy where, in satisfying the client [...] who come along to you and say, "We desperately want some children", to solve that problem is a child".<sup>31</sup>

35. The argument that the intervention of a third party takes reproduction out of the private and into the public domain may be based on two premises. First, that the involvement of a third party (the doctor or clinic) imposes additional professional constraints. For example, Professor Alastair Campbell from Bristol University states that it is justified to intervene in otherwise private choices because issues of professional responsibility arise: "In these cases reproduction ceases to be a purely private matter between partners and is appropriately a concern of the state, as well as of the profession". This was the view expressed by the Minister in giving evidence to us.<sup>32</sup> However, the two issues can be separated. Certainly, clinicians are subject to professional constraints imposed by their own professional bodies, and very rarely, the state, but this is true in all medical practice and does not in itself justify the intervention of the state. Second, it might be argued that the mere fact of third party involvement is enough to render the behaviour in question public rather than private. However, third party involvement in reproduction is also present when doctors operate to reverse a vasectomy operation or unblock fallopian tubes, both of which are intended to achieve the same outcome as assisted reproduction; that is, the birth of a child. Although assisted reproduction is closely regulated, neither of these operations is subject to the same constraints, arguably leading to inconsistency, and discrimination against certain groups or individuals based on the cause of their infertility rather than on any other ethical basis. The Human Rights Act may also be relevant here. If Article 8 is engaged by questions of reproductive liberty, then the Article 14 prohibition on discrimination may also be engaged.

36. Interventions on the grounds of welfare can be usefully divided into medical and psychosocial. The safety of assisted reproduction has been a matter of conjecture, since even the earliest children born using IVF are still only young adults. Professor Alastair Campbell argues that when the state and the professions are involved in parenting decisions "there is an obligation to avoid harm wherever possible. [...] Refusing to select parents could result in complicity in clear harms to children [...] The only ethical issue is what criteria should be employed". The issue is one of degree since few people argue that reproductive freedom should be unrestricted. As Professor Julian Savulescu from Oxford University put it to us, "we should consider the vulnerable and consider the children by balancing the risks and benefits" but whereas Professor Harris asks (in the context of a child conceived using foetal ovarian tissue) "Will this knowledge be so terrible that it would be better that no such children had ever been or were ever born?", Professor Campbell maintains that this view is mistaken because "By preventing a pregnancy through regulation, no child is harmed".

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31 Q 616

32 Q 1308

37. Professor Peter Braude from Guy's Hospital, London and a former member of the HFEA, pointed out the effect that the absence of a regulator had had in the US, where in 66 per cent of cycles, there were more than three embryos replaced, in 32 per cent, there were more than four embryos replaced and, in 11 per cent, there were more than five embryos replaced. This subjects pregnant women and children to risks resulting from multiple pregnancies (see paragraph 268). An issue with this approach is that it could be applied to other – unregulated -- forms of infertility treatment such as ovarian stimulation, which also carries with it a high risk of multiple pregnancy, and various surgical procedures. However, there are few calls to bring this within the regulation of assisted reproduction.

38. Concerns about welfare are particularly acute when they relate to the use of donated gametes and embryos. If anything these have intensified since the Warnock Report, which took the view that this would take place in any case and that it was therefore important that it took place in a regulated environment, was published. It concluded that “An AID child is a very much wanted child: a couple may have had to endure many years of waiting and will consequently cherish the child”.<sup>33</sup>

39. The importance of maintaining a genetic link where embryos and gametes are donated has proved to be a matter of debate, with no clear consensus emerging as to the weight to be given to genetic linkage, although the recent regulations permitting future children to gain identifying information about gamete donors do seem to emphasise biological over social status.

40. In law there are considered to be levels of risk, for example where someone is being exposed to unnecessary danger, at which it is reasonable for the state to intervene, even if the individual has consented to be exposed to that risk. In terms of assisted reproduction, it could be argued that the drugs used stimulate egg production and the risks associated with multiple pregnancy are such that they justify state regulation. While these risks are real and significant, however, they do not obviously fall beyond the level of risk which people are legally permitted to assume. For example, a valid consent to surgery such as heart transplantation (which carries a significant risk of harm) or to involvement in non-therapeutic research projects, is regarded in law as valid so long as it has been taken by a competent individual. The state will only go so far to protect people from themselves, and will intervene only when the risk is deemed unacceptably high or grave. The risks of assisted reproduction, if explained to and understood by, the individual concerned seem to us to sit firmly within those which can be consented to in law.

41. Concerns that individual reproductive decisions may have wider impacts on society are commonly expressed in relation to embryo selection. For example, it may be argued that permitting selection of embryos on the basis of their sex would lead to demographic disaster or the reinforcement of sexist attitudes, both of which would be harmful to the wider society.

42. The demand to regulate morally controversial techniques goes beyond possible harms to individuals or even society. The concern here is more that the use of the treatment offends human dignity rather than any harms that might result from it. This approach

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<sup>33</sup> Department of Health, Report of the Committee of Enquiry into Human Fertilisation and Embryology (The Warnock Report), July 1984



argues that any action or technology that involves comprising human dignity must be rejected. Both the Warnock report and the 1989 Polkinghorne report on the research use of fetuses and foetal material accorded some status to the human embryo and had something akin to ‘dignity’ in mind. This notion that we should not treat the embryo of the human species casually is surely one with which most – if not all – would agree.

43. Witnesses expressing this concern have included the Scottish Council on Human Bioethics, which argues that “an acknowledgement of human identity and personhood with, as a consequence, the protection of human dignity should be the underlying basis on which to draft new legislation.”<sup>34</sup> Human Genetics Alert argues that “The insistence by some commentators on ‘reproductive liberty’ has become the key ideological element in the construction of a free market consumerist model for reproduction, rather than any attempt to free women from patriarchal control over their bodies.”<sup>35</sup> Some faith groups have adopted a similar stance. The Catholic Bishops of England and Wales states that “Increasingly, children are seen as the object of ‘consumer choices’, rather than as new human beings to be accepted unconditionally.” The Christian Medical Fellowship supports the use of science and technology to prevent, treat and relieve the suffering of infertility but believes that “this should be guided by sound ethical principles based on a profound respect for all human life as made in the image of God”.<sup>36</sup> However, even conceding this point does not inevitably provide a strong argument against assisted reproduction. The concept of dignity is difficult to define and would be extremely difficult to fashion into a foundation for legislation. It is also worth noting that human rights conventions considering dignity have in general avoided references to the human embryo. An exception to this is the Council of Europe’s Convention on Biomedicine, to which the UK is not a signatory. In any event, in this section we are concerned with the fate of the embryo created for implantation; it is hard to argue that an embryo’s dignity is in any sense negatively affected by being born. .

44. An alternative perspective to the balance between reproductive freedom and state intervention is provided by utilitarian ethics. Here the emphasis is on measuring the benefits over burdens of particular activities. This approach was rejected by the Warnock Committee. It said “Moral questions, such as those with which we have been concerned, are, by definition, questions that involve not only a calculation of consequences, but also strong sentiments with regard to the nature of the proposed activities themselves.”<sup>37</sup> Thus, for the Warnock Committee, even if evidence were available which could establish that the benefits (for example to the infertile) of unregulated access to assisted reproduction, there were underpinning moral or ethical considerations which also had to be considered, at least in some circumstances. However, the Warnock Committee did not view assisted reproduction in itself as a threshold that should not be crossed over. Thus, it would appear that both libertarian and utilitarian ethics would support the view that, in terms of the embryo intended for implantation, since the creation of the pregnancy is inherently to be regarded as a good thing, the state has no right to intervene in the choices of people to procreate unless evidence of harm can be shown.

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34 Ev 247

35 Ev 288

36 Ev 217

37 para 4

45. Of course, IVF generally involves the creation of a number of embryos, not all of which will be implanted. For some, this is the essentially problematic aspect of assisted reproduction. Indeed, for some this is the principal reason for opposing all assisted reproduction. For others who would not go quite this far, nonetheless the fate of ‘surplus’, ‘spare’ or unselected embryos demands close regulation. On the other hand, given that a choice of embryos exists, some have argued that it is either morally neutral to select one over another, or even that there may be a positive duty on intending parents to select the embryo which has the best chance of a ‘happy’ life.

**46. We accept that a society that is both multi-faith and largely secular, there is never going to be consensus on the level of protection accorded to the embryo or the role of the state in reproductive decision-making. There are no demonstrably “right” answers to the complex ethical, moral and political equations involved. We respect the views of all sides on these issues. We recognise the difficulty of achieving consensus between protagonists in opposing camps in this debate, for example the pro-life groups and those advocating an entirely libertarian approach to either assisted reproduction or research use of the embryo. We believe, however, that to be effective this Committee’s conclusions should seek consensus, as far as it is possible to achieve. Given the rate of scientific change and the ethical dilemmas involved, we conclude, therefore, that we should adopt an approach consistent with the gradualist approach, of which the Warnock Committee is one important example. This does not mean that we will shy from criticism of regulation to date, where we believe it warranted. But it does mean that we accept that assisted reproduction and research involving the embryo of the human species both remain legitimate interests of the state. Reproductive and research freedoms must be balanced against the interests of society but alleged harms to society, too, should be based on evidence.**

47. Many of the decisions about what to regulate or to legislate about depend on the approach taken with regard to the balance of harm and benefit or potential harm and potential benefit. It has become fashionable to specify that authorities (whether that be Governments, agencies, industry, watchdogs etc) should take a “precautionary approach” or adopt the “precautionary principle”. This means different things to different pressure groups, and to different sides of the argument. In respect of medical advances it has never meant “proceed only where there is evidence of no harm”. If it did many of the advances would never be made. In medical research practice it means proceeding through carefully regulated and tightly overseen research stages, requiring –among other things - vigilance and peer review. In clinical practice it means proceed cautiously and in a manner amenable to ethical oversight and clinical audit while there is no evidence of sufficiently serious harm or potential harm to outweigh benefit or potential benefit, while being vigilant in looking for unintended and otherwise adverse outcomes. **We do not see why the area human reproductive technologies should do anything other than proceed under a precautionary principle currently prevalent in scientific, research and clinical practise. This means – as specified in paragraph 46 above – that alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded.**

### *Spare embryos*

48. If embryos are to be used for the purposes of alleviating infertility, there remains the question of what can or should be done with those considered spare or unsuitable for implantation. There are a number of options: they can be destroyed, donated to another individual, stored for later use, or donated for research. This has been a major stumbling block for some individuals and groups, and has had a major impact on the recent Italian legislation, which does not prohibit IVF but demands that only three embryos are fertilised and that all must be implanted in the woman. This law attempts to eliminate the destruction of spare embryos, and donation, storage (except for certain circumstances) and research are forbidden. It could be argued that there is nothing “respectful” about the destruction of an embryo and that this therefore gives it no special status at all, not even that derived from a gradualist approach. The Church of England has addressed this issue in the following way:

“The superabundance of embryos, seventy per cent of which do not implant in the womb, is echoed throughout nature. Every living thing produces infinitely more seed than is ever used for reproduction. Only if the seed is implanted in soil in which it can flourish, as the parable teaches (Mark 4), can there be any fruit. If it is of God’s being to give more than enough, is it appropriate to regard that which is left over as waste, or is it meaningful in some other way? Biologically the generosity of nature is needed for the power of life and species development to overcome the force of entropy. Seed or eggs which do not reproduce are frequently sources of food for other creatures.”<sup>38</sup>

It could, of course, be said that what nature does and what man does are not equivalent. Unlike man, nature cannot be said to have intention. Thus, it might be argued, even if nature creates more embryos than survive to live birth, this is no justification for man to do the same. However, it must be borne in mind also that in IVF the intention is not create embryos to be spare, although it would be seen as a good thing to have a reasonable number from which to select the most viable for implantation. Once created, then, the question is the extent to which the embryo’s status can or should outweigh the potential benefits to be derived from its existence, or the extent to which its existence outweighs the choice of those who do not seek to implant every embryo which has been created and/or stored. At the simplest level, it can be argued that the competition here is between the interests that we have in respecting the human embryo (which is not a legal person) and the rights of born individuals to have their reproductive choices respected. While we agree that this decision is not an easy one, we nonetheless believe that the balance must lie with the rights of those already in existence but subject to appropriate ethical oversight and regulation. The outcome of any other conclusion would be that every embryo created would have to be implanted, thus potentially forcing individuals to have more children than they wish or repeated cycles of unsuccessful IVF, as in Italy. Such a direct invasion of their reproductive rights is hard to justify. Thus, inevitably, some embryos will perish, unless we can find a way of creating only as many embryos as it is anticipated will be implanted. Even then, however, some embryos will not be

selected for implantation because, for example, they carry genetic conditions incompatible with life, or with a life of quality. Again, this is a controversial aspect of assisted reproduction, which we consider in paragraphs 109–146.

### **Research**

49. The view that the embryo acquires human rights at conception would preclude any research being undertaken on it. We have concluded that the embryo should be accorded special status in common with the Warnock Committee. For research this means that the respect given to the embryo needs to be considered in the context of the benefits that might accrue from the research. The Warnock Committee suggested that research on embryos should not be permitted if the purposes could be achieved in any other permissible way or for “frivolous” reasons. This is reflected in the HFE Act in the list of purposes for which research on embryos can be conducted. The Warnock report did not specify what those purposes should be, other than the committee expected it be mainly for the alleviation of infertility and the prevention of hereditary disease. Broadly speaking, this continues to represent the legal position on embryonic research, although additional provisions have recently been added. These will be considered in more depth in paragraphs 331–342.

50. As we have seen, IVF procedures often produce spare embryos. These may either be surplus or of insufficient quality. While the Warnock committee was unanimous on the use of embryos in appropriate and ethical research, four of the 16 members felt that there was a “clear moral distinction” between the use of spare embryos and the creation of embryos specifically for research.<sup>39</sup> These views were based on the following arguments:

- a) That the creation of an embryo for research was inconsistent with the idea that it should be afforded special status.
- b) That, unless prohibited, it would lead to the use of embryos for routine and less valid research.

The majority of the Warnock Committee felt that the medical benefits from the creation of embryos were such that it was justified in certain circumstances. We also subscribe to this view. **We believe that the research on human embryos can be undertaken without compromising their special status but that this research should have proper ethical oversight as set out in Chapter 8 and 9. We further conclude that, where necessary, embryos can be created specifically for research purposes.**

## 4 Problems with the HFE Act

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### Definition of embryo and gamete

51. The 1990 HFE Act defines an embryo in Section 1(1) as “a live human embryo where fertilisation is complete”. This includes “an egg in the process of fertilisation”. Section 1(4) says that the Act’s use of the term gamete covers live human eggs or sperm but not eggs in the process of fertilisation. This definition, based on the process of fertilisation, had caused no problems until researchers at the Roslin Institute in Scotland demonstrated that a technique called cell nuclear replacement (CNR), involving the replacement of an egg nucleus with that of an adult cell, could lead to a live birth. The first example of this was the birth of Dolly the sheep. While the HFE Act had foreseen cloning, it had assumed that this would require the replacement of an embryonic nucleus rather than an egg, and had outlawed cloning only in specific terms, which did not include the method used to create Dolly. At the time, the Government held the view that, although fertilisation had not taken place, this process was nonetheless covered by the HFE Act. An initially successful challenge by the Pro-Life Alliance in the High Court that the HFE Act only referred to embryos that were created by fertilisation was subsequently overturned by the Court of Appeal whose judgment was approved by the House of Lords:

“While it is impermissible to ask what Parliament would have done if the facts had been before it, there is one important question which may permissibly be asked: it is whether Parliament, faced with the taxing task of enacting a legislative solution to the difficult religious, moral and scientific issues mentioned above, could rationally have intended to leave live human embryos created by CNR outside the scope of regulation had it known of them as a scientific possibility. There is only one possible answer to this question and it is negative.”<sup>40</sup>

This purposive approach to the definition of an embryo could be seen as resolving the definition of the embryo. Nonetheless, in its evidence, the HFEA suggests that the definition contained in the HFE Act is unsatisfactory and proposes that “An amended definition of ‘embryo’ and ‘gametes’ might clarify that the remit of the Act also extends to embryos that have been created by other means than ‘fertilisation’ (CNR, parthenogenesis), and to artificially created gametes”.<sup>41</sup> Support for an amended definition comes from Sarah Elliston of Glasgow University: “Given the challenges there have been to them already, I think it is arguable that there are so many different ways of creating something which can develop into a human being that the definitions are not correct”.<sup>42</sup> The solicitor James Lawford Davies points out that the HFEA’s proposed merger with the Human Tissue Authority means that “there will be a range of definitions which will be quite crucial to phrase carefully in legislation relating to human tissue, human material, embryos, gametes,

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40 Lord Bingham of Cornhill, House of Lords, Session 2002-03, 13 March 2003 [2003] UKHL 13 Regina v. Secretary of State for Health (Respondent) ex parte Quintavalle (on behalf of Prof-Life Alliance) (Appellant)

41 Ev 323

42 Q 888

and the processes by which they are created, used and stored”.<sup>43</sup> We will return to this proposed merger later.

52. There are three ways in which the perceived problem of the definition of an embryo can be addressed:

- a) By redefining an embryo, at least defining those types of embryo that fall under legislation, according to the way in which they were created. This has the advantage of clarity but it fails to embrace any future technique that might be developed. For example, it might become possible to reprogramme an adult cell to behave like an embryo. Vivian Nathanson from the BMA says: “The question, really, is whether it is possible to find a simple definition that would capture not only all current scientific possibilities but the ones that people speculate might happen within the next 10-15 years [...] but if one cannot find an acceptable phrase for that then we would still commend putting in the concept of cell nuclear replacement because it is so important”.<sup>44</sup> If this approach were to be adopted, the legislation would need to be sufficiently flexible to allow new forms of embryo to be included. An alternative approach would be to distinguish between fertilised embryos and what Professor Kenyon Mason of Edinburgh Law School termed “laboratory artefacts”.<sup>45</sup> Dr Veronica van Heyningen, a geneticist who contributed to our online consultation, also made this distinction: “I would not [...] think that laboratory experiments where you transplant a nucleus for entirely laboratory purposes into an oocyte [egg [...]] is an embryo”.<sup>46</sup> By making this distinction, as the Human Reproductive Cloning Act 2001 does, it would be possible to provide that only embryos for which fertilisation had taken place could be implanted. The disadvantage of this would be that some of these “laboratory artefacts” may have benefits, both for infertility treatment and avoiding genetic diseases.
- b) By defining an embryo by its capabilities. For example, it could embrace any diploid cell (two sets of chromosomes) with the potential to differentiate. However, Professor Lee M Silver from Princeton University describes a broader definition: “There’s a word biologists use to describe a cell, or group of cells, that by itself can develop into a whole animal or person: That word is ‘embryo’. Each random bunch of eight to 10 human ES [embryonic stem] cells is nothing more or less than a ‘naked’ human embryo – that is, an embryo without its pre-placental ‘coat’”.<sup>47</sup> This comment illustrates the danger that embryonic stem cells might be swept up by such a definition. This problem might be solved by including the provision that the cell(s) must have the potential to develop in the womb in order to be defined as an embryo. However, the cells’ potential might be open to debate and subject to technological advances. The Scottish Council on Human Bioethics cites German legislation in which any totipotent cell (capable of developing into a complete organism or differentiating into any of its cells or tissues), which has been extracted from an embryo which may divide and develop into an individual

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43 See paragraphs 376-377

44 Q 881

45 Q 888

46 Q 202

47 Lee M Silver, Watch What You Are Calling an Embryo; And Other Subtleties That Define the Debate, The Washington Post, 19 August 2001

human being once the necessary further conditions are provided, is considered to be an embryo.<sup>48</sup>

- c) A final option would be to avoid any definition, as is the case in the 2001 Human Reproductive Cloning Act. Using this approach, the term “embryo” would cover the normal usage of the word. We understand that this approach has been taken by the French in recent legislation.

**53. We are concerned that any legal definitions of the embryo based on the way it was created or its capabilities would either be open to legal challenge or fail to withstand technological advance. The attempt to define an embryo in the HFE Act has proved counter-productive, and we recommend that any future legislation should resist the temptation to redefine it. We consider that a better approach would be to define the forms of embryo that can be implanted and under what circumstances. Using this approach, only those forms of embryo specified by the legislation, such as those created by fertilisation, could be implanted in the womb and thereby used for reproductive purposes. Other forms of embryo would be regulated insofar as they are created and used for research purposes.**

## Prohibitions

54. The HFE Act contains a number of absolute prohibitions relating to embryos.<sup>49</sup> This inquiry has not just considered whether these or any prohibitions remain appropriate but also whether they should be extended to limit the discretion of the regulator. Beyond stating that the creation or keeping of an embryo requires a licence, the Act prohibits:

- a) Placing in a woman a live embryo other than a human embryo;
- b) Placing in a woman any live gametes other than human gametes;
- c) Keeping or using an embryo after the appearance of the primitive streak (14 days);
- d) Placing a human embryo in any animal;
- e) Keeping or using an embryo under any circumstances in which regulations prohibit its keeping or use; or
- f) Replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.<sup>50</sup>

Schedule 2 of the Act outlines those activities for which a licence cannot be awarded and are thus effective prohibitions. Paragraph 1(4) states that a treatment licence “cannot authorise altering the genetic structure of any cell while it forms part of an embryo”. It is worth reiterating that placing in a woman an embryo formed by cell nuclear replacement was not prohibited under the Act but put it within the regulatory powers of the HFEA. This situation was later clarified by the Human Reproductive Cloning Act 2001, which

48 Ev 262

49 Section 3

50 The Act specifies the replacement of an embryo’s nucleus and therefore does not cover the cloning technique developed at the Roslin Institute which used an enucleated egg.

states “A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence”. The significance of this legislation will be discussed below (see paragraphs 68–78).

### *Time limits*

#### *Process of fertilisation*

55. The HFE Act’s definition of an embryo includes one in the process of fertilisation, which is complete at the two cell stage. After fertilisation, two pronuclei are formed, one containing the paternal chromosomes from the sperm and the other the maternal chromosomes. The fully formed embryo nucleus does not appear until the two cell stage. When the HFE Bill was first published it limited the definition of an embryo to one that had completed fertilisation at the two cell stage; however, the Government introduced an amendment at the Report stage to expand the definition to include an egg in the process of fertilisation, particularly for the purposes of research.<sup>51</sup> This has recently caused problems following the application for a research licence by the Newcastle Fertility Centre to study cell nuclear replacement on an early embryo as a technique for treating mitochondrial diseases. This is because the HFE Act prohibits “replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo”.<sup>52</sup> The Newcastle team argues that they wish to replace a pronucleus, not a nucleus, and that their project should be permitted under the Act.<sup>53</sup> This issue of definition does not arise in the case if the embryo does not come under the law’s protection until it has completed fertilisation at the two-cell stage. **We see little value in regulating the use of an egg in the process of fertilisation. A unique genetic entity is only formed at the union of the male and female pronuclei and this seems the most appropriate point at which to bring the creation under the protection of legislation.**

#### *The 14 day rule*

56. If the embryo is to be afforded some protection in law it is important to establish criteria for such protection where a gradualist approach is adopted. The HFE Act currently affords protection to an embryo until 14 days, at which point it must either be transferred to a woman or destroyed: the so-called “14 day rule” advocated by the Warnock Committee. After this period of time, an embryo created outside the body must either be implanted, stored for future use or destroyed.<sup>54</sup> This rule is based on selecting as significant the developmental stage of the embryo at which it shows clear signs of differentiation into tissues, and in particular the appearance of the “primitive streak”, the precursor to the spinal cord. This developmental approach is widely accepted: other countries that have also adopted a 14-day rule include Australia, Belgium, Japan and Singapore.<sup>55</sup> Despite this, the 14 day rule has not met with universal approval. For example, the Scottish Council on

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51 HL Deb, 6 March 1990, col 1055

52 Section 3(3)d

53 Ev 283

54 Section 3(3-4)

55 Australian states with legislation are South Australia, Western Australia, Victoria and, in 2005 New South Wales.



Human Bioethics points out that, “the process of human development is a continuous one in which any demarcation would be arbitrary and merely conventional [...] it is indeed impossible to indicate a non-arbitrary point of transition from human non-person to human person”.<sup>56</sup>

57. On the other hand, Professor Julian Savulescu suggested in evidence that one could make a distinction on the basis of the embryo’s capabilities. He argued that we consider death to be at the point at which the brain is no longer capable of conscious thought, and that at this point we allow the withdrawal of life-prolonging medical treatment. It was therefore logical, he argued, to conclude that life in a morally significant sense started at around 18–20 weeks.<sup>57</sup> Professor Robin Gill countered that “We have to take into consideration not just how that person values themselves or what they think or what they feel but what other people feel about them. It makes me extremely uncomfortable if we only value a person for what goes on inside their head”.<sup>58</sup> Having adopted a gradualist approach, the cut-off point at which embryos can no longer be cultured in vitro seems to be uncontroversial outside philosophical or religious discourse. This is largely due to the fact that clinicians and scientists seem to lack the desire or ability at present to culture embryos for longer than 14 days. For IVF, the embryo is typically transferred between days 3 and 5 and, while some centres have attempted to implant slightly later than this (at the blastocyst stage) in an attempt to increase the chances of a pregnancy, the benefits are contested.<sup>59</sup> It has not proved possible for researchers to sustain an embryo in culture for 14 days, although research on artificial wombs is underway.

58. However, as this inquiry has sought to look beyond current medical and scientific practice, we should assume that demands and capabilities will change. Dr Richard Fleming, a contributor to our online consultation, told us, “I imagine that in the future you will have to re-examine it [the 14-day rule]. At the moment there is not much of a call to do so but progress will take us there”.<sup>60</sup> We would consider it negligent not to consider the long-term appropriateness of the 14 day rule, which John Polkinghorne has described as “appropriately cautious and conservatively calculated”.<sup>61</sup> A starting point should be to establish why we need statutory limits on the culture of embryos. Beyond the point of fertilisation, there is no clear cut-off point and it could be argued that providing discretion to the regulator offers a more pragmatic response. It is conceivable, for example, that research could demonstrate that long-term culture of embryos offers the best chance of a live birth. A BBC drama documentary screened in December speculated that there may be value in deriving stem cells from a 19-day-old cloned embryo. In the story, a doctor was being prosecuted for breaching the 14-day-rule of the HFE Act to provide stem cell therapy to a man suffering spinal cord injury as a result of a climbing accident.<sup>62</sup> It is interesting that viewer polls suggested that 80% of the 11,500 votes cast supported a not guilty verdict against the doctor. **We have been told that the 14-day rule is an arbitrary cut off point.**

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56 Ev 249

57 Q 762

58 Q 765

59 NICE, Fertility assessment and treatment for people with fertility problems, February 2004, pp 112-113

60 Q 210

61 JC Polkinghorne, The person, the soul, and genetic engineering, *Journal of Medical Ethics*, 2004;30:593-597

62 IF... Cloning Could Cure Us, *BBC Two*, 16 December, 2004, 2100 GMT

**For many, even those who support assisted reproduction and embryo research, an extension to the 14-day rule would be unacceptable. We accept that there is no case at present for an extension, or indeed reduction. However, we believe that, if scientists or clinicians were able to provide convincing justification for any change, this should be determined by Parliament.**

### *Animals and human cells*

59. Technical developments since 1990 challenge our notions of what constitutes a human embryo and provide new ways of creating viable embryos. In this context, it is worthwhile to discuss the HFE Act's prohibitions relating to the uses of animal and human embryos.

#### *Placing a human embryo in an animal*

60. The placing of a human embryo in an animal raises clear issues of animal welfare but the ethical problems relating to the special status of the embryo are less clear. We are aware of no possible treatment applications that should lead us to question the current prohibition. However, if a spare embryo has been made available for research, then it could be argued that respect for the embryo should prompt us to ensure that it is used for the best possible ends. It has been commented that very little is known about the development of the human embryo in vivo. There have been calls for the application of animal research work to human assisted reproduction.<sup>63</sup> While we are aware of no interest from scientists in extending this work by placing human embryos in animals, it is conceivable that such research could yield valuable insights into the causes of infertility and miscarriage. Such a proposition would make many uncomfortable. Nonetheless, we have set ourselves the task of recommending new legislation that can cope with new technical advances and difficult issues must be taken into account.

61. In the House of Lords debate on stem cell research in 2002, Baroness Warnock said:

“You cannot respectfully pour something down the sink—which is the fate of the embryo after it has been used for research, or if it is not going to be used for research or for anything else. [...] I think that what we meant by the rather foolish expression ‘respect’ was that the early embryo should never be used frivolously for research purposes.”<sup>64</sup>

Once an embryo has been created but is not required for treatment, it must either be destroyed or used for research. It could be argued that its special status demands that it be used for potentially valuable research. It could be argued that if incubation of that embryo in an animal were to yield valuable information about the causes of infertility, then this is an appropriate use for the embryo and consistent with its status. The Warnock report recommended that placing a human embryo in an animal would be a “cause for concern”, but gave no reasoning for its conclusion that undertaking such a procedure should be a criminal offence. If the mixing of animal and human cells raised particular ethical issues, a

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63 Barry Bavister, The role of animal studies in supporting human assisted reproductive technology, *Reproduction, Fertility and Development*, 16 (7): 719-728 2004

64 HL Deb, 5 December 2002, Col 1327

greater area of concern might be the co-culture of human embryonic stem cells with animal “feeder” cells, which is a well-established technique.

62. As Baroness Warnock’s quote demonstrates, the ethical problems concerning the use of embryos surplus to treatment are not clear cut, particularly if no embryo could be incubated in the animal for longer than the statutory maximum duration for in vitro culture. **In considering the subject comprehensively we should not shy away from addressing difficult subjects which may widely be considered ‘taboo’. In this instance, however, we have heard no evidence which would lead us to conclude that there is any merit in relaxing the HFE Act’s prohibition on placing human embryos in an animal for research purposes. Should the government receive expert advice to the contrary, given the ethical issues involved, any such change should be a matter for Parliament and primary legislation.**

### *Placing an animal embryo in a human*

63. The HFE Act also prohibits the placing of an animal embryo in a human. We are aware of no scientific benefits arising from such a procedure and there is no virtue in relaxing the current prohibition.

### *Chimeras and hybrids*

64. Consideration of animal-human chimeras and hybrids is made difficult by the lack of legal definitions. However, the Canadian Assisted Human Reproduction Act 2004 usefully defines a number of techniques that result in the formation of hybrids or chimeras, and we shall employ them here (see Box 2). Sarah Elliston from Glasgow School of Law suggested to us that, if we are to consider how to deal with such creations in law, we have to decide why it is that it [the chimera or hybrid] deserves respect: “Is it because of what it is made up of? Is it its DNA composition? Is it its potential to develop into a human being? What do we mean by human being?” She suggests that it is necessary to speculate what status we would give to an animal-human hybrid if it were to be born.<sup>65</sup>

#### **Box 2: Definitions of chimeras and hybrids in Canadian law.**

A “chimera” is

- i. an embryo into which a cell of any non-human life form has been introduced; or
- ii. an embryo that consists of cells of more than one embryo, foetus or human being.

A hybrid is:

- i. a human ovum that has been fertilized by a sperm of a non-human life form;
- ii. an ovum of a non-human life form that has been fertilized by a human sperm;
- iii. a human ovum into which the nucleus of a cell of a non-human life form has been introduced;
- iv. an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or
- v. a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.

Clause 5 of the Canadian legislation states that creating a chimera or transplanting it into a human or animal is prohibited. Hybrids can be created but not for the purpose of reproduction or transplanting a hybrid into a human or animal.

65. There is some uncertainty about how hybrids and chimeras are dealt with in UK law. The Centre for Bioethics and Public Policy states that “the creation of new genetic human-animal chimeric embryos and fetuses, do not come under the HFE Act”.<sup>66</sup> This uncertainty was shared by some of the researchers who gave evidence to this inquiry.<sup>67</sup> However, a chimera, as defined by the Canadian legislation, might constitute genetic modification of an embryo under Schedule 2(1)(4) (for treatment) or Schedule 2(3)(4). Hybrids formed by the fertilisation of human and non-human gametes are clearly covered by Section 4(1), which demands that such a procedure requires a licence. Schedule 2(1)(f) permits this procedure for the purpose of testing the fertility or normality of the sperm, but only if any embryo formed is destroyed no later than the two cell stage. Hybrids created by the introduction of animal nuclei into a human egg might require a licence if the storage of the eggs is involved. The introduction of a human nucleus into an animal egg would come under the HFE Act if the resulting creation is considered to be a human embryo.

66. While a chimera is unlikely to be able to develop very far, it may have value as a research tool, possibly as a means of testing the ability of stem cell cultures to form all forms of tissue.<sup>68</sup> Similarly, hybrids formed by cell nuclear replacement might have value in deriving embryonic stem cells for research purposes. There have been reports that Chinese scientists have harvested stem cells from embryos created by introducing human cell nuclei into enucleated rabbit eggs. Professor Robin Lovell Badge from the Medical Research Council’s National Institute for Medical Research told us that this technique might overcome the shortage of human cell lines, although he told us that some of this work was “to be taken with a pinch of salt”.<sup>69</sup> The 2000 Donaldson Report on stem cell research stated that the 1990 Act does not control the mixing of animal eggs with other human cells but that this should be prohibited.<sup>70</sup> The Lords Stem Cell Research Committee expressed some surprise at the conclusion since it could raise fewer ethical questions than would the use of a human embryo created using CNR.<sup>71</sup> It should be remembered that the HFE Act aimed to give protection to the human embryo and not gametes or other forms of embryo. Provisions to protect hybrids would require a different ethical justification . **The ethical status of hybrids and chimeras is complex. While there is revulsion in some quarters that such creations appear to blur the distinction between animals and humans, it could be argued that they are less human than, and therefore pose fewer ethical problems for research than fully human embryos. We recognise concerns that hybrids and chimeras could be used for reproductive purposes and recommend that new legislation a) defines the nature of these creations, b) makes their creation legal for research purposes if they are destroyed in line with the current 14-day rule for human embryo cultures, and c) prohibits their implantation in a woman.**

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66 Ev 242

67 Qq 1139-1143

68 Q 1144

69 Q 1141

70 recommendation 6, page 46

71 para 8.18

### ***Embryos not formed through fertilisation***

67. Embryos not formed through fertilisation are covered by two pieces of legislation: the 1990 HFE Act and the Human Reproductive Cloning Act 2001. The latter was introduced when a case was brought by the Pro-Life Alliance, claiming that embryos formed by cell nuclear replacement were outside the HFE Act since they fell outside the definition of an embryo in Section 1(1)a (“a live human embryo where fertilisation is complete”). The initial success of the Pro-Life Alliance’s challenge in the High Court prompted the Government to introduce legislation quickly in order to prevent attempts at reproductive cloning in the UK, although it is debatable whether any attempt was imminent. In the meantime the Government was given leave to appeal to the Court of Appeal, which it did, successfully. Lord Bingham of Cornhill said that the court’s task, within the permissible bounds of interpretation, was to give effect to Parliament’s purpose, and the court ruled against a literal interpretation of the HFE Act. This decision was upheld in the House of Lords. If the Pro-Life Alliance’s challenge had been ultimately successful, the HFEA would not have been able to regulate therapeutic cloning.

### ***Cell nuclear transfer and reproductive cloning***

68. While the safety concerns surrounding reproductive cloning are well recognised, we have sought to explore the relevant ethical issues, which have received less attention. Much of the online discussion on cloning focused on the rights and wrongs of therapeutic cloning, often based on beliefs about the status of the embryo or concerns about the commoditisation of human tissue or future persons. There are a number of objections to the idea of creating a human being genetically identical to a person who is living or who has once lived and fears that the technology could be used to create large numbers of identical, genetically modified individuals. A 1998 study of public attitudes commissioned by the Wellcome Trust found that most respondents exhibited a “widespread and often spontaneous reaction” to human cloning with its use “linked to its adoption by malevolent outside influences such as the military, megalomaniac leaders and rogue scientists”. Even when the science behind cloning and the influence of environmental factors were explained, respondents continued to reject the idea.<sup>72</sup> In evidence, Dr Tom Shakespeare felt that “being foreshadowed by somebody whose genotype to all intents and purposes is identical to yourself is problematic. [...] If you have the same genetic characteristics as one of your parents, then you will see them developing in ways which, to a large extent, you will echo,” although this already true to some extent.<sup>73</sup> On the other hand, Dr Sarah Parry from Edinburgh University reported that, while people have concerns about the impact of a clone on family life and what this means in terms of how it feels to be an individual, when people talked about reproductive cloning, “the conclusion, after going through the range of pros and cons around reproductive cloning, tended to be [...] that maybe it would not be such a bad thing” and “that people did not necessarily think [cloning] would always been seen as such a taboo”.<sup>74</sup>

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72 The Wellcome Trust, *Public Perspectives on Human Cloning: A Social Research Study*, 1998, pp 13-14

73 Q 1028

74 Q 1026-27

69. This leaves us with the dilemma as to how far we should extend notions of reproductive liberty to cloning. There are coherent reasons why it would not be desirable to advocate cloning for anything other than therapeutic research, but the conclusion from this that it should be completely outlawed is more difficult to sustain. Writing in *New Scientist*, Professor Ian Wilmut from the Roslin Institute describes a scenario in which reproductive cloning is used to overcome a genetic disease: an embryo with faulty genes is created through IVF. Stem cells are extracted from the embryo and cultured. The faulty genes are then replaced with healthy ones. The nucleus of a stem cell is then transferred to an enucleated egg and the resultant embryo is then implanted in a womb.<sup>75</sup> In this scenario, a clone has been born but not of an individual who has ever existed. It is not clear that such a child would suffer as a result of its manner of conception. A further example might be the cloning of a still-born child. Patrick Mahon, an identical twin who contributed to our online consultation, argued that this would still not be acceptable since it could only be of benefit to the parents who wanted to clone their dead child. He said “If cloning were in any sense available to help the child then I think there is an ethical issue there and one has to decide what the relative costs and benefits are”.<sup>76</sup> The House of Lords Stem Cell Research Committee concluded that there were “familial and child welfare considerations arising from the ambiguity of the cloned child’s relationships”. Reproductive cloning was not a major element of the Lords Committee’s inquiry. It is, therefore, odd that it “unreservedly endorses the legislative prohibition on reproductive cloning now contained in the Human Reproductive Cloning Act 2001” when there are obvious scenarios in which the welfare arguments it employs do not apply.<sup>77</sup> **We recognise that human reproductive cloning, if possible at all, is not currently safe and that no clinician could legitimately pursue it under existing professional regulation. In addition, we recognise that research in developing reproductive cloning would very likely involve experimentation that is highly unethical. Nonetheless, the patchy legislation around the world suggests that the research will take place somewhere and someone may be able to demonstrate a technique that is safe, effective and reliable.**

70. We were interested to hear the views of the HFEA’s Deputy Chairman, ethicist Tom Baldwin. He told us that he had no principled objection to reproductive cloning being a licensable treatment but that “it would need to be tightly regulated because you need to control carefully the kinds of conditions for which you could use the technology”.<sup>78</sup> Professor Peter Braude told us that “if you were going to make new legislation, it needs to have a mechanism to be flexible enough to respond, but it is not in the current framework of Parliament; they have outlawed cloning. Reproductive cloning is not allowed and there is no flexibility in that”.<sup>79</sup> Interestingly, the view of Professors Baldwin and Braude that cloning should be dealt with by regulation seems to be at odds with the medical and scientific establishment. Dr Vivienne Nathanson from the BMA argued that reproductive cloning should be one of the very few broad prohibitions in a revised HFE Act. The Royal Society is equally hostile. It is a signatory to a statement by the InterAcademy Panel on International Affairs, which states that even if reproductive cloning by somatic (non-

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75 21 Feb 2004

76 Q 190

77 para 5.21

78 Q 677

79 Q 679

reproductive) cell nuclear transfer might be accomplished without undue risk, this would not of itself warrant the lifting of a ban, which would still face “strong ethical, social and economic objections”. Its sister organisation in Edinburgh takes a more pragmatic view, noting that while “there is little prospect of developing a satisfactory technique for human cloning, since the experimental stage would not be acceptable [...] there] may be acceptable reasons for human cloning”.<sup>80</sup> The scenario described by Professor Wilmot is one such case – this is only one example of where the technology is not being used to clone an individual with legal rights. However, it is disappointing that both the BMA and the Royal Society of London seem unwilling to countenance the idea that applications of cloning such as this could have a future. In doing so, they have become unlikely advocates of a prohibitively restrictive application of the precautionary principle. We question whether their stance owes more to the protection of the public image of doctors and scientists; that they fear that a more pragmatic approach to reproductive cloning would leave them open to criticism. It would be unfortunate if our most respected scientific bodies felt unable to take a lead on ethical issues of the day. Even Professor John Polkinghorne from the University of Cambridge states that “with only a very few rogue exceptions, [...] reproductive human cloning [...] is ethically unacceptable”. Yet beyond citing safety, his only further stated objection is the “moral propriety of creating a child who was the identical twin of one of its parents”.<sup>81</sup>

71. The responsible Minister is equally hostile to reproductive cloning, to the extent that she was unwilling even to discuss the issue with us: “I think it raises all sorts of difficult issues and I think there are people here around this table who do understand very well what those views are. I do not want to go down the path of discussing this because it is not up for discussion, it is illegal, and we have no plans to change it”.<sup>82</sup> This is curious since it was the Government’s earlier intention that it should remain a legal but licensable activity. It was only the initial success of the Pro-Life Alliance in contesting the status of embryos created using cell nuclear replacement that led to the Government’s introduction of the Human Reproductive Cloning Bill in 2001 and an outright ban. Evidence to our predecessor Committee in 1998 during its inquiry into *The Cloning of Animals from Adult Cells* from John Battle, the then Minister for Science, Energy and Industry, states that “cloning involving embryo splitting or nuclear replacement in eggs cannot take place because the HFEA has made clear its decision that it will not license any treatment involving such techniques or any research to develop cloning for such treatment purposes”.<sup>83</sup> This is not the same as a ban. **Even if human reproductive cloning were shown to be safe, effective and reliable we would still have grave concerns about many of its applications . However, there are clear examples where the situation is not so clear cut and the ethical debate is highly complex. Professor Ian Wilmot has described a scenario in which the aims are therapeutic and no clone is created of an individual who has ever been born. If there is to be a total prohibition of any form of reproductive cloning, it is important that it is supported by principled arguments why such a technique should be banned even if it were shown to be safe, effective and reliable.**

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80 Ev 202

81 JC Polkinghorne, The person, the soul, and genetic engineering, *Journal of Medical Ethics*, 2004;30:593-597

82 Q 1358

83 Fourth Report of the Science and Technology Committee, Session 1997-98, *The Cloning of Animals from Adult Cells*, HC 1039, Page 2

**Without such arguments, an indefinite absolute ban could not be considered rational. The Minister's refusal to enter into any discussion of reproductive cloning is not an encouraging starting point for an open-minded review of the adequacy of existing legislation.**

### *Therapeutic cloning*

72. As part of this inquiry, we have received a number of written submissions on the subject of therapeutic cloning and the derivation of embryonic stem cells. Indeed, many of the contributions to our online consultation on the subject of human cloning and written submissions to this inquiry have sought to address this issue rather than that of reproductive cloning.<sup>84</sup> It has never been the intention of this inquiry to weigh up the merits of adult and embryonic stem cells. The issues have been comprehensively addressed by the House of Lords Stem Cell Research Committee in 2001 and we are unaware of any new evidence that would require a reassessment of that Committee's conclusions, which we respect. Our interest in therapeutic cloning relates to the adequacy of the 2001 Regulations, which extended the purposes for which embryo research could be undertaken to include the study and treatment of disease; and to the ability of the HFEA to take an informed view as to whether a research project for which a licence was sought could have been undertaken using adult stem cells. We will consider these elsewhere in this report.<sup>85</sup>

### *Embryo splitting*

73. Embryo splitting is a natural process that gives rise to identical twins. However, there are concerns that this could also be achieved deliberately in vitro, for example by dividing an eight cell embryo. In our online consultation, there were objections that this amounted to cloning and, if the resulting embryos were implanted separately, could violate the bonds enjoyed by identical twins. The HFEA considered embryo splitting in 1994 following reports that an American research team had succeeded in growing a split human in Petri dish for several days in 1993. The HFEA concluded that it would consider research applications but not if the intention was to increase the number of embryos for transfer.<sup>86</sup>

74. Under the HFE Act, therefore, embryo splitting is a licensable activity. However, it could be argued that an embryo formed as a result of splitting had been formed by means other than by fertilisation and therefore that implanting the embryo would breach the Human Reproductive Cloning Act 2001. There are reasons why someone would wish to undertake embryo splitting, other than to create identical twins. The parents might carry the gene for a late onset condition for which preimplantation genetic diagnosis was not permitted. While one of the split embryos would be allowed to develop into a fully formed person, the other could be kept in deep freeze. The frozen embryo could then be used to provide a source of embryonic stem cells to treat the "twin" later in life. A second therapeutic application, which could be undertaken under an HFEA licence, would be to split a cloned embryo to increase the chances of deriving a cloned stem cell culture.

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84 e.g. Ev 268, 387

85 JC Polkinghorne, The person, the soul, and genetic engineering, *Journal of Medical Ethics*, 2004;30:593-597

86 HFEA and Human Genetics Advisory Commission, *Cloning Issues in Reproduction, Science and Medicine*, December 1998, para 3.9



75. While a rhesus monkey was born following embryo splitting in 1999, it was one of only four embryos created by splitting an eight cell embryo, suggesting that the technique is far from being safe and efficacious **As with cell nuclear replacement, the risks of implanting a split embryo are high, but a distinction needs to be made between safety of the treatment and the fundamental ethical principles. If embryo splitting for treatment purposes is to be prevented, as with reproductive cloning, this should be based on coherent ethical argument, such as the right not to be purposefully created with a specific genetic identity.**

### *Parthenogenesis*

76. Parthenogenesis can be defined as a form of reproduction in which an unfertilised egg develops into a new individual. It is common among invertebrates and plants, and present in some fish, amphibians, and reptiles. It does not, however, occur naturally in mammals although researchers have been able to stimulate artificially unfertilised mammalian eggs by chemical or electronic means into starting embryo development. This is currently the subject of an HFEA licensed research project by the Newcastle Fertility Centre to derive embryonic stem cells. The lay summary of its application says that the technique may have value in deriving stem cell lines for therapeutic use that are genetically similar to the recipient and so will not be rejected.<sup>87</sup> An advantage of this technique is that it could eliminate the need to destroy potentially viable embryos in order to derive stem cells. While research projects can be licensed by the HFEA, parthenogenetic embryos cannot be placed in a woman under the terms of the Human Reproductive Cloning Act 2001.

77. The Centre for Bioethics and Public Policy has complained that “parthenogenesis raises fundamental questions of what it means to be human and of how humans should be treated. Yet there has been no public debate in this country on this procedure, on the safety and medical issues raised, on the ultimate purpose and outcome of this type of research, nor on the ethical considerations”.<sup>88</sup> The Church of Scotland Society, Religion and Technology Project takes the view that the “moral status of parthenogenetic creations is not clear. [...] If they are not viable because certain crucial factors in their development does not follow the pattern of normal sperm plus egg embryos, are these defective human embryos, or are they not real embryos at all? If they are defective then this suggests that, as with cow-human hybrids, the route may pose at least as many ethical problems as other methods, including nuclear transfer embryos”.<sup>89</sup> The status of an embryo is often said to depend on its potential, yet it is highly unlikely that a parthenogenetic embryo has any more chance of being born than has a gamete. **We regret that the use of parthenogenesis to derive stem cells was not considered by either the Donaldson report or the House of Lords Stem Research Committee. This gives the impression that inadequate consideration has been given to these ethical issues before research projects were licensed by the HFEA.**<sup>90</sup> Nevertheless, we are pleased that this line of research is possible under the current legislation as we take the view that parthenogenesis raises fewer

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87 HFEA research application no R0152

88 Ev 238

89 [www.srtp.org.uk](http://www.srtp.org.uk)

90 Ev 272

**ethical issues than creating an embryo created using CNR, provided that it is not cultured for longer than 14 days.**

### **Genetic modification**

78. The HFE Act's restrictions on the genetic modification of embryos are set out in Schedule 2. Paragraph 1(4) states that a treatment licence "cannot authorise altering the genetic structure of any cell while it forms part of an embryo". Paragraph 3(4) states that a research licence "cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations", thus enabling this prohibition to be relaxed through a statutory instrument. The alteration of the genetic composition of an embryo can be achieved by modifying the gametes or the early embryo. This is termed germline therapy. It would appear that genetic modification of gametes would lie outside the HFE Act if no storage of the gametes was involved before modification. If the desired gene is chromosomal rather than mitochondrial then a version of gene therapy would be used to introduce the gene using a virus. If the intention is to correct defective mitochondrial DNA then cell nuclear replacement can be used to insert the nucleus of the egg that contains the faulty mitochondria into an enucleated donate egg, or it is plausible that healthy mitochondria could be injected into the affected egg. The same technique could also be employed to boost the likelihood of fertilisation for women for whom IVF has failed repeatedly, although Richard Fleming, in contributing to our online consultation, said that early results were disappointing.

79. Defects in the mitochondrial DNA cause more than 50 different inherited metabolic diseases.<sup>91</sup> The Chief Medical Officer considered the treatment as part of his Expert Group review of stem cell research in 2000. He recommended that the technique "would require considerable research before its possible use in treatment could be contemplated. However, subject to the feasibility and safety of the technique being established, the Expert Group concluded that such research appeared to offer the long term prospect of a healthy child for affected families".<sup>92</sup> Because the technique is applied to the egg rather than the embryo, the HFEA is able to license this research under the HFE Act. The use of this technique has attracted the media's attention as, in theory, the resulting child would have three genetic parents, although the genetic proportion of mitochondrial DNA in the human genome is tiny.<sup>93</sup> Most of the 20 genes in the mitochondrial DNA code for proteins are part of the inner mitochondrial membrane and therefore contribute nothing to a person's individuality. Since mitochondrial DNA is passed unchanged down the maternal line (except for rare mutations), the egg donor would no more be the child's genetic mother than the donor's great great grandmother.

80. If the technique was applied to the embryo rather than the egg it is less clear that the HFEA could license a research application; indeed, an application from the Newcastle Fertility Centre to undertake such a study has been rejected on the grounds that it would

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91 Donaldson report, 2000, para 21

92 See para 23

93 Mitochondrial DNA contains around 16,000 base pairs, compared with around 3 billion in the chromosomes. See *BBC News Online* 5 January 2001

constitute an alteration of the genetic structure of the embryo.<sup>94</sup> Even if the appeal against this decision is successful, modified embryos could not be implanted in a woman under the Human Reproductive Cloning Act 2001, despite the fact that no cloning had taken place unless the mitochondrial genome had been eliminated from the germline by injected unaffected mitochondria into the embryo. **Regardless of whether cell nuclear replacement is undertaken on eggs or embryos for the purposes of research on mitochondrial diseases, the aim of the research is the same. Given that we permit experimentation on embryos to investigate heritable diseases, we see no need to distinguish between the techniques in law.**

81. The use of germline therapy on chromosomal DNA is more contentious. In theory the technique could be used to modify any number of human genes; to create designer babies in a very real sense. Equally, it could be used to achieve exactly the same aims as preimplantation genetic diagnosis (PGD). John Polkinghorne asks “If we could eliminate the propagation of Huntington’s by genetic engineering, should we not do so? That would be seen as remedying a defect by restoration to the norm”.<sup>95</sup> In some ways it could be considered less ethically problematic since PGD involves the rejection of “faulty” embryos. In genetic conditions with more than one defective gene, the chances of identifying an unaffected embryo diminish and in many cases may prove impossible. Gene therapy would seek to correct rather than eliminate and, if consistently successful, would involve less wastage. Dr Simon Fishel from the Park Hospital in Nottingham told us “If the technology could be safe and you could introduce to subsequent generations health from what would be a disease position, that, to my way of thinking, is positive medicine, a one-step PGD process, if you like, to ensure that a particular devastating disorder would no longer continue through the family line”.<sup>96</sup> The Centre for Bioethics and Public Policy argues that “Germline engineering is not permitted in this country and most other countries for very good reason – it is risky, has unpredictable results and any errors or unforeseen results would be passed down future generations. The effects could be devastating and irreversible”.<sup>97</sup> Professor Peter Braude told us that, “Every child would be an experiment”.<sup>98</sup> However, if we wish new legislation to be robust, we need to assume that the technology will one day arrive. Absence of imminence is not a reason for inaction. As the Christian charity CARE points out, “introduction of a new technology often follows a common path – first its development behind closed doors, then the winning over of the public with predictions of life-saving advances, then finally, a regulatory regime to fit the already completed package. Clearly it is much better to have regulatory regimes set up earlier in the process”.<sup>99</sup> **Effective and safe germline therapy to treat serious genetic diseases would result in reduced child mortality and morbidity and fewer abortions and destroyed embryos.**

82. The Gene Therapy Advisory Committee (GTAC) is a non-statutory regulatory body set up in 1993. Its principal term of reference is “To consider and advise on the acceptability of

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94 Ev 433, see para 56

95 JME, 2004

96 Q 673

97 Ev 240

98 Q 677

99 Ev 273

proposals for gene therapy research on human subjects, on ethical grounds, taking account of the scientific merits of the proposals and the potential benefits and risks”.<sup>100</sup> However, GTAC considers applications for clinical trials. **We conclude that the absolute prohibition on genetic modification of the pre-14 day human embryo be removed for research purposes and recommend that future legislation, while prohibiting the modification of chromosomal DNA for reproductive purposes, should provide for regulations to be made to relax this ban under tightly controlled circumstances if and when the technology is further advanced.**

## Fresh gametes

### *GIFT and IUI*

83. The HFE Act only brings stored and donated gametes within a regulatory framework. Thus, gamete intrafallopian transfer (GIFT) and intrauterine insemination (IUI) can be undertaken in unlicensed premises if these involve the partner’s sperm. The British Fertility Society is keen for these “outlying treatments” to be brought within the Act as they have “the potential for many of the risks and consequences of IVF”.<sup>101</sup> This is based on the fact that in both cases the woman is likely to be given ovarian stimulation drugs, bringing with them the small but significant risk of ovarian hyperstimulation syndrome (OHSS). Recent technological developments have arguably increased the claims to bring fresh gametes within regulation. Up to a point this will happen anyway with the transposition of the EU Tissue Directive into UK law in April 2006, but the Directive only demands that certain standards are met and does not require the competent authority (currently the HFEA) to provide guidance on the purposes for which fresh gametes can be used. However, as we have already noted, the law permits people to accept even risky therapy. **If the purpose of regulation in assisted reproduction is to protect patients, there is no justification for exempting GIFT and IUI with partner sperm from the legislative framework. However, given our acceptance of the position that the state should intervene only in carefully defined and justified circumstances, where there are specific harms, in reproductive decisions, the common law rules of consent are sufficient to protect patients in the face of these risks. It is consistent with our ethical approach that, rather than adding to the list of regulated fertility treatments, we should be decreasing the level of state intervention. We accept that GIFT and IUI pose similar risks to IVF, but we have already concluded that these risks lie within accepted legal boundaries on what people can consent to. We have not been persuaded, therefore, that regulation should demand anything more than that the highest technical standards are observed.**

### *Internet services*

84. The advent of the internet and the worldwide web has raised novel issues in assisted reproduction services. The Man Not Included website was set up in 2002 and claims to provide “a non-discriminatory, confidential and totally anonymous sperm donation service available to any woman wishing to conceive, regardless of sexual orientation or

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100 [www.advisorybodies.doh.gov.uk/genetics/gtac/](http://www.advisorybodies.doh.gov.uk/genetics/gtac/)

101 Ev 216

marital status”.<sup>102</sup> The service circumvents the HFE Act as the gametes are not stored.<sup>103</sup> Having signed up and paid, a woman will receive, by courier, a flask containing sperm with which she can inseminate herself.<sup>104</sup> The service is aimed at single women and lesbians and would appear to have obvious appeal to these groups (see Table 4). However, the response from Pink Parents UK was not favourable. Lisa Saffron, its Founder and Executive Director, told us that “Because they are outside the HFEA regulation, they are never inspected. They do not have to show their procedures to anyone. [...] They are not offering a service for lesbians, they are exploiting us”.<sup>105</sup>

**Table 4: Advantages and disadvantages of forms of sperm donation.**

	<b>Regulated gamete donation</b>	<b>ManNotIncluded</b>	<b>Known donor insemination</b>	<b>Sex with a stranger</b>
<b>Fresh sperm</b>	-	+	+	+
<b>Anonymity<sup>106</sup></b>	-	+	-	+
<b>Convenience</b>	-	+	+	+
<b>Safety</b>	+	+/-	+	-
<b>Legal protection</b>	+	-	-	-
<b>Cost</b>	-	-	+	+
<b>Legal Protection for sperm donor</b>	+	-	-	-

85. While many single women and lesbians will attach different weights to each of the criteria in Table 4, regulated services do not obviously provide a significant excess of advantages compared to unregulated approaches. Therefore, it appears unlikely that regulating internet services will result in potential customers opting for regulated services as opposed to other unregulated approaches. At the same time, arguments of principle for regulating internet services on the basis that the use of fresh as opposed to frozen sperm does not vitiate the need for regulation would also apply to known donor insemination and sex with a stranger. Regulation of these latter approaches would, however, never be practical. The principal concern to us is that purchasers of this service can be assured of the safety and viability of this service. The HFEA’s position is that, since the sperm is not frozen, it has not been stored. This is based on the fact that sperm lose viability rapidly. While the service screens donors every 12 weeks, this does not apply to each donation. We therefore share concerns of Pink Parents that the service is not subject to statutory safety standards. **The risks to users and their offspring from an internet sperm donation**

102 [www.mannotincluded.com](http://www.mannotincluded.com)

103 Gametes are considered stored by the HFEA when they have been frozen since they otherwise deteriorate rapidly outside the body

104 We met its Director, John Gonzalez, during our visit to fertility clinics on 4 May.

105 Q 354

106 For these purposes, it assumed that single women and lesbians would want an anonymous donor.

service need to be established. There is a case for regulating such services to ensure their quality. It is not clear whether they would be covered by the EU Tissue Directive. If not, we conclude that revised legislation should ensure that such commercial services are subject to the highest technical and safety standards. We would also consider it anomalous if gamete donation that is undertaken in a clinical setting required identifying information to be held in a central database but did not if the donor and recipient were “introduced” over the internet. Our concern is to ensure that the safety and quality standards expected of all assisted reproduction technologies are equivalent.

### *Sperm sorting*

86. A technique for separating sperm on the basis of whether they carry the X or Y chromosome was first developed in the veterinary field by scientists at the United States Department of Agriculture. It works on the basis that the X chromosome is substantially larger than the Y chromosome. The technique was subsequently developed for human use in collaboration with the Genetics and IVF Institute in Fairfax Virginia as a patented technology called MicroSort.<sup>107</sup> Having isolated either X or Y chromosome-carrying sperm, these are then used to inseminate the woman using IUI. MicroSort claims that attempts to achieve a female pregnancy are 91% successful and that attempts to establish a male pregnancy are 76% successful. The EU Tissue Directive would apply to any institution offering this service in the UK. Sex selection can be sought for medical reasons, to avoid a sex-linked genetic condition; and for social reasons, for example “family balancing”. The issue of sex selection will be considered further later.

87. For the moment, the HFEA’s report on sex selection, while recognising that the risks do not appear to be higher than for other, licensed, assisted techniques, argues that the long term risks are unknown. As of January 2004, fewer than 500 babies had been born using this technique.<sup>108</sup> The report further points out that the technique, while better than previous sperm sorting techniques, is still far from being 100% successful and that there are issues that arise if the “wrong” sex is born.<sup>109</sup> While sperm sorting raises many of the same issues as sex selection using PGD, it differs in one important respect. Since no embryos are discarded by virtue of their sex, sperm sorting might be considered as less ethically problematic if concerns about its safety and efficacy have been successfully addressed. We consider the controversial issue of sex selection in more detail below in paragraphs 132–143.

### *Regulation of fresh gametes*

88. The inclusion of fresh gametes in legislation goes to the heart of the arguments about the purpose of regulation. If the HFE Act is about the special status of the embryo then there are no grounds for intervention in the use of fresh gametes. If regulation aims to provide a safe environment for the use of reproductive technologies, then the EU Tissue Directive, in specifying standards for the handling of human tissue and cells, may be all

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107 [www.microsort.net](http://www.microsort.net)

108 This is forming part of a US FDA trial which requires 750 births.

109 HFEA, *Sex Selection: Options for Regulation*, a report of the HFEA’s 2002-03 review of sex selection including a discussion of legislative and regulatory options, November 2003

that is required. However, if regulation has a legitimate role in reproductive decision-making and if existing professional medical codes of practice are insufficient in ensuring the welfare of children born using these outlying technologies, then it is reasonable to ensure that legislation and regulation are consistent, regardless of whether they involve the in-vitro manipulation of embryos. Currently, the HFE Act demands that data on embryo and gamete donations are kept by the HFEA (see paragraph 147). It would be anomalous for one form of gamete donation, where the gametes have been frozen, to require this data to be maintained when another does not, when both forms have involved a third party. **We conclude that while it is appropriate that commercial services involving fresh gametes should be subject to regulation, this should not extend beyond seeking to ensure that there are as few anomalies as possible between different options for donor insemination.**

### *Artificial gametes*

89. Current legislation is further challenged by new techniques in which gametes can be created by a process called haploidisation.<sup>110</sup> The technique could be used to help infertile men or women but it could also allow lesbian couples to have a child (daughter) without a donor. The process could involve stem cells, some of which have the capacity to form gametes, which raises issues regarding their regulation. This scenario was employed during our online consultation. In favour of the use of the technology we heard that “If we do not judge heterosexual couples before we allow them to have children (often without thought or even planning) because it is seen as their ‘right’ then how can we make a decision that affects almost 10% of our population simply based on the fact they have a different kind of fertility issue which is no fault of their own?” However, there was criticism that lesbian parenting could have adverse effects and that the technique further amounted to the commodification of life. For example: “If artificial reproductive technologies are available merely to satisfy the desires of adults (not all of which I acknowledge are frivolous) then we are on a very slippery slope”.

90. These issues are problems are compounded by safety concerns. Research is still at an early stage and any introduction to clinical practice must be rigorously overseen. **Subject to their safety, we recognise that artificial gametes have potential to treat infertility and reduce the need for gamete donors. It is important that, in the use of any cell cultures for reproductive purposes, the original donors must be traceable and their informed consent obtained.**

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<sup>110</sup> A haploid cell, such as a gamete, contains a single set of 23 chromosomes. Normal non-reproductive cells are diploid, i.e. have two sets of chromosomes.

## Welfare of the child

91. The welfare of the child provision is one of the more contentious elements of the HFE Act and prompted widespread concerns of principle and practicality. The provision allows the HFEA and clinicians to make decisions on the reproductive rights of people seeking infertility treatment. Section 13(5) of the HFE Act requires that:

“A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.”

It has been argued that this discriminates against certain people and undermines their liberty. There are also questions about how to enforce the provision and whether, in doing so, there is any effective protection of the welfare of the child to be born. The welfare of the child debate encapsulates arguments on the limits of reproductive freedom.

92. The issue of the welfare of the child issue has taken centre stage in many of the HFEA’s policy decisions. Most recently in its review of preimplantation tissue typing (saviour siblings), it concluded that the benefits of preimplantation tissue typing – to the sick sibling, the new baby and the family as a whole – needed to be balanced against a better understanding of the “possible physical and psychological risks to the child to be born”.<sup>111</sup> The Authority concluded that preimplantation tissue typing should be available, subject to appropriate safeguards, in cases in which there is a genuine need for potentially life-saving tissue and a likelihood of therapeutic benefit for an affected child.<sup>112</sup>

93. There has been a misconception in some quarters that the HFE Act demands that the welfare of the child should be paramount (rather than taken into consideration), in line with adoption law, which states that “The paramount consideration of the court or adoption agency must be the child’s welfare, throughout his life”.<sup>113</sup> Indeed, Melanie Johnson, the Parliamentary Under Secretary for Public Health, came very close to adopting this position in suggesting that the “welfare of the child has to be the overriding main concern of anybody working in this area” and that “the single most important factor is the welfare of the child”.<sup>114</sup> Further support has come from Dr Alexina McWhinnie and Professor Alastair Bissett-Johnson from Dundee University, who describe the current legislation as “too weak to offer any real consideration of the long term implications and consequences for those created by the programmes” and advocate the approach by the Victoria State Government in Australia. Its legislation states that “The welfare and interests of any person born or to be born as a result of a treatment procedure are paramount”.<sup>115</sup> The example of adoption law is often cited in support of the welfare of the child provision, but in our view this approach is not valid. With adoption the state has assumed responsibility for the future of an existing child. With assisted reproduction, the child is

<sup>111</sup> HFEA, Preimplantation Tissue Typing, September 2004, para 37

<sup>112</sup> See paragraph 37

<sup>113</sup> Adoption and Children Act 2002, Section 1(2)

<sup>114</sup> Qq 1309-1311

<sup>115</sup> Ev 412



only theoretical. At the time at which such assessments are made, there is not even an embryo. Moreover, a wealth of expertise is available to assess and evaluate the needs of an existing child, particularly in light of their own individual vulnerabilities. This evidence has no bearing on the non-existent embryo. In reality, this provision is more akin to a ‘fitness for parenting’ requirement, which was historically used to prevent certain ‘undesirable’ groups from reproducing and is now widely rejected.

### **Practical issues and the Code of Practice**

94. The HFEA’s Code of Practice contains detailed guidelines for clinics on how to take account of the welfare of the child. The principles which guide the Authority are:

- a) The respect which is due to human life at all stages of its development;
- b) The right of people seeking assisted reproductive treatment to proper consideration of their request;
- c) A concern for the welfare of the children, which cannot always be adequately protected by concern for the interests of the adults involved; and
- d) A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.

95. The HFEA has issued a consultation document, grandly entitled *Tomorrow’s Children*, on how the application of the welfare of the child could be improved in recognition of the fact that current guidance is 10 years old.<sup>116</sup> A number of problems have been identified. One is the inconsistency with which each clinic approaches the welfare of the child assessment. Sarah Elliston of the University of Glasgow told us that “this provision is notoriously open to wide variation in interpretation. The extent to which it allows arbitrary judgments to be made suggests that serious reconsideration of its retention, or at least a reconsideration of its scope and practical application, is required”.<sup>117</sup> The difficulty here is that, in overcoming this problem, the guidance would have to be extremely specific and possibly inflexible, unless the assessment is made on a very simplistic basis, such as checking whether the parents appear on police registers of violent offenders. Clinics have reported that it is difficult to get GPs to respond to the welfare of the child assessment form and many GPs are uncomfortable with having to perform this function. The Progress Educational Trust said that “Whilst maximising the psychological and social welfare of children is clearly, and rightly, a societal priority, this aspect of the welfare of putative children is in many ways an impossible assessment to make [...] Clinicians should act in their patients’ best interests. However they should not be asked to second-guess those of their patients’ putative children, whilst of course doing all they can do to ensure the physical health of future generations”.<sup>118</sup>

96. The HFEA reported other concerns that the time and cost of carrying out the welfare of the child assessment is disproportionate to any benefit gained. Professor Allan Templeton

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116 Chair’s foreword

117 Ev 368

118 Ev 295

of the Royal College of Obstetricians and Gynaecologists told us that “It has been a distortion of clinical practice; it has been absolutely beyond any effect at all in terms of trying to enhance the welfare of the child”. He argues that there is no need for specific welfare of the child issues within any act as “it is good medical practice”.<sup>119</sup> Witnesses from the British Fertility Society and the Association of Clinical Embryologists told us that they had compared notes in advance of the session. Of the four clinics they represented, they said that their “hit rate” for stopping treatment based on welfare of the child was between 0% and 0.3%.<sup>120</sup> This suggests that if the welfare of the child provision were abolished, we would, in theory, be exposing around 10 children a year to potential harm, even then there are different ways of dealing with potential harm. It is possible, however, that the provision has had a deterrent effect or that patients have withdrawn from treatment when it became clear that inquiries were being made about their background. The HFEA reports that while clinics sometimes make further enquiries to other agencies, they very rarely turn patients down for treatment. When they do, the most common reasons are medical (because the patient has an infectious disease or they are being treated for cancer), psychiatric (because the patient has a mental illness or a drug or alcohol problem) or, occasionally, social (because the couple lives apart).<sup>121</sup> The consultation document sets out a range of approaches to the implementation of the HFE Act’s provision:

- a) The maximum welfare principle, which considers a child’s welfare to be of paramount importance and places the burden of proof upon the prospective parents to demonstrate their competence;
- b) The minimum threshold principle, which places great importance upon the autonomy of the prospective parents and seeks to override their wishes only when their child would be at high risk of serious harm; and
- c) The reasonable welfare principle, which reflects a compromise position.

97. The application of the welfare of the child provision in the HFE Act has been highly unsatisfactory. We welcome the HFEA’s attempts to improve the application of the welfare of the child provision. Ultimately, however, if the welfare of the child provision is to be retained in any revised legislation should be based on the principle that the state has a role in determining who can have fertility based on their personal history and circumstances.

### **Discrimination**

98. The welfare of the child provision has been seen as seen as discriminatory for two reasons. First, as the Royal College of Obstetricians and Gynaecologists argues, it “discriminates between those wishing to use licensed treatment to conceive and those who can conceive naturally”. Mr Tony Gilland, a contributor to our online consultation describes this as “tantamount to licensing parenthood”.<sup>122</sup> Others, while conceding that there is discrimination, suggest that this is reasonable, citing, for example, analogies with

119 Q 1185

120 Q 89

121 HFEA, *Tomorrow’s children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment*, January 2005, p 9

122 Q 156

adoption procedures, in which the background of prospective adoptive parents is carefully scrutinised. The welfare of the child provision is also defended using the same justification for regulation in this field; namely that the intervention of a third party justifies the assessment of the parents. Alistair Campbell argues that “when the state and the professions are involved in parenting decisions (as they are in AHR [assisted human reproduction] and adoption), there is an obligation to avoid harm wherever possible. By preventing a pregnancy through regulation, no child is harmed (unless we believe in pre-existing souls!). Refusing to select parents could result in complicity in clear harm to children”.<sup>123</sup> On the other hand, potential parents are themselves harmed when they are denied the chance to conceive a child and/or are asked intrusive questions as to their suitability as parents. This is particularly the case when they these individuals are not being treated on the NHS. When any third party, such as a doctor, is involved, it is inevitable that patients surrender an element of reproductive autonomy. An important issue is whether the state has a stake and, if so, whether this justifies discrimination against some sectors of society.

### *Need for a father*

99. A possible further area of discrimination is provided by Section 13(5)’s demand that the welfare of the child should embrace the consideration of the need for a father, which was introduced as an amendment in the HFE Bill. This has provoked controversy in that it seems to impose an official view of an ideal family and was clearly intended to restrict the provision of IVF to lesbian and single women. The Royal College of Obstetricians and Gynaecologists (RCOG) argues that “The requirement for a father does not square with the current view of what constitutes a family, and discriminates against single women who may have the financial and emotional facilities to cope with a child on their own or with other support systems, who may need to use donor insemination to conceive safely”.<sup>124</sup> PROGAR (Project Group on Assisted Reproduction), a multidisciplinary body under the auspices of the British Association of Social Workers, recommends that “the child’s ‘need for a father’ in the Act, be replaced by ‘the need for a family’”.<sup>125</sup> In evidence the Minister maintained that the consideration of the “need for a father” was important and should be retained because “as a general rule it is better for the children to be born into a two parent family with both father and mother”.<sup>126</sup>

100. One could argue that requiring only the *consideration* of the need for a father is not discriminatory, since the HFE Act does not actually demand that there is an identifiable father. The solicitor James Lawford Davies told us, considered in isolation, that “on the face of it, the act is not discriminatory. It does not prevent the treatment of single women or same-sex couples”.<sup>127</sup> Pink Parents has undertaken a survey of clinics’ policy on lesbian and single women, which demonstrates that, while some will refuse to treat, many others will not.<sup>128</sup> Lisa Saffron told us that “In practice there are some clinics which accept lesbians and

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123 Ev 356

124 Ev 369

125 Ev 321

126 Q 1314

127 Q 869

128 Lisa Saffron, Can fertility service providers justify discrimination against lesbians?, *Human Fertility* (2002) 5, 42-46

others do not. They interpret the need for a father clause in completely different ways. It is basically a meaningless clause”.<sup>129</sup> The difficulties of the “need for a father” issue are, however, compounded by the HFE Act’s “meaning of a ‘father’” in Section 28. Mr Lawford Davies pointed out that “You can read into it [‘the need for a father’] a degree of discrimination because, elsewhere in the act [Section 28], children born to single women will essentially be legally fatherless, so it does in some way point to the desirability of being born in anything other than a heterosexual couple. I think the inclusion of the term ‘including the need of a child for a father’ then changes the basic premise. That does introduce an element of discrimination, although, again, clinics are quite free to take that into account and to reject it”.<sup>130</sup>

101. As we stated above, the Minister clearly wishes to retain the requirement to consider the need for a father. However, the HFEA has pointed out that, in doing so, her view is contrary to the wishes of Parliament, which passed the Civil Partnerships Act in 2004 and the Adoption of Children Act in 2002. The HFEA’s Chair was reported in January 2004 as saying that “It is absolutely clear if you think about the changes in society and the different ways that families can be constituted that it is anachronistic for the law to include the statement about a child’s need for a father[...]It seems to me a bit of nonsense to have that still in the legislation”.<sup>131</sup> The research of Professor Susan Golombok from City University supports this position. She told us that while there had been little research on the psychological outcomes for children born to single heterosexual mothers through donor insemination, there was “a considerable body of research” on lesbian mother families suggesting that there were no adverse outcomes for their children born using assisted reproduction.<sup>132</sup> **The requirement to consider whether a child born as a result of assisted reproduction needs a father is too open to interpretation and unjustifiably offensive to many. It is wrong for legislation to imply that unjustified discrimination against “unconventional families” is acceptable.**

### *Parental age*

102. In the course of our inquiry, it was reported that a 66-year-old Romanian woman had given birth to a daughter to become the oldest known new mother. There are no upper limits set out in the HFEA’s Code of Practice, merely the guidance that, in considering the welfare of the child, clinics should assess “The age, health and ability to provide for the needs of a child/children”.<sup>133</sup> It is widely recognised that as they approach the menopause women’s chances of achieving a live birth using IVF substantially reduce. Postmenopausal women must rely on donor eggs unless they have some of their own that have been previously frozen. While any welfare assessment would logically seek to determine the ability of the parents to look after the child in the long term, there seems to be hostility to older women having children that cannot simply be based on concerns for the welfare of the resulting child. It seems more likely that this stems from a deep-seated feeling that it is unnatural. Women of natural child-bearing age may have a significant risk of dying before

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129 Q 340

130 Q 869

131 BBC News Online, 21 January, 2004

132 HRT 58

133 para 3.12

their children reach adulthood, for example from a predisposition to breast cancer or diabetes. These are not absolute contraindications to assisted reproduction, nor should they be. Given that men's life expectancy is lower than women's, it might be logical to suggest that if there is an upper limit, the father's age would be of greater concern. Tracey Sainsbury, who formed part of a panel assembled by Infertility Network UK, identified concerns about the health of the mother – “If she has a life-threatening illness and you know she is not going to be around for much longer, then you do look at who is going to be left to care for the child?”<sup>134</sup> On the same panel, Sheena Young told us “there has to be a cut-off somewhere. Within society, we do know that there is a cut-off. In the UK, because of the legislation we have here, in general you will not find older women being treated. It is very rare that you see that happening here. It is not very rare to see that happening in other countries”.<sup>135</sup> If judgements are to be made about the health or age of parents, they should be applied equally to both parents (where there are two) and based on evidence of risk of significant harm. The reaction to the Romanian case seems to be based on ageism and sexism, neither of which is a good basis for legislation.

### *Human rights*

103. Article 12 of the Convention for the Protection of Human Rights states that “Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right”. What the Convention does not say is that men and women have the right to parental responsibility. This distinction is important since it means that, while the State should not prevent someone having a child – by assisted reproduction or other means – it can intervene following birth, through, for example, social services, if it has reasons to believe that child is at risk of harm. In many ways social services are at an advantage since a couple undergoing IVF has entered the healthcare environment and any concerns there that any child born to that couple might be at risk can be relayed at an early stage. To some, it seems foolish to help someone to have a child if it is likely to place a burden on social services. However, most would consider it an infringement of liberty for the State to prevent fertile individuals from having a child in similar circumstances. There is also a danger that social services are lulled into a false sense of security under the impression that couples who have undergone IVF have somehow been screened and there is less need for vigilance. **The State employs social services to protect children from harm. If it has reason to believe that children born as a result of assisted reproduction are at increased risk then healthcare professionals can alert social services at an early stage. Indeed, the law has declined to intervene to protect the welfare of a child not yet born, being satisfied that the foetus in utero cannot be made a ward of court, and that appropriate action could be taken if required following live birth.**<sup>136</sup>

104. The HFE Act could also be considered to conflict with Article 8 of the Convention for the Protection of Human Rights, which states that:

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134 Q 315

135 Q 314

136 Re F (in utero) [1988] 2 All ER 193

“Everyone has the right to respect for his private and family life, his home and his correspondence”.

“There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”

If third party intervention is necessary to enable a couple to have a child, then the nature of that intervention could be considered irrelevant in categorising it as private or public. So, there is no qualitative difference between seeking to assist in establishing a pregnancy by reversing a vasectomy or unblocking fallopian tubes (which require third party intervention but no evaluation of the welfare of future children—including no upper age limit for the intending parent(s)) and using assisted reproductive technologies. Further, unless having a child is seen as a threat to public health or public morals, it is not clear that any of the permitted derogations to Article 8 would apply.

### *Inconsistency*

105. If one accepts that the welfare of the child provision is important and that the involvement of healthcare professionals justifies an erosion of liberty, logic would dictate that any professional intervention to overcome infertility or subfertility should be subject to the same standards. IVF is just one of a number of techniques that include ovulation induction, tubal and uterine surgery, surgical management of endometriosis, IUI and GIFT. Only with the last two is a welfare of the child assessment required, and only if donor sperm is being used. **The exclusive requirement to consider the welfare of the child for fertility treatments where fertilisation takes place outside the woman or involves donated sperm is illogical. If the legislation aims to regulate the treatment of infertility or subfertility then it should cover all forms of interventions. If it wishes to do both then this needs to be clearly stated and justified.**

### *Explicit requirement*

106. Professor Brenda Almond, a former member of the HFEA told us that “there should be no question at all of removing the ‘welfare of the child’ provision [...] New procedures in reproductive medicine mean that the rights and welfare of children can be violated at a stage of vulnerability which it has not previously been necessary to recognise”.<sup>137</sup> However, it does not inevitably follow that because one values the welfare of children that this should be explicitly enshrined in legislation and thereby compromise liberty. For example, the requirement for quality management systems and technical accreditation should lead to higher standards, which one would expect to have a positive impact on the welfare of children born. Dr Alexina McWhinnie and Professor Alastair Bissett-Johnson from Dundee University cite the example of the increased risk of multiple pregnancies as a justification for the welfare of the child provision. As we discuss below in paragraph 268, this issue is of great concern to us, but the welfare of the child provision has noticeably

failed to solve the problem. Dr McWhinnie and Professor Bissett-Johnson use the possibility of multiple pregnancies to argue that the welfare of the child provision be strengthened. A better solution would be to ensure that doctors consider the impact of the treatments they provide on other areas of health services in general and, in neonatal care in particular.<sup>138</sup> Given that a major known threat to the welfare of the embryo/foetus and any subsequent child is associated with multiple pregnancies, it might be more desirable for legislation to specify that a regulator impose limits on the numbers of multiple births on licensed clinics. Dr McWhinnie and Professor Bissett-Johnson also use the example of the donation of third-party gametes, where they draw attention to the psychological problems experienced by donor conceived adolescents and as adults when “seeking a resolution of this 50% gap in their biological/genetic and self identity”.<sup>139</sup> These concerns can be met by banning the process entirely, as is the case in a number of countries, or by making specific provision in legislation, for example by enabling the children born to identify their genetic parents.

**107. The welfare of the child provision discriminates against the infertile and some sections of society, is impossible to implement and is of questionable practical value in protecting the interests of children born as a result of assisted reproduction. We recognise that there will be difficult cases but these should be resolved by recourse to local clinical ethics committees. The welfare of the child provision has enabled the HFEA and clinics to make judgements that are more properly made by patients in consultation with their doctor. It should be abolished in its current form. The minimum threshold principle should apply but should specify that this threshold should be the risk of unpreventable and significant harm. Doctors should minimise the risks to any child conceived from treatment within the constraints of available knowledge but this should be encouraged through the promotion of good medical practice not legislation.**

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138 Q 619

139 Ev 408

## Selection and screening

108. Part of the process of IVF involves identifying the most suitable embryos before implantation. This generally involves an assessment by a skilled eye to establish those most likely to implant and develop. The advent of preimplantation genetic diagnosis opened up many new issues, as the use of embryo biopsy provided the opportunity to select an embryo with the desired genetic or chromosomal composition (see Box 3). The HFEA's jurisdiction over the selection of embryos is provided in Schedule 2 1(d) which enables it to license "practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose".

### Box 3: Techniques for preimplantation genetic diagnosis.

#### Polar body biopsy

A mature oocyte is characterised by the presence of a first polar body that contains a complement of 23 bivalent maternal chromosomes. This structure can be removed and used for genetic testing or for aneuploidy screening of the oocyte before fertilization.

#### Cleavage stage biopsy

Individual cells of the cleaving embryo are distinct and discernible until around the 8–16-cell stage (day 3). One or two cells can be removed and the choice is controversial. Removing two cells reduces the cellular mass of the embryo and, therefore, might reduce its developmental capacity. The accuracy of the diagnosis, however, is likely to be enhanced if embryos are replaced only when the results from both are concordant.

#### Blastocyst biopsy

Biopsy of the embryo at the blastocyst stage (normally on day five or six after fertilization) has advantages in that the embryo can contain up to 300 cells so more cells can be removed without apparent detrimental effect. So far, blastocyst biopsy has not been extensively used in humans because of the difficulty in culturing embryos to the blastocyst stage.

*Source: Peter Braude et al, 2002, Nature Reviews Genetics, 3: 941–943*

## Ethical basis for PGD

109. The reasons for which PGD is licensed, if at all, are some of the most challenging facing the review of the HFE Act, despite the fact that PGD is not common. Professor Peter Braude of Guy's and St Thomas' Hospital told us that in the UK there had only been 500 cases involving PGD since the 1990 Act was passed yet there are around 25,000 IVF cycles each year.<sup>140</sup> Many of the debates focus on the ethical issues we discussed in Chapter 3 of this Report, namely the status of the embryo and the balance between reproductive freedom and the interests of the state and society.

110. Any form of embryo selection is wrong according to some people since it involves the destruction of those embryos that are considered unsuitable. This view was expressed by Alison Davis, a contributor to our online consultation who has spina bifida, hydrocephalus, osteoporosis and emphysema: "I think that both PGD and abortion kill a living human individual. The age at which they are killed is of no significance. If you killed a five year old child or a 30 year old person the fact that you had killed would be significant



and not the age of the individual killed. So I see the moral argument as the same in both”.<sup>141</sup> This position is reflected in the recent Italian legislation in which up to three embryos can be fertilised, but all must be transferred. Further opposition to any form of selection came from Mr John Ford, a contributor to our online consultation, who argued on philosophical grounds that “every single individual is unique and valued and has an intrinsic value as a person and I believe that this selection on genetic criteria reduces that degree of individuality”.<sup>142</sup> It is difficult to see these arguments being made from anything other than a perspective which specifies that full human rights begin at conception as opposed to the gradualist approach in which we have found much to commend.

111. The Nuffield Council on Bioethics’s (NCB) 2002 report on genetics and human behaviour describes the libertarian view of selection. It states that “The main argument in favour of the permissibility of selection is that this is a legitimate exercise of individual liberty. There is, quite generally, a strong presumption in favour of the exercise of individual liberty wherever its exercise does not conflict, directly or indirectly, with the legitimate interests of others”.<sup>143</sup>

112. The NCB also articulates the dignitarian perspective that the “intuitive objection to prenatal selection is that it is ‘interfering with nature’”.<sup>144</sup> This view has been expressed by several of our witnesses. Human Genetics Alert comments that our industrial market society brings with it a “tendency is to subject natural processes to the criteria of industrial production: efficiency, uniformity and quality control, and thereby to create objects/commodities that can be sold to consumers.”<sup>145</sup> It argues that “With the ability to select the characteristics of and even genetically engineer children according to consumers’ desires comes the concern that human beings are becoming just another designed object/commodity within the industrial market system”. The term “designer babies” is often employed to describe any child that has been born as a result of PGD, although in our view this term is highly misleading since they are no more designed than a child who has been born following a negative genetic test during pregnancy. Professor Alastair Campbell from the University of Bristol expresses similar sentiments: “we should view children as *gifts*, not as *products*. On this basis, I argue against conceptions (and pregnancies using PND (pre-natal diagnosis) or PGD (pre-implantation genetic diagnosis)), when these are based on *social* reasons (gender, height, intelligence, physical appearance, etc). These are all examples of treating the child, not as a person in her own right, but as a product, designed by parental wishes”.<sup>146</sup> However, natural conceptions are very much the product of selection—partner selection, often very powerful. Even strong ethical arguments that there should be constraints on reproductive choice do not necessarily mean that legislation should provide that check. As Tony Gilland, a contributor to our online consultation pointed out, there is an important difference between disapproving and disallowing.<sup>147</sup>

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141 Q 173

142 Q 145

143 Nuffield Council on Bioethics 2002, Genetics and human behaviour: the ethical context

144 See Para 13.71

145 Ev 287

146 Ev 357

147 Qq 155, 159

## Eugenics

113. It is sometimes argued that the intention behind selection—particularly to avoid the birth of children with disabilities—is essentially eugenic in its most negative sense. Our relatively recent history of the abuse of technical expertise reminds us of the need for caution. Tim Lewens from the University of Cambridge has described how “The ghost of eugenics haunts much contemporary discussion of the rights and wrongs of genetic screening”.<sup>148</sup> It is also, however, worth reminding ourselves of what eugenics is. Eugenics is defined by the Concise Oxford Dictionary as “the science of using controlled breeding to increase the occurrence of desirable heritable characteristics in a population”. Negatively, eugenics can also be defined as the deliberate policy of preventing the birth of those whose characteristics are thought to be undesirable, and it is with this practice at a state level that the term is most commonly associated. The Office of the Chief Rabbi uses the term to describe the selecting in of a characteristic, e.g gender, as opposed to screening out for genetic disease.<sup>149</sup>

114. Human Genetics Alert states that “Many disabled people view the medical surveillance of reproduction, and, in particular, prenatal screening, as a continuation of the eugenic practices of the early 20th century. It coins the term “consumer eugenics”. Its director, Dr David King, who contributed to the online consultation, told us that “I do not blame any parents for [avoiding having a child with a disability], it is perfectly understandable, but it does, I think, harm our society in terms of the elimination of diversity”.<sup>150</sup> Dr Calum McKellar was concerned that “we are starting to hear in bioethical conferences more and more about eugenics. [...] We do not even talk about, it is a sort of taboo topic, but it is resurfacing and it is something that has to be looked at”.<sup>151</sup> The problem, as John Gillott of the Genetic Interest Group has pointed out, stems from “whether or not these procedures [genetic screening] are thought to be ‘eugenic’ will depend on what that emotive term is taken to mean”.<sup>152</sup>

115. The real fear of routine prejudice or discrimination is linked with the enforcement of policies which overtly declare the lack of worth of certain individuals. The kinds of choice to which Dr King refers are qualitatively different. Professor Julian Savulescu from the University of Oxford argued that “What was wrong with the Nazi eugenic programme was that the State imposed a blueprint of perfection on couples seeking to have children by forcing sterilisation of the ‘unfit’ and removed their reproductive freedom”.<sup>153</sup> Professor Robert Edwards told the Committee that what could be termed eugenic practices were being undertaken in Cyprus, where the government has signed a deal with US scientists to screen all the embryos of people carrying the gene for  $\beta$ -thalassaemia and transfer unaffected embryos in an attempt to eradicate the disease.<sup>154</sup>

148 T Lewens, What is genetics?, *Journal of Medical Ethics*, 2004;30:326-328

149 Ev 373

150 Q 169

151 Q 157

152 John Gillott, Screening for disability: a eugenic pursuit?, *Journal of Medical Ethics*, 2001; 27:ii21-ii23

153 Julian Savulescu, Deaf lesbians, “designer disability” and the future of medicine, *BMJ* 2002;325:771-773

154 Q 1046

116. Equally, it could be suggested that the Genetics White Paper, *Our Inheritance, Our Future*, published in June 2003, which outlines the Government's strategy for future screening programmes and proposes specific antenatal and neonatal screening tests that are to be made available either immediately or in the near future, has a eugenic intent, even although it does not seek to impose screening.<sup>155</sup> It proposes that "all pregnant women are offered antenatal screening for Down's syndrome and are then counselled by midwives to help them make an informed choice" by the end of 2004–05. It also states that "An antenatal screening programme for sickle cell and thalassaemia will be in place aiming to offer screening to around 200,000 pregnant women a year, initially targeting areas of high prevalence for these diseases".<sup>156</sup> **If ensuring that your child is less likely to face a debilitating disease in the course of their life can be termed eugenics, we have no problem with its use. State programmes that impose a genetic blueprint are another matter. They should be outlawed as part of any regulation of assisted reproduction. Use of the word eugenics must not be used as an emotive term of abuse to obscure rational debate.**

### *PGD and abortion*

117. The HFEA states in its Code of Practice that indications for the use of PGD are expected to be consistent with current practice in the use of (post-implantation) prenatal diagnosis (PND).<sup>157</sup> There are concerns over whether this is an appropriate benchmark. Prenatal diagnosis embraces a range of tests, including ultrasonography, amniocentesis, chorionic villus sampling, foetal blood tests and maternal serum tests, none of which would be undertaken before 9 weeks. The application of the gradualist approach to the status of the embryo would suggest that a 5–day old embryo should be accorded fewer rights (or less respect) than a 9–week foetus, although this does not consider the rights or welfare of the pregnant woman; although where she consent to the proposed action in each case, her rights do not provide a confounding factor, in deciding the balance. Professor John Polkinghorne states: "I recognise that embryo research and abortion cannot simply be equated, for the latter involves the ethical interests of a highly relevant third party, the woman carrying the foetus. Yet the difference between these two time limits is very great. The discrepancy suggests to me that we have some more work to do in the search for a consistent understanding of moral truth and its application to medical ethics".<sup>158</sup>

118. The basis for the comparison is that both PGD and PND have at the least theoretical risks attached to them but to apply the same clinical indications to both is only justified if these risks are equivalent. The HFEA surveyed the scientific literature on the risks associated with embryo biopsy in relation to its policy review on preimplantation tissue typing. It cited two studies and reported that "These studies showed consistently that the sample of children studied did not show a significant increase in incidence of serious abnormalities at birth, or, where information was available, at 1 and 2 years of age.

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155 See paragraphs 3.28–3.39

156 See Paragraph 3.29

157 See Paragraph 14.21

158 JC Polkinghorne, The person, the soul, and genetic engineering, *Journal of Medical Ethics*, 2004;30:593–597

Nevertheless, there are as yet no long-term follow-up studies of PGD offspring available”.<sup>159</sup>

119. Jayson Whitaker told us “when we first suggested PGD to our consultant, we were told, ‘You can’t do that here but what you can do is get pregnant, you can have amniocentesis, you can have a test and then you can terminate.’ I am not anti-abortion, I am not pro-life, people can do what they want to do, but the human and emotional and ethical cost for my wife of being pregnant, carrying a child and then terminating was the unethical question. That was actually suggested to us as an alternative, a legal NHS approved alternative that could be done here. That, to me, was disgusting”.<sup>160</sup> The Royal Society of Edinburgh agrees that “restricting PGD to serious conditions might mean that the (arguably) ethically less troubling option of non-implantation would be subject to more rigorous controls than the (arguably) more troubling ethical option of pregnancy termination with prenatal diagnosis”.<sup>161</sup> **It is possible to sex a child using ultrasound and seek a termination and if PGD reduces the demand for abortion then this is a good thing. While we recognise that abortion legislation recognises the right of the woman, our gradualist approach to the status of the embryo leads us to conclude that there is a mismatch between the protection afforded an embryo created in vitro before it is implanted and one at a later stage of development in a woman’s uterus.**

### ***Reasons to undertake PGD***

120. There are essentially four reasons for undertaking preimplantation genetic diagnosis:

- a) To select an embryo which is more likely to implant and develop;
- b) To select an embryo unaffected by an inherited genetic disease;
- c) To select an embryo which is a tissue match for an existing person who would benefit from a transplant of (probably) umbilical cord stem cells; or
- d) To select an embryo with a desired characteristic for non-medical reasons.

121. The HFEA’s Code of Practice sets out the criteria for which PGD can be licensed. First, PGD will be available only where there is a significant risk of a serious genetic condition being present in the embryo (see Table 5). The HFEA says that in any particular situation the following factors are expected to be considered when deciding the appropriateness of PGD:

- i. The view of the people seeking treatment of the condition to be avoided;
- ii. Their previous reproductive experience;
- iii. The likely degree of suffering associated with the condition;
- iv. The availability of effective therapy, now and in the future;

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159 Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing, July 2004

160 Q 577

161 Ev 202

- v. The speed of degeneration in progressive disorders;
- vi. The extent of any intellectual impairment;
- vii. The extent of social support available; and
- viii. The family circumstances of the people seeking treatment.

**Table 5: Examples of conditions licensed for PGD in the UK.**

<b>Condition</b>	<b>Category</b>
Cancer predisposition (eg Familial Adenomatous polyposis coli (FAP), Li-Fraumeni syndrome, Neurofibromatosis type 2)	Specific diagnosis
Autosomal dominant disorders (eg Crouzon Syndrome, Huntington's disease, myotonic dystrophy)	Specific diagnosis
Autosomal recessive diseases (eg sensorineural deafness, Cystic Fibrosis, Spinal muscular atrophy, ectodermal dysplasia)	Specific diagnosis
Haemoglobinopathies (eg Beta thalassaemia, Sickle Cell Disease)	Specific diagnosis
Chromosomal reciprocal translocations, deletions and insertions, Robertsonian translocations, gonadal mosaicism	Specific diagnosis
Chromosome 13, 16, 18, 21, 22, X, Y	Aneuploidy screening using fluorescent in situ hybridization (FISH)
X-linked conditions( eg Adrenoleukodystrophy, Hunters, Haemophilias, Lesch Nyhan syndrome, Wiskott-Aldrich, Duchenne and Becker muscular dystrophy, lymphoproliferative syndrome, Fragile X mental retardation)	Sexing and specific diagnoses

### *Selecting the "best" embryo*

122. The selection of the most viable embryo for implantation is largely uncontroversial in that it is an extension of what has been undertaken with the naked eye, although there are concerns that some of the screening techniques are expensive and do not necessarily increase the chances of a live birth.<sup>162</sup> This process is termed preimplantation genetic screening since it does not give a diagnosis but identifies, for patients thought to be at a higher than average risk of conceiving abnormal embryos, whether their embryos have certain abnormalities present. It is unfortunate that the NICE guidelines did not cover selection issues apart from recommending that there should be further research to improve the use of single embryo transfer.<sup>163</sup>

162 NICE, Fertility assessment and treatment for people with fertility problems, February 2004, page 119

163 NICE, Fertility assessment and treatment for people with fertility problems, February 2004, page 93

### *Avoiding a genetic disease*

123. The option of selecting out single gene disorders such as cystic fibrosis, Duchenne's muscular dystrophy and Huntington's disease is generally welcomed by patient groups, but there are concerns expressed by some disability campaigners that this sends out signals that disability is unacceptable or that disabled people are inferior. This argument is reinforced by the contemporary adoption of the perspective that disability is a social and not a medical phenomenon. Using this argument, broadly speaking, what renders a person's life of limited quality is not the fact of their condition (physical or mental) but rather society's failure adequately to accommodate them. However, many within the disability rights lobby would in fact concede that intending parents may have a legitimate interest in avoiding the birth of a child with a condition that they believe will not be in its future interests. Indeed, the Government's policy, as espoused in *Our Inheritance, Our Future*, is to make screening for certain conditions more, rather than less, available; implicitly, therefore, to provide people with the capacity to terminate affected pregnancies.<sup>164</sup> It is at least arguable that selection at the pre-implantation stage is less morally weighty than is the termination of an affected pregnancy: the plausible outcome of pre-natal screening.

124. The application of selection becomes more problematic when the expression of the gene is not 100% and when there are available cures. The use of PGD for cancer predispositions and to eliminate carriers of genetic conditions is likely to remain controversial. We took evidence from Dr Maureen McHugh, a contributor to our online consultation who has Parkinson's disease. She stated that "If it were possible to deselect an embryo at the very early pre-implantation stage to exclude the possibility of Parkinson's disease, then I think it would be morally wrong to allow that embryo to develop further. [...] This is not discriminating against disabled people and it is not murder. It is simply trying to prevent disability, pain and misery".<sup>165</sup> **We have concerns about the criteria imposed by the HFEA. PGD is limited in that it can only be used to screen out disorders and thus it cannot be used to create "designer babies" . We see no reason why a regulator should seek to determine which disorders can be screened out using PGD. Nevertheless, clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements.**

### *Preimplantation tissue typing*

125. There are a number of genetic conditions that result in blood disorders. Techniques for treating these include transplants of haemopoietic stem cells (precursors of blood cells) from a tissue-matched donor. Sources of such stem cells are the bone marrow and the umbilical cord blood. In recent years it has become possible to screen embryos to establish whether the pregnancy could provide a source of stem cells, ideally from the cord blood but potentially from the bone marrow of the born child (the "saviour sibling"). The technique has proved controversial in the UK and elsewhere, often on the basis that children are being "designed" to meet the needs of an existing person. Although some groups object to preimplantation tissue-typing (PTT) in principle, for others the argument has hinged on whether or not the child born as a result of the test was at risk of developing

<sup>164</sup> Department of Health, *Our inheritance, our future – realising the potential of genetics in the NHS*, Cm 5791, June 2003

<sup>165</sup> Q 192 footnote 2

the condition. These situations have arisen in the UK in the notable cases of the Hashmi and Whitaker families (see Boxes 4 and 5).

**Box 4: The Hashmi case**

Mr and Mrs Hashmi have five children. The fourth, a son Zain, was born with a blood disorder known as beta thalassaemia major. By the time that he was 2½ years old he had to take a daily cocktail of drugs and to submit to regular blood transfusions in hospital. Mrs Hashmi had been aware that she had a genetic predisposition to producing children with this disorder and, when pregnant with Zain, had undergone prenatal testing to see whether he would be born with the disorder. The test failed to disclose that this was indeed the position.

Zain's condition might be cured by a transplant of stem cells from someone with matching tissue. The stem cells could be supplied from blood taken from the umbilical cord of a new born child, or from bone marrow. The most likely source of matching tissue would be a sibling. Statistically, Mrs Hashmi has one chance in four of producing a child with matching tissue, although the odds are somewhat longer of producing such a child who is not affected with beta thalassaemia major. None of Zain's three elder siblings have tissue that matches his.

Mrs Hashmi decided to have another child, in the hope that it would have matching tissue. She conceived, but prenatal testing showed that the child would have beta thalassaemia major, so she underwent an abortion. She conceived again, and a healthy son was born, but unfortunately his tissue did not match that of Zain. At this point Mrs Hashmi met Dr Simon Fishel from the Park Hospital in Nottingham to ask him whether it would be possible for her to be impregnated in this country with an embryo selected as a tissue match for Zain. Dr Fishel applied to the HFEA for a ruling as to whether an IVF clinic could properly apply for a licence to administer treatment including tissue typing. On 22 February 2002, the HFEA granted a licence to carry out the treatment. Mr and Mrs Hashmi made two attempts to produce a child by IVF treatment involving PGD and tissue typing. In the first, 15 embryos were produced. Only one proved to have an exact tissue match, but it carried the beta thalassaemia disease. In the second, 10 embryos were produced. Two of these proved disease free and to have a tissue match with Zain. One was implanted in Mrs Hashmi, but no pregnancy resulted.<sup>166</sup>

**Box 5: The Whitaker case**

Charlie Whitaker suffers from a rare form of anaemia called Diamond Blackfan syndrome. Diamond Blackfan syndrome is rare and it can be inherited, but Charlie's parents, Jason and Michelle Whitaker, have been tested and they are not carriers. A stem cell transfusion from a tissue matched individual, would, as in the case of Zain Hashmi, cure Charlie of the disease.

The Whitakers have a daughter whose tissue does not match Charlie's and so they approached Mohamed Taranissi of the Assisted Reproduction and Gynaecology Centre in London. He applied for a licence from the HFEA to have their embryos screened and tissue typed in a procedure which could have produced a baby that could have provided a cure for their son.

In August 2001 the HFEA were refused permission on the basis that, unlike Zain Hashmi, Charlie's disease was not inherited but arose from a spontaneous genetic mutation. This means that the chances of Mr and Mrs Whitaker having another baby with the same condition are negligible.

The couple travelled to the US to have the biopsy undertaken there. The process was successful and Jamie Whitaker was born in June 2003 in Sheffield. Blood tests confirmed that Jamie was a tissue match, so stem cells from his umbilical cord can be used to treat Charlie. This has now been undertaken and it is understood that the treatment has been successful.

126. There is clearly a distinction in many people's mind between PGD and PTT where the born child is not at risk of a genetic condition. Some concerns are based on principles of human dignity: using PTT the child is not born for its own sake, i.e. is solely a means to an end. Professor John Harris has criticised this argument, stating that "it's difficult [...] to find evidence or even persuasive anecdotes that if people are treated as means, they are necessarily treated as mere means, or exclusively as means or solely as means. [...] even if this were to be the case, even if we could make sense of this idea, the children would be so

<sup>166</sup> Extracted from the judgement of Lord Phillips of Worth Matravers, 16 May 2003

unloved and treated so unacceptably badly that it would cause psychological damage is a piece of reckless speculation for which there is no evidence”.<sup>167</sup>

127. Welfare arguments stem from suggestions that the use of the technique would have an impact on the relationships in the family. The Christian Medical Fellowship raises important issues for the families seeking PTT, yet these are matters for doctors to explain clearly in advance and not for regulation or legislation. Mr and Mrs Whitaker initially hoped that their second child, conceived naturally, would be a tissue match for Charlie.<sup>168</sup> There was nothing to prevent them from producing a child for this purpose, yet the resulting child is now having, in theory, to deal with having been a failed donor.

128. There are concerns about the safety of the biopsy process, which become more acute when the embryo has nothing to benefit from the process. The HFEA reviewed literature on the impacts on families of sibling bone marrow and cord blood donation and found that no relevant, transferable problems had been identified. It also found little to prompt concerns about the long-term effects of biopsy.<sup>169</sup> It has been argued that no embryo has an interest in being biopsied since it does nothing but reduce the chances of it being implanted. It has also been suggested by the Christian Medical Fellowship that PTT should not be permitted because of the degree of stress on the mother; low success rate; the need for many eggs; the expense; and the technically demanding nature of the laboratory work.<sup>170</sup>

129. The term “saviour sibling” has been coined, yet little attention has been given to the prospect of saviour sons or daughters, or even nephews and nieces. The HFEA ethics committee, while supporting the use of PTT for siblings, drew the line at the use of the technology to benefit other members of the family. To make this distinction implies that there is evidence to suggest the psychological impact on the child, and the nature of the family’s relationship, would be different if the recipient of the stem cells were not a sibling. The HFEA’s review of its policy acknowledged this issue but stated merely that it raised “distinct and significant issues” and should be the subject of further consideration.<sup>171</sup> **We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.**

### *Non-medical reasons*

130. There is nothing in the HFE Act that indicates that selection for non-medical reasons should not be permitted; however, HFEA’s guidance makes it clear that PGD should only be used for serious genetic conditions. We have commented above that developments in the technology will mean that there will be complex issues to resolve concerning genetic

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167 John Harris, *Sex Selection and Regulated Hatred*, *Journal of Medical Ethics Online*, December 2003

168 Q 594

169 HFEA, *Preimplantation Tissue Typing*, November 2004

170 Ev 220

171 See para 36



predispositions for diseases and genetic carriers.<sup>172</sup> An even more controversial area would be the use of PGD for social reasons. .

### *Sex selection*

131. Sex selection has become widely accepted as a legitimate route for the avoidance of sex-linked disorders, although as we have already noted this is not completely uncontroversial. Pressure, albeit from a limited number of individuals, to obtain access to sex selection using pre-implantation genetic diagnosis for non-medical reasons ultimately led the HFEA to issue a consultation document and report on this area.<sup>173</sup> The HFEA identified three means by which the sex of a child could be determined:

- a) PGD;
- b) Sperm sorting; and
- c) Selective termination of pregnancy.

132. Each raises distinct issues but in this discussion we will focus solely on the implications of sex selection and how this should be reflected in legislation and regulation. While PGD is covered by the HFE Act, sperm sorting is not and would require the scope of the Act to be widened to include fresh and not stored gametes only (see paragraph 89). Termination is regulated by the Abortion Act 1967.

133. There are three reasons why a family might wish to choose the sex of a child for non-medical reasons:

- a) To have a family that includes children of both sexes (known as ‘family balancing’);
- b) To rebuild a family after the death of a child with another of the same sex; and
- c) To fulfil a general preference for children of one sex over another. This could be related to economic, cultural or social reasons.<sup>174</sup>

134. There are a number of objections to sex selection:

- a) Demographic impacts;
- b) International implications;
- c) Psychosocial impacts;
- d) Ethical considerations; and
- e) Sex discrimination.

135. In giving evidence to the US President’s Council on Bioethics, Nicholas Eberstadt from the American Enterprise Institute said that there were a number of countries around

<sup>172</sup> See para 93

<sup>173</sup> HFEA, Sex Selection; Options for Regulation, November 2003

<sup>174</sup> Parliamentary Office of Science and Technology, Sex Selection, postnote Number 198, July 2003

the world where the ratio of boys to girls being born was 107:100, which, he argued, could not happen naturally.<sup>175</sup> China and India are popularly cited examples. However, it cannot be assumed that this would happen in the UK. First, it makes the assumption that people would all choose the same way; that is all, or at least a significant majority, would chose either boys or girls, leading to a socially destructive shortage of one sex or the other. Second, sufficient numbers of people would need to utilise sex selection for their choices to contribute to this “demographic disaster”. A team of researchers from the University of Giessen in Germany looked at sex preferences in Germany and in the UK (see Table 6). These showed that only a small proportion had a preference for all or mostly one sex, and that these were similar for both sexes.

**Table 6: Gender preferences in the UK and Germany.**

<b>UK (excluding the small percentage of undecided)</b>	<b>Germany (excluding the small percentage of undecided)</b>
16% said they did not care about the sex of their children, 68% said they wanted an equal number of boys and girls, 6% would like more boys than girls, 4% would like more girls than boys, 3% would prefer only boys, 2% would prefer only girls, 16% would prefer a first born boy, 10% would prefer a first born girl 73% had no preference for their first born	58% said they did not care about the sex of their children, 30% said they wanted an equal number of boys and girls, 4% would like more boys than girls, 3% would like more girls than boys, 1% would prefer only boys, 1% would prefer only girls, 14.2% would prefer a first born boy 10.2% would prefer a first born girl: 75.6% had no preference for their first born

Source: *Human Reproduction*. Vol 18. No 10 pp2231–2234, 2238–2239

136. Some communities within the UK do have a decided preference for boys over girls, and permitting such choices leads to increased opportunities for reinforcing sexist attitudes. Research at De Monfort University on attitudes to infertility among south Asian communities in the UK shows that a social need for male children is widespread and that the failure to produce a male child could almost be regarded as a form of infertility in some families. Culturally, the birth of male children is reported as a cause for celebration in a way that is not the case for female children.<sup>176</sup> While the data for the UK as a whole suggests that there would be few demographic implications resulting from any relaxation of limits on sex selection, there may be communities where this would be the case. Further research is required to establish these impacts.

137. Even if there are those who have a strong preference for children of one sex, this is not necessarily a reason for banning sex selection since it could be restricted to those families who wished to have a balance of both sexes, i.e. family balancing. Professor Martin Richards from Cambridge University reports that research suggests that “were sex selection to be made available in the UK very few would use it and its use is unlikely to have any significant effect on the overall sex ratio of children born”.<sup>177</sup> He told us that in the US sex selection based on sorting the sex determining Y or X sperm and artificial insemination has

175 Seventh Meeting, Thursday, October 17, 2002

176 Ev 352

177 Ev 364

been commercially available since 1995 for family balancing but has only been used by some 2,000 couples.<sup>178</sup>

138. The most high profile case in the UK has been that of the Masterton family (see Box 6), whose desire to have a girl falls into category b) in paragraph 134. In their letter to the HFEA in January 2000, they suggest that the birth of a daughter could alleviate Louise Masterton's depression and cite the opinion of a clinical psychologist to that effect.<sup>179</sup>

**Box 6: The Masterton case**

Alan and Louise Masterton from Monifieth near Dundee lost their youngest child, a three year old daughter Nicole, in 1999, in a domestic accident. The Mastertons, who have four sons, campaigned for the right to rebuild their family with a daughter.

Louise Masterton had been sterilised after the birth of Nicole and so sperm sorting followed by artificial insemination, which is available and unregulated in the UK, was not an option. The Mastertons wanted the Human Fertilisation and Embryology Authority (HFEA) to allow them to undergo IVF treatment and select a female embryo using pre-implantation genetic diagnosis (PGD). They argued that their family had a psychological need for a daughter. However, the HFEA will only consider an issue if a clinic applies to them for a licence. The Mastertons could not find a UK clinic that was prepared to take up the case on their behalf and so sought treatment in Italy instead. However, only one male embryo was produced, which was donated to an infertile couple.

139. The HFEA has drawn on theoretical psychosocial harms in formulating policy on sex selection, invoking the precautionary principle. It concerns us that the potential for harm is often quoted without recourse to a growing body of evidence of its absence. Ms Philippa Taylor, a contributor to our online consultation, told us that while she would not oppose sex selection for social reasons if evidence of lack of harm could be found, she remained confident that "you will not find there is no psychological impact on children from sex selection". She used in support of her view an anecdote of a man whose failing marriage could be traced back to the fact that his parents had wished him to be a girl.<sup>180</sup> Others might use this as evidence to support the use of technologies to determine sex. If sex selection had been available to the man's parents then the daughter would not have had to face the same intolerable feeling of rejection. Also, if this takes place in the normal course of events, what justification is there for citing psychological problems when technology has been involved?

140. It has been suggested that sex selection would sanction sex discrimination. This argument has been employed by Baroness Kennedy of the Shaws, at the launch of our online consultation. The available data suggest that most people in the UK want a "balanced" family which suggests that any sexist attitudes are not being expressed in the choice of gender. It could be argued, as Josephine Quintavalle did at the launch of our online consultation, that the UK should consider the impact on other countries resulting from a relaxation of guidelines on sex selection. It could be argued that by permitting people to choose the sex of their child in this country we are legitimising the choices among cultures where boys are preferred. A difficulty here is that the practice of selecting boys is widespread, as we reported in paragraph 136, yet often this takes place in countries where the law prohibits this and where the use PGD or sperm sorting is unlikely to be a

178 Ev 364

179 Ev 338

180 Qq 141-143

significant factor in gender imbalances. It is important, however, that the United Kingdom, does not take a purely insular view. What is allowed here will, of course, be cited as a precedent by other countries. It may also make it harder for the UK to criticise sex selection in other countries, however, abominably it is presently carried out, for instance by the murder of baby girls in some countries or by abortion. In terms of future-proofing, it is also important to consider that PGD may through scientific advance become much more widely available in the future in other countries, for instance for sex selection in China or India, the countries most cited as having demographic imbalance. **The UK should carefully consider the current evidence there available now about such imbalances and harms before allowing blanket changes our laws and regulations on sex selection.**

141. In paragraph 113, we discussed the objection to the selection of embryos on that this undermines the status of children as gifts rather than products. We find this an unsatisfactory argument when it is applied to the screening out of genetic disorders but believe that it has more merit when it is applied to desired characteristics such as sex and tissue type.

142. Doubts have been cast over the validity of the data gathered by the HFEA in support of its conclusions on sex selection. However, even if the HFEA exaggerates the public's hostility to sex selection for social reasons, we have little reason to doubt that a majority of the British public oppose it. Professor Tom Shakespeare from Newcastle University has provided confirmation of this from his own research.<sup>181</sup> Nevertheless, we do not see this as adequate grounds for prohibition. In paragraph 46, we stated that while reproductive freedom needed to be balanced against harms to individuals and society, these claims of harm needed to be based on evidence. In 2001, the Ethics Committee of the American Society of Reproductive Medicine concluded that:

“Until a more clearly persuasive ethical argument emerges, or there is stronger empirical evidence that most choices to select the gender of offspring would be harmful, policies to prohibit or condemn as unethical all uses of non-medically indicated preconception gender selection are not justified.”<sup>182</sup>

**The onus should be on those who oppose sex selection for social reasons using PGD to show harm from its use. However, the use and destruction of embryos does raise ethical issues and there are grounds for caution. The issue requires greater analysis than has been afforded it by the HFEA and we urge greater efforts to establish the demographic impacts across all sectors of society and the implications for the creation and destruction of embryos in vitro before new legislation is introduced. On balance we find no adequate justification for prohibiting the use of sex selection for family balancing.**

### *Other desired characteristics*

143. As sex has a simple genetic basis, sex selection is available now and is, as the HFEA has recognised, a pressing policy issue. The selection of physical and mental characteristics is further away, partly because of the lack of interest from the medical community and the

181 Ev 363

182 Preconception gender selection for nonmedical reasons, *Fertility and Sterility*, Vol 75, No 5, May 2001, 861, at p. 863

fact that the genetic basis of many desirable characteristics is less well understood and likely to involve multiple genes. As Professor John Robertson, Chair of the Ethics Committee of the American Society for Reproductive Medicine has stated, “popular accounts of PGD assume that it will eventually be used to select for such non-medical traits as intelligence, height, sexual orientation, beauty, hair and eye colour, memory, and other factors. Because the genetic basis of those traits is unknown, and in any case is likely to involve many different genes, [...] it is unrealistic to think that non-medical screening [...], with the possible exception of perfect pitch, will occur anytime soon”.<sup>183</sup> A limitation of PGD is that it can only work using the available raw material. Even in single gene disorders, it is not always possible to identify a suitable embryo for implantation. If more than one gene is involved the chances shrink still further. Consequently, the debate has been more philosophical than practical and generally our witnesses have stressed a significant difference between the use of selection for social rather than medical reasons. Jayson Whitaker, who has sought to use PTT to select a child who is a tissue match for an existing sibling (see Box 4), told us that “There is a big difference between a child who can run fast and one that has difficulty running”.<sup>184</sup> A contrary view is held by Professor Julian Savulescu, who told us that parents had a moral duty to do the best for their children. He argued that it was therefore illogical to prevent the use of a technology if the benefits outweighed the risk.<sup>185</sup> As we have stated, the argument is largely an academic one, but we have been keen in preparing this Report not to become mired in what is currently possible and what is not. We should use the current impracticality of screening for desirable social characteristics to engage in a rational debate on the subject. One danger is that the pursuit of the desired embryo might require the creation of a large number of embryos, which raises ethical issues concerning the destruction of embryos (unless they were donated) and health concerns if this required repeated cycles of hormone treatment to stimulate egg production. We are aware that the Human Genetics Commission is holding its own inquiry into reproductive decision-making and we look forward to reading their conclusions.

### *“Undesirable” characteristics*

144. While the selecting out of serious genetic conditions has been generally supported by our witnesses, the issue as to whether families should be allowed to choose what some might consider to be a negative trait has proved to be more complicated. For the most part these discussions have been theoretical rather than based on real cases. The most high profile example so far did not involve assisted reproduction. A deaf lesbian couple in the United States deliberately created a deaf child by using as a sperm donor a deaf friend with five generations of deafness in his family. The couple do not see deafness as a disability but as a defining part of their cultural identity and see signing as a sophisticated, unique form of communication.<sup>186</sup> We employed a similar scenario as part of our online consultation, in which a married, fertile achondroplastic dwarf couple wish to have a achondroplastic child on the basis that a child of normal height would cause practical problems in their home.

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183 J A Robertson, Extending preimplantation genetic diagnosis: medical and non-medical uses, *Journal of Medical Ethics* 2003;29:213-216

184 Q 599

185 Q 757

186 Julian Savulescu, Deaf lesbians, “designer disability” and the future of medicine, *BMJ* 2002;325:771-773

Many of the comments opposed this idea, although many did so based on their opposition to any form of selection. A view expressed was that just because we should not discriminate against the disabled, it did not necessarily follow that disability was a good thing.

145. Cases such as these have split those who otherwise are attracted by notions of reproductive freedom. Len Doyal, Professor of Medical Ethics at Queen Mary, University of London, argues that “procreative freedom should be maximised in relation to reproductive technologies” with one exception; “the use of reproductive technology to *produce* rather than to *prevent* children who are physically harmed” on the grounds that “when serious physical harm is foreseeable with certainty and it can be avoided, it should be”.<sup>187</sup> In slight contrast Julian Savulescu from Oxford University argues that there should be “strong presumption in favour of procreative autonomy” but that, while a decision to have a child with worse life opportunities than another child is wrong, any interference in the decision is only justified if there is a significant interest of that particular child in not being born at all or a public interest.<sup>188</sup> We can imagine that many clinicians would baulk at the idea of selecting, for example, a deaf child using PGD, but we do not feel that the creation of a child with reduced life opportunities is sufficient grounds for regulatory intervention, else we might logically deny poor people IVF. Professor Tom Shakespeare told us that PGD should not be allowed to select out “minor or trivial” conditions such as restricted growth or deafness.<sup>189</sup> On this basis, it is difficult to argue that they should not be selected rather than deselected. A more challenging but unlikely scenario would be the desire to select a child who would suffer obvious discomfort (rather than disadvantage), or worse. In this area there needs to be further debate.

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187 Ev 355

188 Ev 359

189 Ev 363

## Donation of gametes and embryos

146. Since the HFEA register was set up in 1991 over 25,000 children have been born as a result of donated sperm, eggs or embryos. Around 13,000 donor insemination cycles are carried out annually and the Department of Health estimates that 12,000 donor conceived people were born before the HFEA register was set up.<sup>190</sup> The use of donation as a form of fertility treatment raises many issues and our inquiry has been conducted against the backdrop of a Department of Health review of the provision of information to children born through donor insemination (the anonymity issue) and an HFEA review of the regulation of gamete and embryo donation.

### Anonymity

147. The 1990 Act demanded greater levels of confidentiality than is the case in other areas of medical practice. Section 31 of the Act provides for the setting up of a Register, containing information on “(a) the provision of treatment services for any identifiable individual, or (b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman, or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services”. Under the original regulations, when these children reach 18 they could ask the HFEA to confirm that they were born as a result of donated sperm, eggs or embryos. Those intending to marry, including those who plan to do so before their 18th birthday, may also ask whether the HFEA Register shows that they are related to the person they intend to marry.

148. The Department of Health issued a consultation on the provision of information to people born as a result of sperm, egg or embryo donation in December 2001. On 21 January 2004, the Public Health Minister announced that the Government would be introducing legislation that will lift anonymity from future sperm, egg and embryo donors and allow donor conceived children to access the identity of their donor when they reach the age of 18. This was achieved through the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, which were passed on 18 May 2004. The new rules will allow children conceived from future sperm, egg and embryo donations to access more information about their genetic origins.

149. There are many arguments for and against the lifting of donor anonymity presented to us in evidence. These are summarised in Table 7.

Table 7: Arguments for and against the lifting of gamete and embryo donor anonymity.

For	Against
<p>Information about the circumstances of one's conception can play an important role in the formation of an individual's personal identity.</p> <p>Information about a donor's medical and family history would have potential value in informing the donor offspring's lifestyle choices.</p> <p>It is unethical for the State to hold information on someone that is unavailable to that person.</p> <p>Older, more mature, donors with a strong sense of altruism can be recruited.</p> <p>Consistent with ruling on Rose case, which demonstrated that the Human Rights Act was engaged (see Table 3), although it did not go on to rule on the merits of the case which would involve a balance of rights.</p>	<p>It would create a major disincentive for people to donate.</p> <p>There can be no absolute right to know one's parents; otherwise we parents would be required by law to inform children who their genetic parents are.</p> <p>Prospective parents may travel overseas to get anonymous donation.</p> <p>Prospective parents wishing to retain anonymity, may switch to unregulated forms of gamete donation, such as man not included or sex with strangers.</p> <p>Parents may be less likely to tell their children that they were born through donor insemination for fear of "losing" them to their genetic parent, thereby negating the possibility of benefit from any of the first two listed advantages.</p>

150. The new regulations will not be retrospective. People donating sperm, eggs or embryos before April 2005 will not be identifiable. When the new regulations do come into force, they will not impact on a donor's responsibilities to any child born as a result of their donation. As now, they will have no financial or legal obligations towards the child. However, PROGAR is concerned that the HFE Act "omitted to provide 'amnesty' for people who donated gametes prior to the Act's implementation. This has left these donors uncertain as to whether they might have any legal responsibility towards their donor offspring, and fearful as to whether any offspring might have a financial claim on them. We have no evidence from donor-conceived people that they would make any such claim but there is research in progress which has revealed that the possibility of it is very troubling for some past donors. PROGAR believes that that is unjust and that it may be hindering past donors from registering with UK Donorlink".<sup>191</sup> Walter Merricks from the Donor Conception Network also expressed concerns to us about pre-1991 donations, in that there is no legislation or guidance concerning the records of such donations. He told us that "There is nothing to prevent the destruction of those records at the moment. I know of one doctor who was responsible for a number of treatments [...] and there are some records in his house, and who knows whether or not he is going to destroy those or his wife may do so".<sup>192</sup> **We recommend that the Government clarify the position relating to any financial obligations of donors before 1990. It would be regrettable if such donors did not come forward under the mistaken impression that they would become financially liable for the upbringing of children born as a result of an altruistic donation.**

191 Ev 321

192 Q 241



151. It has been argued that the changes in the law regarding the anonymity of donors will have limited impact because of the limited number of parents who tell their children the nature of their conception. The Donation Conception Network argues that the “welfare of donor conceived children demands that only those who are clearly committed to telling their children should be offered donor treatment” and uses the example of adoption, where proposed adopters are required to undertake to tell their children the facts about their adoption and are not accepted as adoptive parents unless this had been agreed to.<sup>193</sup> The Government has decided against forcing parents to tell their children the fact of their donor insemination and does not propose to volunteer the information. Either of these approaches would seem more sensible than proposing to treat only those who promise to tell. It recognises that this provision could not be enforced and indeed we can see no way in which clinics could make any meaningful attempt at determining the intentions of parents. We have discussed above (see paragraph 94) that the analogies with adoption are limited. While we recognise the value of openness, interfering with the relationship between the child and its parents seems an unwarranted intrusion. The Donor Conception Network further argues that the right to know, embodied in the new regulations, should be conferred on both child and donor. It suggests that donors should be entitled to know whether children have been born as a result of their donation and if any offspring have expressed a request for their donor’s identity, rather than being contacted direct without warning.<sup>194</sup> **We have sympathy with the view that if children born following donor insemination have a right to know their genetic parents, donors have some the rights to non-identifying information about any children born as a result of their donation. We recommend that the Government address this anomaly in its review of the HFE Act.**

### *Supply of donors*

152. The major contentious issue involving the ending of anonymity is its effect on the supply of donors. Dr Simon Thornton of the Park Hospital in Nottingham told us that since the Department of Health published its consultation on donor anonymity in December 2001, there had been “a large drop in the number of donors coming forward” and that a number of sperm banks had closed down.<sup>195</sup> Mrs Liz Corrigan from the Bristol Centre for Reproductive Medicine told us that her clinic’s donor programme was among those that had closed down since all its current and recent donors refused to donate if anonymity were lifted.<sup>196</sup>

153. The Parliamentary Under Secretary for Public Health told the First Standing Committee on Delegated Legislation during the debate on the Draft Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 on 18 May 2004 that “In certain other countries, donor-conceived people have access to identifying information about their donor. I understand that patient organisations in Sweden, the Netherlands and the state of Victoria in Australia value the changes that have been made. I also understand that there are indications in Sweden that, although donor

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193 Ev 334

194 Ev 334

195 Q 119

196 Q 120

numbers dropped initially, they rose again”.<sup>197</sup> The Minister has announced a publicity campaign to encourage new donors and will be appointing a PR agency. Currently around 250 men donate sperm each year (as anonymous donors) and 1,100 women donate eggs (again anonymously).

154. During our visit to Stockholm we were told that, in the 1980s, 250 children were born by donor insemination each year. We heard that, after the law ending anonymity was passed in 1985, the number of inseminations declined but that the practice did not end. Currently, around 60 children are born each year by donor insemination and it was estimated that another 200 are conceived abroad. We understand that the waiting list for donors is several years’ long.<sup>198</sup> The Department of Health said that the Minister’s statement about the Swedish case was based largely on a report commissioned from Professor Eric Blyth at the University of Huddersfield. He reported that the change in legislation in Sweden resulted in a decline in donor recruitment, but that it was not possible to ascertain the scale of the reduction. He provided anecdotal data that recruitment had recovered following the change in legislation.<sup>199</sup> It is difficult to reconcile the Department’s statements with the comments we heard first hand in Stockholm. A possible solution is that the Department’s evidence related to the number of donors rather than the number of children born through donation. A flaw in their approach is that it relied on input from existing clinics that offer donor insemination. We have heard that in the UK some clinics have ceased operating the service. In Sweden the same effect was observed, with five of the 10 clinics closing.<sup>200</sup> Those that continued the service may have managed to maintain their own supplies despite an overall drop in the number of donors. This may seem a minor point but this has been used to provide a misleading picture of donation post-anonymity. **We regret the Department’s poor use of evidence in policy-making and its failure to commission and have published the necessary research underpinning its decision on the removal of donor anonymity.**

155. Victoria’s Infertility Treatment Act 1995, came into force on 1 January 1998, requiring all donors to be identifiable to any offspring when they turn 18. The Infertility Treatment Act superseded the Infertility (Medical Procedures) Act 1984, which had been in force since June 1988. The 1984 Act had established a donor registry and, while it enabled a donor to remain anonymous, it provided donor offspring with the right to access non-identifying information and, with the donor’s consent, access to his identity. It has been reported that since 1998, sperm stocks have become depleted and the BBC website reported on 14 January 2005 that Monash IVF clinic in Melbourne has written to all male politicians under the age of 45, appealing for them to set an example by donating sperm. According to the clinic’s medical director, Prof Gab Kovacs, before the law changed, Monash IVF clinic had around 20 new donors a year, while only five men signed up last year. The BBC website has reported that, in December 2004, an Australian fertility clinic in Albury, south-west of Sydney, offered students in Canada a free two-week holiday in Australia in return for sperm.

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197 Stg Co Deb, First Standing Committee on Delegated Legislation, Draft Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, 18 May 2004, Col 11

198 Data from the National Board for Health and Welfare

199 Ev 429

200 Data from the National Board for Health and Welfare

156. One solution to the problem of supply following the removal of anonymity is to introduce a twin-track approach, which would discourage anonymity but not prevent it. This raises a number of issues. The HFEA commented that “this would seem to give a determining role to the decisions of the parents, who would be able to choose whether to use donated gametes where there was no identifying information”.<sup>201</sup> Also, Professor Golombok told us that “those children whose parents have opted for a non-identifiable donor who then found out would be at a disadvantage and might be even more concerned about it because they would know that their parents had the choice and then opted for the non-identifiable donor”.<sup>202</sup> This is, however, speculation based on surmise founded on anecdote, as it is not clear that there would be any such children, suffering any such harm and if there were that would not outweighed by increased secrecy with the ending of donor anonymity. Discovery of non-paternity is far more common a problem and it is not clear that anyone is arguing a child’s right to know.

157. Much of the argument in favour of ending donor anonymity has depended on anecdotal (perforce) testimonies from the off-spring of gamete donation who describe the painful experience of either not being able to trace their biological parents, or not being told that they were donor-conceived or both. In many of these cases it is the keeping of the secret that has caused the pain or undermined family relationships rather than the fact of donor-conception per se or the consequent inability to trace the donor. The major drawback of ending donor anonymity on the basis of these experiences is that there is a powerful argument that the ending of such anonymity would result in a greater likelihood of parents not telling the child because the fear (rational or not) of rejection in favour of an identifiable biological parent outweighs the advantage of having identifying information to transmit. Even were such children given a right to know at age 18 that they are donor conceived and therefore can obtain identifiable information should they wish – which the Government has noticeably not provided for – this may simply result in the increased use of unregulated services where anonymity is provided. The experience of Sweden and use of Danish clinics provides strong evidence for this. As a result of these unintended consequences there may be more secrecy and possibly more harm caused. **Given the threat to donor supply, it would have been better to have attempted to conduct research on parental attitudes to secrecy in the context of anonymity versus identifiable donors before changing the system entirely to one where anonymity is ended.**

158. **While the arguments for and against changing the status of donors are complex, opinions seem to centre on the relative weight given to the pain of infertility and the welfare of the offspring. Despite this, most would agree that, in principle, openness is a good thing. The task is to promote as much openness as possible without sacrificing the availability of donated gametes. In our view the benefits from the removal of anonymity are not such that the change justifies the likely impact on the number of donors. We therefore favour a twin track approach. While patients and donors should be aware of the benefits of openness and the regulator should provide for those who wish to adopt this strategy.**

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201 HFEA, Response to the Department of Health’s Consultation on ‘Donor Information: Providing Information About Sperm, Egg and Embryo Donors’, July 2002, para 17

202 Q 998

159. The new Regulations will enable children born from donation to trace their biological parent(s) when they reach 18 years. There is evidence that if the children were told of their status when they are young, between 3 and 5 years, their reaction was generally one either of curiosity or disinterest.<sup>203</sup> We were told by Marilyn Crawshaw from PROGAR that one of their concerns was unplanned or accidental disclosure of information at a later age anyway.<sup>204</sup> If openness is a good thing, it seems also that early openness is even better, yet the law currently make children wait a decade or more before they can find out who the donor in their case is. When he was 12, David Gollancz discovered the fact that he was born following donor insemination. He told us that he would have liked to have known the donor's identity then: "It would have meant that the figure in my imagination which occupied that space was a real person with a name and a history. Even if I could not meet them, they would be a real person as opposed to a ghostly insubstantial figure".<sup>205</sup> We understand that Swedish law that children born as a result of donor conception are entitled to identifying information about the donor when they are "sufficiently mature".<sup>206</sup> **We have been told that, the earlier the child is told that they were born from donor gametes the better, yet parents wishing to tell their child that he or she was born using donor gametes may wish to avoid telling them if they then are unable to know anything about the donor. We recommend that certain non-identifying information is available to the child so that they can request it upon being told by their legal parents that they were conceived using donor insemination.**

160. Having entered statute in June 2004, the Government is unlikely to want to reopen the issue again, although we welcome the Minister's apparently open mind.<sup>207</sup> The original HFE Bill was given a free vote, as were the research purposes regulations in 2001. However, there was no free vote on the donor anonymity regulations in standing committee. **In recognition of concerns about the supply of donors, the Department of Health has launched a PR campaign to recruit new donors. By the time revised legislation is placed before Parliament, data should be available that give an indication as to whether the removal of anonymity will have a long-lasting effect on the supply of donors. With this information, Parliament can decide to what extent the removal of anonymity is a price worth paying.**

### ***Regulation of embryo and gamete donation***

161. In November 2004 the HFEA issued a more general consultation document on the Regulation of Donor-Assisted Conception, which sought views on screening and selection of donors, the number of children per donor, compensation and remuneration, supply and distribution of gametes and embryos, storage and recruitment.

162. The issue of the remuneration of donors has been subject to a long-running discussion. Section 12(e) of the HFE Act states that "no money or other benefit shall be

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203 E Lycett et al, School-aged children of donor insemination: a study of parents' disclosure patterns, *Human Reproduction*, published online January 2005

204 Q 960

205 Qq 239-240

206 C Gottlieb et al, Disclosure of donor insemination to the child: the impact of Swedish legislation on couples' attitudes, *Human Reproduction*, 2000,15; 9, 2052-2056

207 Q 1344

given or received in respect of any supply of gametes or embryos unless authorised by directions”, i.e. the HFEA has discretion. The HFEA issued a consultation document in February 1998 on the Implementation of Withdrawal of Payment to Donors, following a “decision in principle to phase out payment to gamete donors”.<sup>208</sup> At present, the HFEA’s Code of Practice states that “Gamete donors must be paid no more than £15 for each donation plus reasonable expenses”.<sup>209</sup> **We look forward to the results of the HFEA’s consultation on the remuneration of embryo and gamete donors. We are concerned that the HFEA should be placed in a position in which it is forced to make decisions that could provide an incentive or disincentive to donors. This is a political decision best left to Parliament .**

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208 Letter to Ruth Deech, Chair of the HFEA from John Horam MP, 25 March 1997

209 para 4.26

## Counselling

163. The HFE Act states that “A woman shall not be provided with any treatment services [...] unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper”.<sup>210</sup> The HFEA’s Code of Practice says that treatment centres are expected to ensure that at least one member of staff is appointed to fulfil the roles of counsellor and must:

- a) Hold either a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above; or
- b) Hold an Infertility Counselling Award; or
- c) Hold a professional social work qualification recognised by one of the UK social care councils; or
- d) Be able to provide evidence of working towards accreditation through the British Infertility Counselling Association/British Fertility Society Infertility Counselling Award; or
- e) Be able to provide evidence of membership of a recognised professional counselling body with a complaints/disciplinary procedure and has agreed to abide by an appropriate code of conduct or ethics.

164. In addition the HFEA demands that treatment centres provide a private and comfortable room for counselling and maintain good relationships with independent counselling organisations so that patients can obtain counselling, in addition, or as an alternative, to the centre’s resources. Despite these quite detailed requirements, it is evident that the availability of counselling is a thorny issue in clinics. In its written evidence the British Infertility Counselling Association (BICA) stated that it wished to see mandatory implications counselling for all regulated procedures: “BICA considers that implications counselling for all donor-assisted conception should be mandatory and that consideration should also be given to mandatory implications counselling for all prospective recipients of ART procedures”. It suggests that this is in line with international trends (e.g. in Australia and Canada).<sup>211</sup>

165. The demand for mandatory counselling is radical and raises several issues. First, whether the potential psychosocial implications of assisted reproduction are so serious that patients should be counselled whether they like it or not; second, why we should single out regulated treatments when non-regulated treatments may present similar problems; and third, do we have any evidence that counselling brings about the desired effects.

166. On the first point, there are obvious concerns. Forcing people to be counselled could easily be considered an infringement of liberties and might be counterproductive if the parents felt that it had been forced on them. However, we must recognise that, while

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<sup>210</sup> See paragraph 4.26

<sup>211</sup> Ev 292

standard IVF has come a long way since 1978, there is still only a 50% chance of taking home a baby. It is not difficult to imagine the distress of couples who have failed in their attempt, possibly expensive and drawn out, to have a child. Professor Susan Golombok told us that “It is important to differentiate between those who are successful in treatment and those who are not. For those who are not, the evidence seems to be that [...] it is very difficult and distressing but, over time, this diminishes, albeit there is a small minority left with long-lasting problems. I do not think it is right to assume that everybody who has unsuccessful treatment will then be plagued by all kinds of psychological problems for years to come”.<sup>212</sup> Dr Jim Monach of BICA told us that studies had shown that “infertility and childlessness generate the second highest levels of anxiety and depression of all medical conditions”.<sup>213</sup> Dr Monach told us that, while evidence for the efficacy and effectiveness of counselling in a range of other circumstances is strong, it seems that there have been few attempts to determine its effectiveness in assisted reproduction.<sup>214</sup> Professor Golombok told us that “I do not think [...] that there is a great deal of evidence that it is beneficial, but that does not mean that, were good studies to be carried out, that benefits would not be found”.<sup>215</sup> In its supplementary evidence, BICA provided supporting references for the effectiveness of infertility counselling. The Department of Health has stated that “[there is] evidence of counselling effectiveness in mixed anxiety or depression; most effective when used with specific client groups [...] psychological therapies have benefit in a range of somatic complaints including gynaecological problems”.<sup>216</sup>

167. There are examples elsewhere in the world where counselling is mandatory.<sup>217</sup> In Canada, the 2004 legislation requires licensees “to the extent required by the regulations, make counselling services available to the person and ensure that the person receives them”.<sup>218</sup> However, we are unwilling to make recommendations to that effect. Indeed, the wording of the current legislation seems perfectly adequate. We were surprised that, when we challenged BICA on the wording, Sheila Pike told us “Perhaps the term ‘mandatory counselling’ is not the best way to describe it. I do not believe that you can impose counselling on anybody but I do believe that you can offer a realistic opportunity to people”.<sup>219</sup> Her concern was on the interpretation of “suitable opportunity” in the Act and that counselling should become a “routine procedure, just as routine as an initial clinical consultation”.<sup>220</sup>

168. We were pleased that, in its supplementary evidence, BICA moderated its demands, suggesting that “perhaps [it would be] more helpful to see this as a matter of clinics strongly encouraging certain groups of patients to seek counselling”, although it maintains that counselling might be a requirement in the case of those embarking on donor gamete

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212 Q 973

213 Q 916

214 Q 944

215 Q 973

216 Department of Health Treatment choice in psychological therapies and counselling: evidence based clinical practice guideline, 2001; Ev 393

217 Q 917

218 Clause 14(2)(b) and (c)

219 Q 942

220 Q 943

treatment, surrogacy or egg sharing.<sup>221</sup> In our view the interpretation of the Act in the Code of Practice is acceptable as there are limits to how regulation can force the routine use of counselling on health care professionals. It has been apparent during this inquiry that the value of counselling is not fully appreciated by clinicians, and indeed some seem to regard it with thinly disguised contempt. This is, in our view, at the heart of the problem, not the legislation or regulation: this needs to be resolved at a professional level. The Draft Standards for Assisted Conception Units, compiled by ACE and BFS on the instigation of the HFEA, do contain standards relating to the role of counselling within a treatment centre: “The management shall, with the aid of organisational charts [...] define the organisation and management of the clinical, laboratory and counselling services and their place in a parent organisation”. If implemented, this should provide a framework for all professionals working in, and in association with, treatment centres to develop a constructive working relationship. While assisted reproduction is a relatively new area of clinical practice, the emphasis on the drive to improve treatment services has, not surprisingly, been on improving clinical practice and, along with an established research culture, a substantial body of data has built up providing evidence, or otherwise, for the efficacy of different procedures. This has not been the case with counselling. **While we believe that clinicians should adopt a more sympathetic attitude to infertility counselling, counsellors must work harder to develop an evidence base to support their practice. Only in this way can they hope or deserve to receive the respect of their clinical colleagues. We see no role for legislation or regulation in facilitating this process.**



## Research

169. The Human Fertilisation and Embryology Act 1990 requires the HFEA to regulate the creation, storage and use of embryos for research throughout the UK. The purposes for which research is licensable are outlined in Schedule 2, Section 3 of the HFE Act. Initially, research was permitted for five purposes:

- a) promoting advances in the treatment of infertility;
- b) increasing knowledge about the causes of congenital disease;
- c) increasing knowledge about the causes of miscarriages;
- d) developing more effective techniques of contraception; or
- e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

170. The HFE Act was amended in 2001 through the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, which added the following three purposes:

- a) increasing knowledge about the development of embryos;
- b) increasing knowledge about serious disease; or
- c) enabling any such knowledge to be applied in developing treatments for serious disease.

171. These regulations allow the use of embryos for therapeutic research, including that using embryonic stem cells. The HFEA has received over 150 applications for human embryo research licences since it was established in 1991.

## Fertility research

172. There are a number of concerns about Schedule 2(3) of the Act. The demand for clinical trials licences reflects a concern that the HFEA has had no way of allowing the introduction of new techniques in a controlled manner. The Peckham Report comments that “Before a new treatment covered by the Act can be used it must have an HFEA licence, which is not approved until expert review has satisfied the HFEA that the treatment is safe. However, as things stand, there is no legal requirement for clinical testing and/or trials to rigorously assess new treatments before they are introduced”.<sup>222</sup> When ICSI became available, having been initially successful following a laboratory mistake, the HFEA could only prohibit or allow the technique to be undertaken.<sup>223</sup> Its only tool was to demand stricter licensing requirements. A problem has been that the HFEA has been unable to license a clinical trial; it can issue a licence for a treatment or research purposes only. It cannot issue a treatment licence unless it is satisfied either that it is for “practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine

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222 Box 1, p.3

223 ICSI = intracytoplasmic sperm injection. A single sperm is injected directly into an egg to aid the creation of an embryo.

whether embryos are suitable for that purpose” and the activity is “necessary or desirable for the purpose of providing treatment services”.<sup>224</sup> The HFEA suggests that Schedule 2 (3) of the HFE Act needs consideration. It says that the ability to issue clinical trials licences might give greater control over the introduction of new techniques and technologies into clinical practice. This is disputed by Professor Alison Murdoch. She argues that “If I wanted to introduce a new drug into my clinical practice, there are various processes that I go through. If it is a drug that has been tried and tested, I would go to my Trust, I would go to the Drugs and Therapeutics Committee; I would give them the evidence to show that it was better than the existing [drug] and was cost effective and would be introduced into clinical practice. If it were a new drug, I would go through phase one, phase two and phase three so as to do it; it would go to Ethics Committee and patients would be informed and it would be appropriately funded. In terms of introducing clinical trials, I do not see any need to introduce any different model”.<sup>225</sup> **The HFEA is able to attach conditions to any licence that it awards and it could already use its existing licensing system to ensure that certain techniques were only used as part of a clinical trial. We recognise that powers to award a clinical trials licence might have advantages for the HFEA but we would be nervous about the creation of any further bureaucratic hurdle introduced to the setting up of clinical trials.**

173. A further problem with the HFE Act, identified by the HFEA itself, relates to training in techniques for assisted reproduction and embryo biopsy. Individuals can currently only receive training under a research licence, whereas the introduction of training licences would allow the proper regulation of training. This move would have obvious benefits. Currently, new staff can only be trained if they are working in centres where research is being undertaken. This limits the ability of smaller centres to develop the necessary expertise. Problems may arise in seeking consent to use embryos in this way, which would be compounded by the poor supply of “spare” embryos. **It is not appropriate that embryos donated for research should be used to train staff and it could be argued that the HFEA is acting illegally by awarding research licences in the knowledge that the primary purpose is training. Furthermore, training in the handling of embryos should not be limited to those centres that are undertaking research. Training staff to handle embryos for the purposes of providing treatment should be possible under treatment licences as long as it is made clear to donors of embryos what they will be used for.**

### **Therapeutic research**

174. The 2001 Research Purposes Regulations were intended to clear the way for human embryonic stem cell research, including research using cells from derived embryos. To a great extent this has been the case now that the status of the embryo has been resolved at the Court of Appeal. The issues surrounding such research were addressed by the House of Lords Select Committee on Stem Cell Research in 2001. It reached the following conclusions:

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224 Schedule 2(1)1d, Schedule 2(1)2

225 Q 1118

- a) If the full therapeutic potential of all forms of stem cell are to be realised, fundamental research on ES cells is necessary, particularly to understand the processes of cell differentiation and dedifferentiation;
- b) The Government should take an active part in any move to negotiate an international ban on human reproductive cloning;
- c) The Department of Health should examine with the HFEA the possibility of drawing up indicative guidance as to what constitutes serious disease for the purposes of the Regulations;
- d) When the Government brings forward legislation it should consider making express provision for such basic research as is necessary as a precursor for the development of cell-based therapies;
- e) A regulatory body to regulate clinical research using stem cells would become necessary;
- f) A stem cell bank should be set up and, before granting any new licence to establish human ES cell lines, the HFEA should satisfy itself that there are no existing ES cell lines in the bank suitable for the proposed research.

175. Eleven research projects relating to embryonic stem cells have now been licensed. Two licences— one to the Newcastle Fertility Centre at Life, and one jointly to the Roslin Institute and King’s College, London – have been awarded for therapeutic cloning.<sup>226</sup> Nevertheless, there are some outstanding issues concerning the adequacy of the drafting of the research purposes regulations. The House of Lords Stem Cell Research Committee expressed concern about the new regulations’ ability to provide for this basic research:

“[...] it is in the nature of the science that, before research into ES as well as adult stem cells can lead to therapeutic applications, there must be basic research; and, given that the Regulations explicitly recognise the development of treatments for serious diseases as one of the new purposes, it would be perverse if basic research were not implicitly incorporated. The Committee confidently believes that Parliament cannot have intended to will the therapeutic end without also willing the necessary means to that end.”<sup>227</sup>

The derivation of embryonic stem cell lines is not a straightforward matter, as researchers from Newcastle and King’s College London explained at the HFEA’s Research Conference in November 2005, nor is the process of cell nuclear replacement. Professor Alison Murdoch estimates that it takes 100 “spare” embryos to create a single stem cell line.<sup>228</sup> Valuable basic research could be undertaken in perfecting these techniques yet it would yield no information on serious disease, nor arguably increase knowledge about the development of embryos.

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226 There is an appeal for judicial review over the HFEA’s Newcastle licence.

227 para 8.15

228 Q 1130

### *Stem cell bank*

176. The HFEA makes it a condition of licences for research on stem cells that “Applicants will be required to place a sample of all cell lines in the UK Stem Cell Bank”.<sup>229</sup> There are concerns, expressed by the Wellcome Trust and others, that the guidelines for the UK Stem Cell Bank will impose restrictions on the purposes for which cell lines can be used.<sup>230</sup> Professor Alison Murdoch told us “We should not have regulations for the sake of it, we should look at the risks and what we are trying to protect against and I think the risk of what you are doing in the lab helping to learn how stem cells grow is actually very small”.<sup>231</sup> Professor Peter Andrews from Sheffield University agrees that regulation of stem cell lines should be kept to a minimum, since “Once a line of hES [human embryonic stem] cells has been established in culture, it is just that – namely a group of cells, and it is no longer an embryo. [...] At this stage, the major ethical milestone, namely whether or not to use an embryo to derive an ES cell line, has been passed”.<sup>232</sup>

177. The UK Stem Cell Bank’s Code of Practice has no legal force; however, its draft Code states that embryonic stem cell lines may be used only for:

- a) Research which has the long term goal of helping to increase knowledge about serious diseases and their treatment;
- b) Basic cell research which underpins these aims; and
- c) Development of cell-based therapies for clinical trials in respect of serious human diseases.

178. The first criterion reflects the wording of the research purpose regulations. The second takes into account the concerns of the Lords Stem Cell Research Committee. However, in combination, the two criteria are inconsistent with Professor Andrews’s hope that further limits on the use of the cell lines should not be imposed. The Steering Committee has clearly stated its desire to be consistent with the will of Parliament and the Lords Stem Cell Research Committee but we are unconvinced that consistency in this case has much merit. On ethical grounds there is little basis for providing such protection for a cell culture, and on scientific grounds it is unfortunate that researchers cannot use the cell lines to tackle a wide range of diseases that are causing great discomfort and impose a huge burden on the NHS.

179. The inconsistencies highlighted above expose the illogicality of the regulations passed in 2001. If a research team wished to derive stem cells to research therapies for a “trivial” disease, these would be deposited in the stem cell bank and there is every likelihood that another research team would use the cell line to research a “serious” disease. We believe that the creation of a stem cell line should be grounds in itself for awarding a licence.

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229 HFEA, Regulations of Research on Human Embryos, [www.hfea.gov.uk](http://www.hfea.gov.uk)

230 [www.hfea.gov.uk](http://www.hfea.gov.uk)

231 Q 1127

232 Ev 380

### *Stem cells and clinical trials*

180. The House of Lords Stem Cell Research Committee noted that, when the prospect of clinical studies involving gene therapy emerged, the Gene Therapy Advisory Committee (GTAC), was established by the Department of Health to provide further oversight of such studies from scientific, medical, safety and ethical standpoints. It identified a need for a body to regulate clinical trials involving embryonic stem cells when this stage was reached and recommended either the creation of a body like GTAC or the extension of its remit. While this has merits, we believe that given its expertise the Government should give consideration to extending the role of the stem cell bank include the regulation of clinical trials.

### *Stem cell research funding*

181. We have not sought to investigate the funding of stem cell research; however, in the course of this inquiry, our attention has been drawn to some funding issues. We are aware that one of the Roslin Institute's Dolly team, Alan Colman, left to continue his research in Singapore because of the greater financial support there. In a Californian referendum, known as Proposition 71, researchers in California are now eligible for \$295 million a year for 10 years to work on embryonic stem cell lines, despite the ban on federal US funding being used for this purpose. Although there may be practical problems in California (the research must be carried out in facilities without federal funding), we have concerns that the UK's position as a "world leader in embryonic stem cell research" is under threat.<sup>233</sup> We have noted with great interest Sir Chris Evans's plans to set up a £100 million stem cell research foundation. The Research Councils have recently begun a £40 million two year cross-Council programme for stem cell research, which will fund projects running over several years.<sup>234</sup> **The budget allocations for the 2004 Spending Review were published in March 2005 without any specific reference to stem cell research. We recognise that the Research Councils have no interest in investing in research teams if they have no interest in sustaining them in the medium term. However, we recommend that they monitor the success of applications in this area made in open competition and bid for ring-fenced funds in future Spending Reviews if funding in stem cell research projects declines.**

### *Conclusion*

182. When the HFE Act was passed, the five allowed research purposes all related to fertility. However, it could be argued that, when the research purposes were extended to embrace therapeutic research, this covered all the reasonable grounds for which embryo research could be undertaken. An alternative approach would be to remove research purposes from legislation but ensure that there is rigorous peer review of any proposal involving embryos. Professor Murdoch told us "one possibility of restructuring the Act is that you actually avoid putting these dogmatic statements in primary legislation and maybe devolve that to a secondary body of the good and great [...] That will give us the flexibility to move on much more quickly than having to do it as we did with nuclear transfer, go

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233 Ev 280

234 £9.25 million in 2004-05 and £30.75 million in 2005-06. see Ev 436

back to primary legislation and actually change the Act to do it”.<sup>235</sup> Baroness Warnock has regretted that her report employed the term “respect” with regard to the embryo but said, in 2002, that the word was used to mean that “the early embryo should never be used frivolously for research purposes”.<sup>236</sup> It is debatable whether the MRC would fund frivolous research. A problem here is that the MRC is by no means the only funder of embryo research. The Warnock Committee made it clear that research applications received by the HFEA should have been scientifically peer reviewed.<sup>237</sup> We discuss the research licensing process in relation to ethical oversight and make recommendations for a new approval system for embryo research in paragraph 331–342.

## Criminality and compliance

### *Breaches of the HFE Act*

183. Section 41 sets out the offences for breaching the provisions of the HFE Act or contravening licence conditions. In the cases of placing in a woman a live embryo other than a human embryo or any live gametes other than human gametes, mixing animal and human gametes, placing a human embryo in an animal or keeping or using an embryo after 14 days, the penalty is up to 10 years in prison. We have commented on the various prohibitions in the HFE Act and concluded that legislation should be more flexible, particularly with regard to research (see paragraphs 331–342). We are also concerned by the size of the maximum sentence. **That the embryo only gradually acquires human rights is a widely accepted view. In this light, the maximum sentence of 10 years for breaching some of the prohibitions in the HFE Act seem unduly harsh.**

### *Person responsible*

184. The HFE Act (Section 17) demands that centres conducting licensable procedures nominate a person responsible “under whose supervision the activities authorised by a licence are carried on”. The legal status of this person was tested recently in a case of an embryologist at two clinics in Hampshire at which women were deceived into mistakenly believing that embryos had been implanted. In a key judgement it was concluded that the person responsible was not criminally liable. However, the embryologist was found liable and sentenced to 18 months in jail. This is the only prosecution under the HFE Act. The Royal College of Obstetricians and Gynaecologists says that “The role of the ‘person responsible’ is unclear when a misdemeanour extends beyond their immediate practical remit[...] It seems inappropriate that sanctions should apply specifically to one person and that these sanctions are only within the Criminal law”.<sup>238</sup> The British Fertility Society argues that implementation of the NICE guidelines will shift provision to the public sector and that, since NHS governance is robust, “the role of the ‘person responsible’, unique in the health care setting, should be replaced by the more conventional model of lead clinician, clinical director or lead scientist. Accountability for compliance with the

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235 Q 1128

236 HL Deb, 5 December 2002, Col 1327

237 para 13.11

238 Ev 369

regulatory requirements must fall to the Chief Executive (in the NHS model, or similar functionality in the private sector) as it does with all other aspects of health care”.<sup>239</sup> **The legal role of the person responsible is outdated. While the law did not confer liability on the person responsible for the misdemeanours of a member of staff, it still seems sensible to separate responsibility in respect of compliance with the HFE Act and compliance with technical standards. Standards would become the responsibility of the Trust Chief Executive (or equivalent in the private sector) while responsibility for compliance with the provisions of the HFE Act would be retained by a senior member of the clinic.**

### **Breaches of regulation**

185. Non-compliance with the Code of Practice, conditions of licences and directions is not an offence under the HFE Act but the HFEA is given the powers to consider any breaches when renewing licences. The HFEA has suggested that it needs a wider armoury of sanctions to “give the Authority more teeth in addressing situations which might require a firm response, but where suspension or revocation of the licences could not be justified”.<sup>240</sup> Dr Simon Thornton of the Park Hospital in Nottingham agrees that, while the HFEA can impose conditions on a licence, the only available penalty is the removal of the licence, which he describes as “a fairly blunt instrument”.<sup>241</sup> However, Section 22 of the HFE Act allows the Authority to suspend a licence with immediate effect for up to three months where it believes it has grounds for revocation of a licence, thus enabling clinics to sort out something that is potentially very serious but appears remediable. The clinic is able to keep the stored gametes but can address risks identified in the provision of treatment that have not been addressed.

186. The Eplan management consultancy highlights the conflict between the HFEA’s role in promoting risk management in centres and its ability to revoke licences: “the body which is responsible for the alert system is also the body that is responsible for holding licensed centres to account for their failings and imposing sanctions where they see fit. There is an inherent conflict between these two roles and this is certain to impact upon centres’ openness and willingness in reporting incidents or near misses where they believe it could have an adverse impact upon their licensing”.<sup>242</sup> **We agree that the regulator needs a wider range of sanctions but we are concerned that the emphasis is on penalty and not on improving standards and systems. The incompetent and the unethical needs to be closed down but the vast majority in the middle need to operate in a regulatory environment which encourages them to improve. There should be no deterrent to self-reporting.**

187. According to Sarah Elliston from Glasgow University, standards of practice might be thought to be most appropriately dealt with by professionally-led bodies with relevant expertise in issuing evidence-based guidelines. She suggests that non-compliance might be dealt with by the common law or by regulatory bodies such as the General Medical Council

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239 Ev 215

240 Ev 325

241 Q 6

242 Ev 348

(GMC) in terms of failure to meet standards of professional practice. Alternatively it could be dealt with by legal regulation that requires practitioners to comply with professional practice guidelines, although this would be an unusual step. A further option would be for an independent body, such as the present HFEA, to itself issue guidelines on acceptable standards and to make compliance with them a condition of treatment, under a scheme such as licensing.

### ***Professional discipline***

188. There is a large number of professional bodies regulating the conduct of healthcare professionals. In April 2003, on the basis of the report of the Bristol Royal Infirmary Inquiry chaired by Sir Ian Kennedy, the Government established the Council for the Regulation of Healthcare Professionals (now the Council for Healthcare Regulatory Excellence, CHRE) under the NHS Reform and Health Care Professions Act 2002.<sup>243</sup> The CHRE is a statutory overarching body, covering all of the UK and separate from Government. It promotes best practice and consistency in the regulation of healthcare professionals by nine regulatory bodies, including the GMC. The CHRE can appeal against unduly lenient judgements by the regulatory bodies. A notable example is the referral of the GMC's decision in the case of Professor David Southall, a consultant paediatrician who had accused a father of murdering his two babies after watching a television documentary. He was found guilty of professional misconduct but was not struck-off.

189. The law gives the GMC four main functions:

- a) Keeping up to date registers of qualified doctors;
- b) Fostering good medical practice;
- c) Promoting high standards of medical education; and
- d) Dealing firmly and fairly with doctors whose fitness to practise has been questioned.

190. The GMC has set out the duties of a doctor and issued guidelines on Good Medical Practice (see Box 7). To our knowledge, no doctor engaged in IVF has been subject to GMC sanction, although, in April 2002, the GMC decided not to proceed with its case against Professor Ian Craft, director of the London Fertility Centre. He had faced charges of serious professional misconduct for ignoring medical guidelines in treating a woman in her forties and for mistakenly implanting gametes in a faulty fallopian tube.<sup>244</sup>

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<sup>243</sup> Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995 (the Kennedy Report), 2001, Cm 5207

<sup>244</sup> BMJ 2001;323:826



**Box 7:**  
**Duties of a doctor**

- Make the care of your patient your first concern;
- Treat every patient politely and considerately;
- Respect patients' dignity and privacy;
- Listen to patients and respect their views;
- Give patients information in a way they can understand;
- Respect the rights of patients to be fully involved in decisions about their care;
- Keep your professional knowledge and skills up to date;
- Recognise the limits of your professional competence;
- Be honest and trustworthy;
- Respect and protect confidential information;
- Make sure that your personal beliefs do not prejudice your patients' care;
- Act quickly to protect patients from risk if you have good reason to believe that you or a colleague may not be fit to practise;
- Avoid abusing your position as a doctor; and
- Work with colleagues in the ways that best serve patients' interests.

In all these matters you must never discriminate unfairly against your patients or colleagues. And you must always be prepared to justify your actions to them.

**Good Medical Practice**

The third edition of the GMC's Good Medical Practice covers:

- Good clinical care;
- Maintaining good medical practice;
- Teaching and training, appraising and assessing;
- Relationships with patients;
- Working with colleagues;
- Probity; and
- Health.

191. The HFEA and the GMC have a memorandum of understanding setting out cooperation and collaboration in relation to licensed assisted conception services. In terms of this, the HFEA may identify for the GMC in the course of an inspection or licence application an issue that might raise a question about an individual doctor's fitness to practise.<sup>245</sup> The multiple murders carried out by Manchester GP Harold Shipman prompted the Shipman Inquiry to consider the role of the GMC in regulating the medical profession. Dame Janet Smith, Chairman of the Inquiry, concluded in its fifth report that "I have been driven to the conclusion that the GMC has not, in the past, succeeded in its primary purpose of protecting patients. Instead it has, to a very significant degree, acted in the interests of doctors".<sup>246</sup> In response to the Shipman Inquiry the Secretary of State for Health, John Reid, asked Liam Donaldson, the Chief Medical Officer, in January 2005 to conduct a review into patient safety to report later in 2005. The review will identify measures to:

245 A Memorandum of Understanding: Human Fertilisation and Embryology Authority, General Medical Council, December 2004

246 The Shipman Inquiry, Fifth Report - Safeguarding Patients: Lessons from the Past - Proposals for the Future, December 2004, Cm 6394, para 148, [www.the-shipman-inquiry.org.uk](http://www.the-shipman-inquiry.org.uk)

- a) Strengthen procedures for assuring the safety of patients in situations where a doctor's performance or conduct poses a risk to patient safety or the effective functioning of services;
- b) Ensure the operation of an effective system of revalidation; and
- c) Modify the role, structure and functions of the GMC.<sup>247</sup>

**192. The primary aim of healthcare regulation should be to protect patients. We believe that this can best be achieved by creating a culture in which good practice is encouraged rather than the focus being on penalising poor service. If individual practitioners have performed below acceptable standards, the professional regulators should act in a manner that protects patients. We recognise the Government's efforts to improve professional regulation through the creation of the Council of Healthcare Regulatory Excellence. While these changes need to "bed down", we welcome the commitment to strengthen regulation.**

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<sup>247</sup> "Government moves to protect patients", Department of Health press release, 2005/0030, 27 January 2005

## 5 Operation of the HFEA

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193. The recommendations and conclusions in the previous Chapter require a new role for the regulator when the legislation is revised. This Chapter provides further guidance on the role of the regulator, but some of the recommendations are relevant to the HFEA as presently constituted, reflecting the fact that it is likely to be at three years before new legislation can be implemented.

### Nature of the HFEA

194. The HFEA is a non-departmental public body under the Department of Health. However, the Department classifies it as a body at arm's length to Government and while Ministers over see the performance of the organisation, they do not intervene in the policy decisions made by the HFEA. The Authority is funded in part by grant in aid and by licence fees. In 2003–04 fee income was around £3.5 million and grant in aid was around £4 million. According to its 2003–04 annual report, the Authority is supported by 91 employees, working out of central London offices.

### Composition of the HFEA

195. Membership of the Authority is set out in Schedule 1 of the HFE Act, which states that all the members of the Authority (including the chairman and deputy chairman who shall be appointed as such) shall be appointed by the Secretary of State. This is now undertaken in accordance with the guidance from the Commissioner for Public Appointments (the 'Nolan' Guidelines). The Act sets out several criteria for membership. First, the Chair or the Deputy Chair must be lay members, i.e. they cannot be someone who is, or has been, a medical practitioner; someone who is, or has been, concerned with keeping or using gametes or embryos outside the body; or someone who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so. There must be a lay majority on the Authority but no more than two thirds and there must be at least one medical practitioner and at least one with experience of assisted reproduction. The number of members is not specified in the Act but in practice there have been around 20 and at present there are 17. The composition and status of members (as of January 2005) is shown in Table 8.

Table 8: Current membership of the HFEA.

Member	Category	Expertise	Date app. Started
<b>Suzi Leather</b>	Chair (Lay)		06.03.02
<b>Hossam Ibrahim (Sam) Abdalla</b>	Professional	Clinical	01.10.04
<b>Tom Baldwin</b>	Lay	Philosophy	26.02.01
<b>David Barlow</b>	Professional	Clinical	10.12.97
<b>Chris Barratt</b>	Professional	Embryologist	15.01.02
<b>Ivor Brecker</b>	Lay	Management & Dentistry	09.05.01
<b>Clare Brown</b>	Lay	Patient Experience	02.12.02
<b>Iain Cameron</b>	Professional	Clinical	26.02.01
<b>Neva Haites</b>	Professional	Geneticist	02.12.02
<b>Richard D Harries</b>	Lay	Bishop of Oxford	07.11.03
<b>Jennifer Hunt</b>	Professional	Clinical	07.11.03
<b>Emily Jackson</b>	Lay	Law	12.06.03
<b>Maybeth Jamieson</b>	Professional	Embryologist	02.12.02
<b>Simon Jenkins</b>	Lay	Media	10.05.01
<b>Walter Merricks</b>	Lay	Patient Experience, Law & Finance	02.12.02
<b>Sara Nathan</b>	Lay	Media	07.11.98
<b>Sharmila Nebhrajani</b>	Lay	Management, Accounting & Media Scientist	02.04.98

### *Expertise*

196. We have heard two principal concerns about the membership of the Authority. The first is that it lacks sufficient expertise. While the lay membership may have considerable expertise in genetics, bioethics and medical law and comprise non-medically trained health care professionals, the Authority will have between six and nine professional members (currently seven). This imposes severe constraints on the range of expertise available. We are aware for example that for much of the HFEA's life there was no clinical embryologist member, which is remarkable given that these are the individuals who are handling and manipulating the embryos. It also means that it is likely that there will only be one individual with first hand experience of PGD (since the HFEA website lists only eight licensed centres), which is one of the most contentious areas that the Authority handles. Given that not all members can attend all Authority meetings, it is likely that no spectrum of scientific and clinical opinion will be present and possible that policy decisions are made without any genuine expert opinion at all. Generally, attendance by Authority members is

good, which reflects well on the commitment they have to the work of the HFEA. For the 20 meetings between September 2002 and July 2004, the average attendance approached 15 and on only three occasions went as low as 10. We should not be surprised at the lack of expert membership since the lay majority was seen as important by the Warnock Committee. It recognised that the regulating body would need access to scientific and medical expertise and that there should “significant” representation from these areas. However, it made clear that the body “is not exclusively, or even primarily, a medical or scientific body. It is concerned essentially with broader matters and the protection of the public interest”. It recommended that there should be “substantial” lay membership and that the chair should be a lay member.<sup>248</sup>

197. The Department of Health considers the HFEA “to have the appropriate expertise and balance of membership to deal with the complex ethical, legal, scientific and technological issues it faces”, placing it in a very small minority.<sup>249</sup> The Royal College of Obstetricians and Gynaecologists (RCOG) believes that “the body regulating this area should have sufficient expertise in its make up to tackle some of the difficult clinical, scientific and ethical issues presented to it”.<sup>250</sup> The RCOG says the expert component of the Authority has been reduced in recent years and would like to see professional bodies formally represented. The strains on members to get to grips with technical issues was made clear by the academic lawyer, Emily Jackson. Quoted in the April 2004 edition of HFEA Update, the organisation’s newsletter, she says “It can [...] be difficult for non-scientific members to get to grips with some of the technical questions that arise in the licensing process.”

198. Comment on Reproductive Ethics (CORE) agrees that the HFEA lacks both the scientific background and organisational structure to become involved in the complex issues of embryonic stem cell research and the authority, expertise and sufficient neutrality to make important ethical decisions in relationship to fertility treatment or stem cell research.<sup>251</sup> It also contends that the HFEA is dominated by those with an involvement or vested interest in IVF. **We share the widespread concerns about the extent of the scientific and clinical expertise of Authority members, but recognise that the principle of the lay majority is important and should not easily be discarded. We believe that ultimate authority on issues of public concern should lie outside of the scientific and medical communities. At the same time, it is important that any decisions are informed by the science and medicine.**

199. The HFEA has a Scientific and Clinical Advances Group, which currently has 10 members. The group is appointed by the Chair from the Members of the Authority and consists of not less than five members, including a proportion of lay members. Non-Authority members may be co-opted on to the committee, subject to ratification by the Authority but these must always be in a minority.<sup>252</sup> The group can meet up to six times a year and its principal functions are to keep under review scientific and clinical developments affecting activities in which the Authority has an interest and to make

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248 para 13.4

249 Ev 198

250 Ev 283

251 Ev 267

252 Scientific & Clinical Advances Group (SCAG) Terms Of Reference, [www.hfea.gov.uk](http://www.hfea.gov.uk)

recommendations about such developments to inform the Authority's discussions and policy formulation. The presence of lay members on SCAG is curious since it has no powers and lay input can easily be made at Authority level. We shall consider the HFEA's use of evidence in support of its policies in paragraphs 266–278. Suffice to say, at this point, that the HFEA's announcement of an international Horizon Scanning Expert Panel in December 2004 to provide an assessment of upcoming scientific and technical developments rather suggests that SCAG was not well equipped to fulfil its duties.

200. These problems in the composition of the HFEA stem from the fact that the HFE Act sought to combine expert and lay representation on the Authority. It is clear that the Warnock Committee intended lay members to be the ultimate authority, in which case we suggest that the Committee's aims would be better served by an Authority comprised exclusively of lay members but which was informed by a properly constituted advisory committee that fully reflected the range of scientific and medical views and expertise. It is also possible that professional bodies could be given formal observer status, as the Department of Health is on the Authority (and on various HFEA committees) and the Human Genetics Commission is on the HFEA's Ethics and Law Committee.

### *Licence committees*

201. Licence committees are made up of six members drawn from the Authority. Thus the danger that relevant expertise is not present to inform a decision is even higher, particularly since anyone on the Authority who worked in a field that was the subject of a licence would be unable to take part in the deliberations. In the past, the workings and membership of licence committees have been shrouded in mystery. However, the HFEA published minutes of the research licence committee relating to its decision to award the Roslin Institute a licence to conduct therapeutic cloning.<sup>253</sup> This meeting makes an interesting case study. Of the six members on the committee – Emily Jackson, Ivor Brecker, Maybeth Jamieson, Neva Haites, David Barlow and Sara Nathan – only the first three attended. They had plenty of company, however, with Sam Abdalla (an Authority member and Clinical Adviser), Trish Davies, Director of Regulation, Frances Clift, Legal Adviser, Ross Thacker, Research Officer, and Claudia Lally, Secretary to the Committee, also in attendance.<sup>254</sup> We appreciate that this licence application was unusual for a number of reasons but we are struck by the number of non-members present at the licence committee meeting needed to help it reach an opinion.

### *Representation*

202. A second but related issue is the extent to which the HFEA should somehow be representative of society, and in particular in respect of the limitations placed on membership by the Department of Health. CORE told us that “Nobody from a pro-life perspective who has applied to join the HFEA over the last thirteen years has even been called for interview. The job description for membership openly stipulates that those who apply must subscribe to the objectives of the HFEA”.<sup>255</sup> The Minister insisted that the

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253 See para 240

254 HFEA, Licence Committee meeting minutes, 12 January 2005, item 6

255 Ev 265

Authority represented a “very diverse set of backgrounds representing all the ethical, scientific, patient, lay, as well as professional issues that you might want to see” except anyone who is “fundamentally opposed basically to the work the HFEA is doing”. However, she maintained that “I do not think anybody is not allowed to be on the body”.<sup>256</sup> The HFEA’s Chair is more hostile to the idea: “I think that you must subscribe to the acceptability of IVF and the acceptability of embryo research. I do not think that you could sit on the Authority and exercise the kind of decision-making that we have to do if you were fundamentally opposed to the activities that we regulate. To me, that would be a nonsense. It would be extremely difficult to make decisions”.<sup>257</sup> It is curious that the Chair of the HFEA said that appointments have “historically been a matter for ministers” as the Minister maintained that she did not get involved in the “detailed handling arrangements”.<sup>258</sup> The Department told us that future appointment exercises will be conducted by the NHS Appointments Commission, with input from the Chair of the HFEA but that the final decision on the appointment of members will remain with the Secretary of State.<sup>259</sup>

203. We are unable to find anything that actively excludes those who have a principled opposition to assisted reproduction in the literature produced by the Department of Health in 2003 but evidence provided by the Department demonstrates that Authority members were sought with well-defined areas of expertise and experience. In 2002 the Department advertised for members in the following areas:

- a) Clinical genetics
- b) Embryology
- c) The ability to represent the wider patient experience
- d) Finance, accountancy and resource management

204. In 2003, members were sought in these areas:

- a) Legal
- b) Medical practitioner with expertise in assisted conception treatment (involving in-vitro fertilisation and donor insemination);
- c) Religious/faith ministry or theology;
- d) Infertility counselling.

205. We requested information from the Department of Health on how many applications to join the Authority had been turned down because the individuals had a principled opposition to assisted reproduction. The answer, for 2002 and 2003, is, we learn, zero. However, if we assume that no-one with such views is likely to be employed in assisted conception services, the number of categories for which someone opposed to assisted

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256 Q 1332

257 Q 1259

258 Q 1335

259 Ev 428

reproduction could apply is limited. It is interesting to note that for each of the eight vacancies advertised since 2002, there were around 30 applicants.<sup>260</sup> Even if certain views are not excluded, as such, the odds are very stacked against a successful application. Given that the HFEA's Chair will in future provide input to the appointments process, these odds have lengthened still further.

206. Perhaps it is worth considering whether the Department should explicitly seek members with a principled opposition to assisted reproduction. On one hand this could create problems. The Authority is charged with regulating assisted reproduction and embryo research within the limits set out in legislation. As the HFEA's chair pointed out, it is hard to see how someone with such views could contribute to discussions on a licence committee to consider, for example, an application to derive stem cells from an embryo.<sup>261</sup> On the other hand, campaigners such as Josephine Quintavalle have made a valuable contribution to various debates and it could be argued that her application for judicial review in relation to preimplantation tissue typing is a valuable public service.

207. An important distinction must be drawn between encouraging applications from individuals with certain views and any attempt to make the Authority representative. The Christian Medical Fellowship complains that "The composition of the HFEA does not accurately reflect the range of ethical views held by scientists, ethicists and faith communities in the UK".<sup>262</sup> It is hard to see how any appointment process could achieve this in practice. As Professor Neil McClure from Queen's University, Belfast put it, "I do not have a problem with a pro-life representation but there are so many different facets of society – religion, colour, pro-life, pro-abortion, the whole range – which small groups that make up society are you going to have representation from?".<sup>263</sup> **We have sympathy with the view that those with principled opposition to assisted reproduction should be represented have been unreasonably excluded from a place at the principal forum for debates on assisted reproduction and embryo research. It cannot, however, be a simple matter of reworking the job description for Authority members, since the presence of those opposed to assisted reproduction and embryo research would change the very nature of the organisation. The representation of views needs to be considered as part of a thorough assessment of the regulatory and advisory structures operating in this field. The composition of the regulator must either be substantially reformed or mechanisms found to improve the range and quality of advice it receives.**

## Remit of the Authority

### *Regulatory and advisory roles*

208. The Authority has two principal functions: as a regulator and an advisory body. Section 8 of the HFE Act sets out the HFEA's role as an advisory body, charging it to "keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and

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260 Ev 428

261 Q 1259

262 Ev 217

263 Q 109



advise the Secretary of State, if he asks it to do so, about those matters". This is quite distinct from its regulatory functions and this dual role is problematic. In short, while the regulatory role obliges it to work within the Act and discharge its duties accordingly, the advisory function challenges it to find fault with the legislation on behalf of the Government. We have heard concerns that these roles are incompatible and the All-Party Parliamentary Pro-Life Group argues that the regulatory and advisory role of the HFEA should be split, with the advisory role assumed by a national bioethics committee.<sup>264</sup> The problem is best illustrated by considering incidences where the Authority, either corporately or individually, has made statements that are at odds with the HFE Act. On an individual level, we have sympathised with the view that it would be inappropriate to appoint individuals to the Authority whose views are at odds with the principal aim of the HFE Act which was to allow assisted reproduction and embryo research to take place in a carefully regulated environment. Less clear cut is when an Authority member has a strong view that a particular element of the HFE Act should be amended or deleted.

209. Section 8a of the HFE Act states that the HFEA should "keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters". In general advice given to ministers would be considered confidential and thus we cannot know how the HFEA has performed this function and in what circumstances. An obvious situation would be when the Authority feels that changes to legislation would be desirable. An early example in the life of the HFEA might have been in relation to the restrictions on confidentiality provided in the HFE Act, which, it became quickly apparent, were unworkable (see Table 2).

210. At the beginning of this inquiry, the HFEA provided us with a list of elements in the HFE Act which required attention. This has been very useful to this Inquiry. Chief Executive Angela McNab told us that there had been discussions about how the HFE Act needed looking at since she had been appointed nearly two years earlier. A recent example of advice to Government, concerning sex selection, is more open to scrutiny since it was commissioned by the Department of Health, came in the form of a published report and followed a public consultation.<sup>265</sup> We discuss its findings in paragraphs 362.

211. The HFEA's consultation document on the welfare of the child provision, *Tomorrow's Children*, recognises that in seeking the views of the public and professionals its questions must address the "how" rather than the "if".<sup>266</sup> Despite this, the HFEA's Chair Suzi Leather told us that "The Authority believes that the welfare of children is a sensible, central principle in the Act" but that has not prevented her from criticising the Act.<sup>267</sup> She told the BBC in January 2004 that "It is absolutely clear if you think about the changes in society and the different ways that families can be constituted that it is anachronistic for the law to include the statement about a child's need for a father[...]It seems to me a bit of nonsense to have that still in the legislation."<sup>268</sup> She confirmed this in evidence in stating

264 Ev 223; we discuss the merits of a national bioethics committee in paragraphs 347-353

265 see authority minutes, March 2002

266 HFEA, *Tomorrow's Children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment*, January 2005

267 Q 1257

268 BBC News Online, 21 January 2004

“My personal position is that children flourish best within a stable relationship between two people”.<sup>269</sup>

212. The LCF has drawn our attention to Suzi Leather’s introduction to the HFEA’s Annual Report for 2002–03 in which she says “We must continue to be a watchdog for patients, a guardian of Parliament’s intentions, a supporter of good clinical practice, a protector of disciplined and lawful research and above all a protector of the interests of all those whose births we have celebrated in this special year.”<sup>270</sup> The LCF points out that “It is not the Authority’s role to be a guardian of Parliament’s intentions. That is the constitutional role of our courts of law and, in certain circumstances, Parliament itself. The Authority’s role, as a public body created by statute, is simply to perform Parliament’s intentions as set out in the 1990 Act.”<sup>271</sup> The LCF may be guilty of an overly literal reading of Ms Leather’s comments but the HFEA still needs to establish whether it can be a guardian of Parliament’s intentions at the same time that it is seeking to promote legislation that is at odds with Parliament’s intentions, even if she disagrees with those intentions.

213. Perhaps less contentious was Ms Leather’s condemnation of reproductive cloning during her address to the HFEA Annual Conference on 21 January 2004. She commented on newspaper reports at the time in which Dr Pavos Zavos indicated that he had cloned a human baby: “I would urge the governments of all countries where people intent on reproductive cloning may seek to work, and professional clinical bodies worldwide vehemently to oppose the unethical ambitions of Dr Zavos”. It is worth remembering that before Bruno Quintavalle made an initially successful application for judicial review on whether embryos created by cell nuclear replacement were covered under the HFE Act, it was Government’s intention that the HFEA regulate – not ban – cloning. Ms Leather should not issue sweeping condemnations and recognise that, however, unlikely or inappropriate it may seem to her, Parliament might wish to keep a more open mind on this issue, which would place her in a difficult position.

214. The day before Emily Jackson joined the HFEA, she published an article in which she said “The welfare of children who do not yet exist is, in simple and crude terms, none of the law’s business”.<sup>272</sup> Professor Jackson told us that the article did not say that; it simply pointed out that the provision was “problematic” and “ambiguously worded” and recommended that we read the whole article. Her views were not incompatible with the legislation, she said.<sup>273</sup> We did re-read the whole article and found it most stimulating, and we agreed with most of what she said. However, the statement “the principle is an unjust and irrational barrier for people who need assistance in order to have children , and that it should be removed from the statute” is quite clearly incompatible with the HFE Act. We are disappointed that she chose to deny what she had written. We were not attempting to trip her up but explore to what extent Authority members should agree with the wording of the HFE Act, and why some contrary views appear in practice to be excluded, while

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269 Q 1244

270 Human Fertilisation and Embryology Authority Twelfth Annual Report and Accounts 2002/03

271 Ev 231

272 Fertility treatment: abolish the 'welfare principle', Emily Jackson, Spiked Online, 11 June 2003

273 Q 1254

manifestly others are not. Many of our witnesses have expressed similar sentiments on this issue, including the Royal College of Obstetricians and Gynaecologists. However, they do not have a legal obligation set out in Section 13 of the HFEA Act, to make decisions that “take account of” the welfare of the child.

215. In paragraphs 147–161, we discussed the issues surrounding the Government’s decision to introduce Regulations removing the donor anonymity provisions set out in Section 31(4). It has been suggested to us in confidence that certain members sought to join the HFEA with the primary intention of pushing through this change. This would be a highly regrettable situation. We do not expect Authority members to join with completely open minds. For a daily payment of £169, we would expect the job to appeal only to those with a passionate interest in the subject; nevertheless we would consider it inappropriate to use the Authority as a lobbying platform.

216. There are further concerns is that the HFEA has been campaigning, corporately, for changes in legislation.<sup>274</sup> We are concerned that the HFEA has crossed the boundary from regulation to advocacy in its treatment of gamete donation. Its consultation on the Regulation of Donor-Assisted Conception published in November 2004 states that “As the regulator of donor-assisted conception, it is not the HFEA’s function to promote or encourage donation or treatment”.<sup>275</sup> However, the HFEA’s corporate memory is failing it. In 1998, its Consultation on the Withdrawal of Payment to Donors states that it was the HFEA’s intention that “payments to donors should be phased out in such a way as to minimise any adverse effects, particularly any reduction in the supply of sperm donors”. As a result it set up a working group to consider ways of maintaining sperm supply and increasing egg supply.<sup>276</sup> More recently, in response to the Department of Health’s consultation on donor anonymity, the HFEA stated that it has “been keen to encourage a culture of altruism with respect to donation[...] [and] that the withdrawal of payments to donors may negatively impact on the supply of donors,” which implies that donation is a “good thing”.<sup>277</sup> **We have heard that membership of the HFEA has so far been reserved for proponents of assisted reproduction and embryo research. It is therefore not surprising that its individual members would wish to see greater availability of licensable activities. Nevertheless, by promoting gamete donation in its corporate publications it has acted outside its statutory remit and crossed a boundary that risks compromising public trust.**

217. We appreciate that the HFEA might feel it is in a no-win situation. It is damned if it does not consider the legal implications of its regulation and damned if it suggests how these problems should be resolved. The HFEA’s Chief Executive Angela McNab told us that “I think it is appropriate that the HFEA can draw to people’s attention where there may be inconsistencies or where there may be a need for society and Parliament to review certain areas”.<sup>278</sup> **It is reasonable for the Authority to draw attention to problematic areas in legislation, indeed it would be negligent if it were not to do so, but there is a**

274 Ev 218

275 February 1998, para 58

276 para 1.3

277 HFEA, Response to the Department Of Health’s Consultation on ‘Donor Information: Providing Information About Sperm, Egg And Embryo Donors’, July 2002, para 36

278 Q 476

**clear distinction between drawing attention to problems and inconsistencies and espousing solutions.**

### *Statutory boundaries*

218. There is concern that the HFEA has exceeded its remit and is, in the words of the Christian Medical Fellowship, “altering statutory boundaries”.<sup>279</sup> The Lawyers’ Christian Fellowship (LCF) has made a number of allegations, arguing that “the HFEA misunderstands its functions, purports to perform functions that are not within the 1990 Act, and indicates that it would like to extend its jurisdiction even further.” The LCF draws our attention to the HFEA’s core functions. It argues that “There is no statutory basis for saying that developing policy is a ‘core function’ of the Authority. Its core functions are set out in Section 8 of the Act. The word ‘policy’ does not appear there or anywhere else in the 1990 Act.”<sup>280</sup> The LCF is correct that the HFE Act did not define any policy-making role, but it is difficult to understand how it could discharge its functions without making policy. We have heard criticisms that there has been inconsistency in the decisions by HFEA licence committees.<sup>281</sup> We have also heard about the length of time required for the approval of licence applications, particularly for research.<sup>282</sup> The removal of the HFEA’s policy function would mean that licence committees would be operating in a vacuum, forced to make decisions from first principles. This would be a lengthy process liable to result in different conclusions for similar cases. The HFE Act also demands that the HFEA provide advice to the Secretary of State on request. Once again it is difficult to see how this duty could be discharged without a reasoned discussion by the Authority based on a strong body of evidence leading to an agreed view, a process otherwise known as policy-making. The LCF further suggests that “The wording of the 1990 Act should be clarified so that there can be no doubts as to the functions to be performed. This is not to say that the wording of the 1990 Act should be extended to cover the functions that the Authority currently purports to perform.” It argues that “The statutory functions of the Authority should be separated out and performed by separate independent bodies”.<sup>283</sup> **We conclude that the HFEA could not have discharged its statutory duty without developing a policy-making function; nevertheless, any revised legislation should more clearly define the presence or absence of a policy-making role for the regulator.**

219. The LCF also criticises the HFEA for publicising its own role. Section 8(b) says the HFEA should “publicise the services provided to the public by the Authority or provided in pursuance of licences”. It says that there is a distinction between publicising its functions and itself. This seems a minor point and it should only concern us if in publicising itself it incurs significant sums of public money. The Authority has also issued press releases “welcoming” court decisions that support its interpretation of the law and scientific developments in therapeutic cloning.<sup>284</sup> The HFEA has to interpret the law as best it can

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279 Ev 217

280 Ev 230

281 Ev 419

282 Ev 419

283 Ev 235

284 For example: 8 April 2003, Court of Appeal allows tissue typing for human embryos under strict conditions; 25 June 2004, Court ruling on storage of embryos: Natallie Evans.

but it should not be a matter of public celebration if the court's view coincides with its own legal advice.

220. In its leaflet *Embryo Research* the HFEA states that it “encourages research while ensuring that it is carried out responsibly and for good reason.”. The LCF argues that the HFEA has no duty to encourage research. Section 8(a) of the HFE Act states that the HFEA shall “keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act”. According to the LCF, “if anything, the function of the Authority is to act as a check on research rather than to encourage research in this area”.<sup>285</sup> One might argue that the HFE Act says nothing about acting as a check either. The HFEA's function is to establish that the research applications it receives fall into one of the eight purposes for research currently allowable under the Act. HFEA Chief Executive Angela McNab told us that it was “appropriate in our regulation of research that we are not obstructive”.<sup>286</sup> The Christian Medical Fellowship is resigned to the fact that it is “inevitable that scientific experts on the HFEA will be enthusiasts for new research and development” but Ms McNab should recognise that lack of obstruction is not the same as encouragement.<sup>287</sup> **The HFEA must be aware that many individuals and organisations will pore over its statements for evidence of misdeeds. It is unfortunate that it has provided so much ammunition to its critics. As the Science and Technology Committee, we are pleased that the HFEA sees the value of scientific research; however, we accept that it is not its role to encourage licensable embryo research, merely to consider whether applications that it receives conform to the wishes of Parliament.**

### ***Policy-making and the Code of Practice***

221. Policy decisions are communicated through three principal mechanisms. The first of these, and the most important, is the Code of Practice. The Authority is required by Sections 25 and 26 of the HFE Act to produce a Code of Practice. The Act states “The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.”.<sup>288</sup> The HFEA is obliged to consult “such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate” on the contents of the CoP and the Authority must seek approval from the Secretary of State.<sup>289</sup> While the CoP is not legally binding in theory, a licence committee is entitled to refuse a licence if the CoP is not observed. The most recent edition, the sixth, is over three times the length of the first (see Table 9). We recognise that the HFEA has attempted to produce more “helpful” documents with the HFE Act republished at the relevant points. It is also true that PGD was not covered in the first edition. Nevertheless, the HFEA should consider whether some of its “help” is either welcome or useful.

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285 Ev 232

286 Q 471

287 Ev 220

288 Section 25(1)

289 Section 26(1-2)

Table 9: Date and length of editions of the HFEA's Code of Practice.

<b>Edition</b>	<b>Date</b>	<b>Length in pages</b>
<b>First</b>	1991	55
<b>Second</b>	1993	56
<b>Third</b>	1995	74
<b>Fourth</b>	1998	76
<b>Fifth</b>	2001	73
<b>Sixth</b>	2004	169

222. The Authority meets monthly and each meeting will generally make policy decisions. Table 10 gives some recent examples. In many cases, these follow consultation exercises or internal reviews.

Table 10: Examples of significant policy decisions made during Authority meetings.

<b>Meeting</b>	<b>Policy decisions</b>
<b>November 2003</b>	Egg giving should no longer be permitted. <sup>290</sup>
<b>May 2004</b>	Storage vessels for gametes and embryos (dewars) should be alarmed and samples should be split for those patients whose fertility may be impaired by medical treatment.
<b>July 2004</b>	Preimplantation tissue typing should no longer be confined to cases where the child to be born is at risk of an hereditary genetic disease.

223. The HFEA communicates with licensed centres by letters from either the Chair or the Chief Executive. In general the Chief Executive's letters provide guidance rather than updates on policy (see Table 11). There are exceptions. In August 1999, the then Chief Executive wrote to centres on interim licensing guidance for PGD and guidelines for the licensing of embryo biopsy practitioners.<sup>291</sup> This was highly significant in that this placed restrictions on which clinics could undertake PGD.

290 Egg giving is the process whereby a person seeking IVF treatment agrees at the outset to go through one treatment cycle in which all the eggs collected are donated to a second person, followed by a further IVF cycle for their own treatment at reduced cost. The issue was discussed at the 20 November 2003 meeting but the decision was not minuted. However, the HFEA issued a press release on 1 December stating that it had written to clinics asking them not to practise egg giving.

291 CE.99.08

Table 11: Chief Executive's letters.

Date	Reference	Title
05-08-2004	CE(04)07	Various developments
01-08-2004	CE(04)06	Historic Audit Project
05-07-2004	CE(04)05	Freedom of Information Act and Communications with the HFEA
27-05-2004	CE(04)02	Correcting HFEA Data and new Forms
23-04-2004	CE(04)01	Duties of the Person Responsible

224. Letters from the Chair (see Table 12) often contain updates to the CoP. There is a clear anomaly in terms of the requirements of the Act with regard to the CoP and “letters” from the HFEA. While in many cases the HFEA may well have consulted on a policy change before informing the centres, there is no requirement to have done so. Since it is likely that any policy change will be contained in the subsequent edition of the CoP, it is likely that in some cases the views of professionals will only have been considered after they have been obliged to conform with a policy change.

Table 12: Examples of Chair's letters.

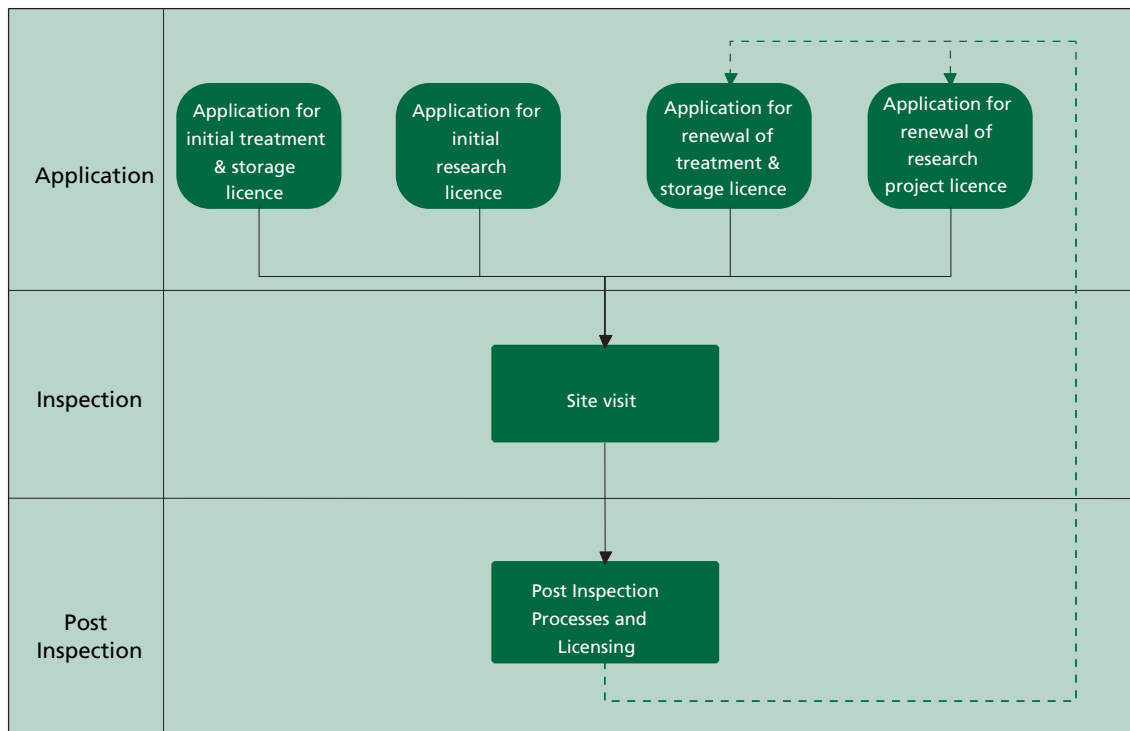
Date	Reference	Title
04-08-2004	CH(04)05	New Guidance on Preimplantation Tissue Typing
03-08-2004	CH(04)06	Changes in the process for the recognition of ICSI and Polar Body /Blastomere Biopsy Practitioners. Revised guidance on preimplantation testing.
15-06-2004	CH(04)04	HFEA Donor information forms
07-06-2004	CH(04)02	Revised Directions on Witnessing
07-06-2004	CH(04)03	Guidelines on the safety of equipment used to store cryopreserved gametes and embryos in Assisted Reproduction Laboratories
28-05-2004	CH(04)01b	Arms Length Review
09-01-2004	CH(04)01a	Revised HFEA Code of Practice (6th Edition)

225. This anomaly is not the fault of the HFEA and we were pleased to see that it suggests in its evidence that new legislation should enable a more flexible approach.<sup>292</sup> **It is right and proper that the HFEA should seek to update the protocols set out in the Code of Practice, which is, in effect, a rule book for centres licensed under the Act. The HFEA has not so far employed the internet to its full potential and we believe that its policy decisions should be consolidated in a single document as far as possible and as quickly as possible into a single digital entity.**

## Inspection and licensing

226. Sections 16–22 of the HFE Act set out the processes by which licences are awarded and the inspection process. Inspections cover record keeping (section 13), conditions for the storage and disposal of licensed material (section 14), and the suitability of staff, equipment and working practices (section 17). Following the granting of a licence, the inspection at any particular centre is annual unless a licence committee ‘[...]considers an inspection in that year unnecessary’ (sections 9 and 10). The HFEA’s application of the licensing and inspection procedure are shown in Figure 1.

**Figure 1: The HFEA’s inspection and licensing process.**



## Inspection

227. We have heard a number of concerns about the adequacy of the inspections. Criticisms of the inspection process fall into two categories: the first relates to the HFEA’s practice and the second to more fundamental issues relating to the nature of the inspection and licensing set out in the legislation (see Box 8 for a description of the inspection process). In particular, we have heard stinging criticism from three centres about the HFEA’s practice. Mohamed Taranissi of the Assisted Reproduction and Gynaecology Centre made a number of complaints.<sup>293</sup> These were:

- a) His clinic was unable to correct statistical errors contained in an inspectors’ report.
- b) The HFEA had provided inaccurate information to the media about another clinic’s claim that it had been the first in the UK to use aneuploidy screening of embryos.



- c) An inspection team had been advised to take covert photographs during an inspection in case the clinic amended patient records following receipt of a critical inspection report. The same team had been requested to send its report the HFEA's senior management. Normal practice is for a draft report to be prepared for the inspection team. A revised draft report is then sent to the clinic to correct inaccuracies. The report is then sent to the HFEA's licence committee.

228. The London Fertility Centre, under its director Professor Ian Craft, is concerned that "decisions are inconsistent between IVF centres for similar breaches and disproportionate criticism has been levelled at LFC".<sup>294</sup> Robert Winston, Professor of Fertility Studies at Imperial College London, describes the inspection process as "flawed", citing conflicts of interest among inspectors, and inconsistent reports.<sup>295</sup>

**Box 8: HFEA inspections**

HFEA inspections are normally carried out by a team which includes:

- a) A Senior HFEA Regulatory Manager – Chair
- b) An HFEA Regulatory Officer (who will write up the inspection)
- c) An HFEA Clinical Inspector
- d) An HFEA Scientific Inspector
- e) An HFEA Social and Ethical Inspector

Inspections can take up to two days depending on the size and type of the centre, although most only take one full day. On the visit the inspection team will normally be expected to cover:

- a) General consideration of the licence application
- b) Meetings and interviews with the senior members of staff at the centre
- c) A full tour of the centre to inspect premises and equipment

The inspection team will, after the visit, prepare a report on the centre for the HFEA Licence Committee considering the application.

229. Problems with the HFEA's inspection procedures have not escaped the Department of Health. The HFEA is sent an "end of year" letter from the relevant health minister. In July 2002, the then Parliamentary Secretary of State for Public Health Hazel Blears wrote to Suzi Leather, Chair of the HFEA, complaining that a complete overhaul of its regulation and inspection procedures was essential, but that despite a number of recommendations from a whole raft of reports these had not been implemented. Ms Blears wrote that this was "unacceptable". In September 2002 the Authority set up an independent steering group to look at how the HFEA could improve its work and services, under the chairmanship of Robert Nicholls, a former Chief Executive of Oxford Regional Health Trust. The steering group concluded that while stakeholders were supportive of the HFEA's functions, they were deeply critical of its working practices. On the inspection process, the group recognised that any professional inspection can create an atmosphere of tension and mistrust but that there seemed to be "a particularly high degree of antipathy to the HFEA's inspection arrangements" and that inspections were perceived to be "strong on

294 Ev 419

295 Ev 425

administrative detail but inconsistent and ineffective in identifying below standard or unethical practice”.<sup>296</sup>

230. The HFEA’s inspection processes were dealt with in some detail by Professor Brian Toft’s Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, West Yorkshire (see Box 9). Professor Toft concluded that these adverse events were caused by a mixture of inadvertent human error and systems failure. These “vulnerabilities within that inspection system” included several problems with the inspection process, in particular the role of the HFEA executive and the training of inspectors.<sup>297</sup>

**Box 9: Adverse events at The Leeds Teaching Hospitals NHS Trust.**

Professor Brian Toft’s Review Panel investigated four adverse events at The Leeds Teaching Hospitals NHS Trust. The first incident involved the incorrect identification of sperm samples, mixed race twins were born to a Caucasian couple. In this case Professor Toft concluded that it was impossible to say with certainty at what point in the process the misidentification of sperm had occurred. However, a number of weaknesses were found in the practices and protocols used in the embryology laboratory. The second incident also involved the incorrect identification of sperm samples, but in this case the error was identified and the embryos were not used. In this case the embryologist concerned was at a loss to explain how the error might have occurred. However, there was a shortage of staff at the time and as a consequence the embryologist concerned had a very heavy workload. A further adverse event led to a patient’s eggs being compromised following the failure of the cryopreservation process. The embryologist stated that she had simply forgotten to check the level of the liquid nitrogen before starting the freezing process. In this case a number of potential vulnerabilities were identified in the centre’s induction training process. The final event led to the embryos of a couple being discarded without their consent occurred because the letter they sent to the centre authorising the continued cryostorage of their embryos had not been filed with their medical notes. Professor Toft found that this was the result of a combination of scattered document storage facilities, an uncoordinated archiving system for medical records plus staff shortages and pressure of work at the centre.

*Source: The Toft Report, paras 16–21*

231. The HFEA has been aware of criticisms that its inspections were excessively burdensome. In 1999, the HFEA took advantage of its discretion to reduce the frequency of inspection allowed in Section 9(8–9). It introduced a system involving a full inspection for all organisations making their first application for a licence, which if successful, resulted in the organisation being granted a one-year licence. After three years a licence committee would evaluate the centre’s performance and grant a three year licence if this was satisfactory. In its evidence the HFEA describes a number of further attempts it has made to improve licensing (see Box 10). Dr Simon Fishel of the Park Hospital in Nottingham agreed that improvements had been made: “It has been speeded up. The HFEA has changed in its practice dramatically in recent years to the better and in terms of interaction with clinics. We have seen a real effort to improve its communication and its involvement in the processes that we are concerned about”.<sup>298</sup>

<sup>296</sup> Improving the performance of the Human Fertilisation and Embryology Authority, Independent Steering Group Recommendations to the HFEA, September 2002

<sup>297</sup> Q 411

<sup>298</sup> Q 649

232. When the Department published the Toft report in June 2004, the HFEA declared that it was already complying with 85% of his recommendations. However, Professor Toft advocated that “an external body should look at the recommendations of any inquiry and make sure they are implemented in full or at least an explanation is given as to why they have not been implemented in full”.<sup>299</sup> The Department has told us that it alone will be monitoring progress.<sup>300</sup> This seems to be a casual approach to ensuring that such “vulnerabilities” in inspection process are eliminated.

**Box 10: The HFEA’s improved licensing processes.**

- Targets to improve the regulation of clinics. These concern response times for licence applications (3 months for treatment, 4 months for research applications), the conduct and planning of inspections and the follow-up of inspection reports.
- A dedicated website for all licensed clinics, outlining HFEA procedures, spelling out our targets and keeping licence holders informed of our activities.
- A new incident alert system as part of an overall safety agenda, which also includes a programme of unannounced inspections.
- Training and expanding our inspection team, including nurse and counselling inspectors. We have also piloted gathering patient feedback during inspections, which we will roll out in the whole inspection programme.
- A new clinics database. Together with the improved register it can now be used far more effectively to streamline inspection processes (focussing on identified cases and practices that represent an increased risk) and policy making. In addition, we will now use a far broader range and depth of data to provide more meaningful information for the new edition of our patient guide.

233. Poor practices are an obvious source of concern but criticisms of the underlying basis for inspections is potentially more damning. The British Fertility Society (BFS) considers the application of the regulations through the licensing and inspection process to be an overly bureaucratic, top heavy and time consuming process which does not address the key areas of medical concern. Inspection should be limited to trouble spots and applications for new licences with fewer inspections for the renewal of licences.<sup>301</sup> Dr Sue Avery of the Association of Clinical Embryologists is less complimentary: “There is no observation of practice; there is no time to take evidence that people are actually doing what they say they do and compared with [...] other laboratory accreditation systems, the time that is spent looking at a practice is so small that it is really valueless”.<sup>302</sup> It has been suggested that the current licensing system be replaced by a form of accreditation, which describes the processes that should take place rather than how they should be undertaken. This is the basis of ISO accreditation and tissue banking standards drawn up under the auspices of the British Fertility Society. **Advocates of the role of the HFEA have argued that it has succeeded in maintaining public confidence in a highly contentious area. If this is the case, it is hard to see how this can be maintained if its inspection processes are attracting sustained criticism.**

299 Q 389

300 Ev 428

301 Ev 216

302 Q 23

### *EU Tissue and Cells Directive*

234. The EU Tissues and Cells Directive was adopted by the Council of Ministers on 2 March 2004 and published in the Official Journal of the European Union on 7 April 2004. The Directive introduces new legal requirements for all units involved in the donation, procurement, preservation, testing, processing, storage and distribution of gametes (but not embryos).

235. Although the Directive sets out the governing principles and the broad areas to be covered, it does not spell out the detailed regulatory requirements that tissue banks and assisted conception clinics will have to meet. These will be determined by an expert committee established by the European Commission and made up of Government representatives from the 25 Member States. A group of 9 Member States (including the UK) will meet initially to draft the requirements. This will be followed by a meeting of all 25 Member States in July and a stakeholder consultation, which ended on 1 October 2004. The Commission is currently finalising the requirements for the accreditation, designation, authorisation or licensing of tissue establishments. Among the most contentious issues are the required air quality standards. Member States are obliged to comply with its provisions no later than 7 April 2006. The Department of Health has decided to take up the option in the Directive that allows deferment (derogation) of its application for one year for those establishments already licensed by the HFEA at April 2004. The HFEA and the Human Tissue Authority have been named as the competent authorities, although the Government intends to merge these bodies (see paragraphs 376). As far as reproductive cells are concerned, the Directive will be transposed into UK legislation by an amendment to the HFE Act by way of regulations. **The EU Tissue Directive will provide a welcome impetus to improve and maintain the technical standards in treatment centres. However, we urge the Government and the HFEA to ensure that the standards applied are appropriate and proportionate.**

### *Inspectorate*

236. The HFEA's inspectorate is made up of external specialist inspectors, who are typically individuals who work full time in some particular aspect of the work regulated by the HFEA. These fall into four categories and are listed in the Annual Report:

- a) Clinical inspectors (31 listed in 2003–04 Annual Report)
- b) Embryo biopsy inspectors (5 listed in 2003–04 Annual Report)
- c) Scientific inspectors (23 listed in 2003–04 Annual Report)
- d) Social and ethical inspectors. (15 listed in 2003–04 Annual Report)
- e) Others (2 listed in 2003–04 Annual Report)

The HFEA says that it is recruiting its own clinical inspector to carry out a proportion of inspections consistently and to monitor the performance of external inspectors.

237. At present, we understand that a site visit would generally take around four hours.<sup>303</sup> We have been told that it is “difficult to comprehend how, perhaps with limited time at their disposal, they are able to read and digest up to 1000 pages of information relating to a centre’s activities, in some cases only a matter of a few days before the inspection is due to take place.” It is likely that the EU Tissue Directive will impose greater demands on inspection teams. Professor Neil McClure from Queen’s University Belfast highlighted the problem of an increase in the length of inspections in that his university is unlikely to take kindly to paying him a salary to do someone else’s work with no benefit to his employer.<sup>304</sup> Professor Robert Winston attributes some of the inconsistency in inspections to the large number of inspectors (76 in the 2003–04 Annual Report).<sup>305</sup> Suzi Leather told us that she envisaged that the HFEA will be moving shortly to an in-house professional inspectorate.<sup>306</sup> This will please Professor Winston, who reports that “for some years the HFEA has been urged to ensure that there is an established inspectorate, simply employed to do that job only”.<sup>307</sup> **We welcome the HFEA’s decision to appoint an in-house professional inspectorate. However, it is important that these inspectors have the confidence of the assisted reproduction community and we recommend that its views are taken into account before appointments are made.**

### *Comparison with animal procedures*

238. A useful comparison can be made with the regulation of animal experimentation. Under the Animals (Scientific Procedures) Act 1986, a project licence shall not be granted for any programme unless the Secretary of State is satisfied that it is undertaken for one or more of the following purposes:

- a) the prevention (whether by the testing of any product or otherwise) or the diagnosis or treatment of disease, ill-health or abnormality, or their effects, in man, animals or plants;
- b) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;
- c) the protection of the natural environment in the interests of the health or welfare of man or animals;
- d) the advancement of knowledge in biological or behavioural sciences;
- e) education or training otherwise than in primary or secondary schools;
- f) forensic enquiries;
- g) the breeding of animals for experimental or other scientific use.<sup>308</sup>

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303 Q 23

304 Q 114

305 Ev 425

306 Q 1235

307 Ev 425

308 Section 5(3)

The comparison of assisted reproduction with animal procedures is useful since regulation takes place in a changing environment, in this case due to the pressure to limit animal experimentation through the 3Rs (replacement, refinement and reduction). The inspection of facilities is undertaken by the Animals (Scientific Procedures) Inspectorate but there is a separate advisory body, the Animal Procedures Committee. The House of Lords Select Committee on Animals in Scientific Procedures considered the burden of regulation in 2002. The criticisms of the regulation it reported – that it is slow, bureaucratic and lacking accountability – sound eerily familiar. Key differences with the regulation of assisted reproduction and embryo research are that regulation is undertaken “in house” by the Home Office, that the inspectors are full time professionals and that the advisory body is distinct from the regulatory committee. While there is little demand that assisted reproduction should not have a distinct regulatory body, in other ways the framework is not dissimilar to the one we have recommended. It is worth noting that there have been criticisms that the inspectorate is too close to the people it is regulating and that it has been difficult to recruit inspectors. The Lords Committee also expressed concerns that the Animal Procedures Committee needed to be clearly separated from the Home Office regulators.<sup>309</sup> As with assisted reproduction, the costs of regulation are borne by those being regulated. The Home Office currently makes annual charges £252 for each establishment plus £226 per individual licence holder. An establishment may have up to 100 personal licence holders, thus a large establishment would have to pay in excess of £20,000 per year. There are significant structural differences between the regulation of assisted reproduction and animal procedures. With animal procedures, regulation is undertaken within a central Government department (rather than at arms length from Government) and is supported by an advisory committee (rather than an Authority supported by an executive, and has a professional inspectorate. While there are differences in the areas being regulated, is not clear to us that these justify the organisation differences that exist.

## Licensing

### Licence committees

239. We have also heard concerns about the functioning of licence committees. One is that they are insufficiently open. It has been difficult to determine the membership, meeting times and agendas of licence committees. We accept that patient and commercial confidentiality may be at stake in some cases, but we urge the HFEA to publish as much as it can on its website without being asked. GeneWatch catalogued the problems it had had in extracting information about the therapeutic cloning application from Newcastle Fertility Centre, despite there being “no legal obstruction to the HFEA’s licensing committee minutes or other relevant information being in the public domain”. Genewatch was eventually supplied, several months after the application had been awarded, with a copy of the first cloning application together with peer reviewers’ comments and the minutes of the licensing committee.<sup>310</sup> During this inquiry, the HFEA has made great efforts to distinguish between licensing decisions and policy decisions, particularly relating

309 House of Lords, Report of the Select Committee on Animals in Scientific Procedures, Session 2001-02, HL Paper 150-I, paras 5.28-5.52

310 Ev 422

to preimplantation tissue typing. Its task would be easier if the functioning of its licence committees were not so opaque. **It is unacceptable for the HFEA to attempt to withhold information relating to licence applications if it has no legal basis for doing so. Information relating to licence applications and licence committees should be made available on the internet as a matter of course.**

240. In some contentious cases, the patient has sought to discuss their treatment with the committee but been refused. Jayson Whitaker, who sought a licence for preimplantation tissue typing, complained that “the HFEA, decided our case without coming to see us and without talking to us. They would not speak directly to us, it had to go through the clinic. Our clinic did a very good job of putting the application in for us but we did ask them whether we could bring our own specialist witnesses and whether we could apply ourselves and speak to them in person and if they could come and see our life for a day and then pass judgment, but instead they just relied on their rules and regulations.” [...] they just *carte blanche* said, “No, it is not possible. You are not invited. It is not public.”.<sup>311</sup> The Masterton family, who wished to use PGD to select a female embryo, had similar experience. Mr Masterton told us “I knew the PGD issue was a contentious issue. I asked whether I could represent our position at that lay member committee. I said I would be happy to come, present our position and leave after our case had been considered. I received a letter from HFEA about a week later saying that these decisions were made behind closed doors and there was no facility.”.<sup>312</sup> There are good reasons why patients should not have direct access to the licence committee. It could be argued that the committee needs to make a dispassionate appraisal of the information before it yet many cases may have tragic circumstances that could have a significant emotional impact on the committee. The HFEA seems, however, to have had a change of heart. At its January 2005 meeting it agreed that “written representations would be accepted though all stages of the Licence Committee process and that patients could attend in person at the representation stage” if the initial application has failed. **There may have been good reasons why licence committees were unable to hear directly from the patients, but cases must be dealt with sensitively and without needlessly erected bureaucratic walls. We are pleased that the HFEA has decided to adopt a more open policy in the future.**

### Research

241. In our short inquiry on Developments in Human Genetics and Embryology, which reported in July 2002, we heard criticisms from researchers about the way research licences were issued. Professor Austin Smith, a stem cell researcher at Edinburgh University, reported that the HFEA was “inefficient [...] and lacking in specialist knowledge” and “a slow and reactive” body.<sup>313</sup> Dr Robin Lovell-Badge from the MRC’s National Institute for Medical Research reported that researchers had found the HFEA frustrating to deal with and that there has been criticism from researchers regarding the time the HFEA takes to process licence applications.<sup>314</sup> In 2000–01 the HFEA had missed its targets for licence

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311 Qq 568-573

312 Q 274

313 Fourth Report of the Science and Technology Committee, Session 2001-02, Developments in Human Genetics and Embryology, HC 791, July 2002, para 7

314 As above

renewal (for both treatment and research) by some margin, especially for research licences. We concluded that “Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy”. During this inquiry, Professor Robert Winston from Imperial College told us that approval from the HFEA was “time-consuming and laborious” and reported that “a leading British embryologist [...] left the field simply because she found the HFEA and its overbearing approach on her research to be so invasive”.<sup>315</sup> The Association of Medical Research Charities warns that “Licensing and inspection should not involve a heavy-handed approach, but should start with the assumption that scientists are applying to carry out such work for the public benefit and with integrity”.<sup>316</sup>

242. Since our last report, the HFEA has set up a dedicated Research Licence Committee, and has recruited specialist research regulation staff, who have the appropriate level of experience and expertise. The new staff will be primarily dedicated to research regulation and will give this work priority at all times. This reflects criticism about the speed with which research licence applications are dealt with. The Better Regulation Task Force (BRTF) report on scientific research regulation recognised the need for regulation in this area of science, and highlighted the importance of demonstrating that HFEA licence decisions are independent and evidence-based.<sup>317</sup> We will discuss the process by which research applications are approved in our discussion on local research ethics committees in paragraphs 331–343. **We welcome the efforts that the HFEA has made to improve its research licensing procedures and we hope that these prove effective. However, we believe that there needs to be a thorough analysis of the process by which research involving embryos is approved so that we do not lose sight of what the process is trying to achieve.**

### *Preimplantation genetic diagnosis*

243. In January 2005 the HFEA has announced a new policy to streamline the approval of applications for PGD. Under the new guidelines, if a clinic with proven expertise in performing embryo biopsies applies for a licence to carry out screening for a particular condition, which is already being carried out successfully in another clinic, the HFEA will approve the application without having to go through the full licence committee process, providing the same technique and methods are used. However, some applications will still be considered on a case-by-case basis:

- a) PGD/HLA tissue typing;
- b) PGD for late onset conditions;
- c) PGD for susceptibility genes.

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315 Ev 425

316 Ev 320

317 Better Regulation Task Force, *Scientific Research: Innovation with Controls*, January 2003, Section 5



Previously, centres had to submit an application to the HFEA for each new condition for which they wish to test and for each new test that they wished to use.<sup>318</sup> The Progress Educational Trust had criticised this process on the basis that licensing decisions could take six months and this might have a significant impact on the ability of older women to conceive.<sup>319</sup> The HFEA's streamlining of the licensing process for preimplantation genetic diagnosis will have been good news for clinics. However, it does undermine its Code of Practice since it effectively introduces an accepted list of conditions for which PGD is available. In this case, it would be preferable for the HFEA to publish a list of conditions for which PGD would be acceptable.

**244. The regulation of preimplantation testing is highly unsatisfactory. We recognise that the HFEA has legal jurisdiction but this does not mean that it has a duty to regulate its use beyond ensuring that it is performed to the highest standards within statutory boundaries.**

### *Preimplantation tissue typing*

245. The HFEA first considered the issue following a public consultation on PGD, conducted by the then Advisory Committee on Genetic Testing (see Table 13). The Human Genetics Commission took over responsibility for this subject when it was formed in December 1999. A joint HFEA/HGC Working Party was established in late 2000 and its conclusions were published in November 2001.<sup>320</sup> Unfortunately, the consultation document had not sought responses on the preimplantation tissue typing issue but the Joint Working Group concluded that “there were sufficient ethical difficulties with this approach [where an embryo is selected to provide a tissue match for transplant to an existing family member] that it should be subject to further discussion before its use was considered”.<sup>321</sup>

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318 Code of Practice, para 14.7

319 Ev 294

320 Outcome of the Public Consultation on Preimplantation Genetic Diagnosis, HFEA/HGC Joint Working Party, November 2001

321 para 29

Table 13: Timeline of HFEA policy on preimplantation tissue typing.

<b>1999</b>	HFEA publishes interim policy on the licensing of PGD. Public consultation on PGD conducted together with the then Advisory Committee on Genetic Testing, which does not, however, directly address the question of preimplantation HLA typing
<b>Aug 2000</b>	Birth of Adam Nash in Colorado, the first baby to be born following PGD and HLA typing. Stem cells from Adam's umbilical cord were later used to treat his sister Molly, who was suffering from Fanconi Anaemia
<b>Dec 2000</b>	HFEA/HGC Joint Working Party established to take forward the findings of the 1999 HFEA/ACGT consultation on PGD and to make recommendations
<b>Sept 2001</b>	Application received from the Park Hospital, Nottingham, for PGD/HLA treatment for Mr and Mrs Hashmi whose son, Zain, was affected by $\beta$ Thalassaemia major
<b>June–Nov 2001</b>	HFEA/HGC Joint Working Party agrees recommendations. They are adopted by both the HFEA and the HGC.
<b>22 Nov 2001</b>	Ethics Committee Opinion on selection of preimplantation embryos to produce tissue donors (after 3 previous discussions of the issue from November 2000 onwards). It recommends licensing of HLA typing both with and without PGD.
<b>29 Nov 2001</b>	HFEA agrees a relatively restrictive policy on HLA tissue typing, distinguishing between cases where PGD was necessary to avoid a disability in the future child – and cases where HLA was performed “on its own”.
<b>22 Feb 2002</b>	HFEA Licence Committee agrees to issue licence to CARE Nottingham for the treatment of Mr and Mrs Hashmi.
<b>12 July 2002</b>	CORE granted permission to apply for judicial review (this permission was initially refused in May 2002)
<b>29 July 2002</b>	HFEA Licence Committee turns down application from ARGC for HLA tissue typing for Mr and Mrs Whittaker
<b>20 Dec 2002</b>	CORE application succeeds at first instance – HLA tissue typing held to be unlawful.
<b>15 May 2003</b>	HFEA issues revised guidance on preimplantation testing via Chair's Letter (03) 04. As the legality of HLA typing at the time is considered uncertain, the section relating to HLA typing is not included in this guidance. The new guidance on PGD moves away from an 'objective' list of conditions that would merit PGD and towards greater emphasis on the couple's and clinician's views and decision making. This guidance is incorporated into the 6 <sup>th</sup> (and current) Code of Practice early in 2004.
<b>16 May 2003</b>	Court of Appeal overturns earlier High Court decision. It is within the powers of the HFEA to licence HLA tissue typing.
<b>6 Nov 2003</b>	Two further licenses granted to CARE Nottingham to provide HLA/typing with PGD for two couples with children affected by two inherited forms of Thalassaemia (Ms B and Mr A and Mr and Mrs L)
<b>Feb–July 2004</b>	HFEA conducts a review of its policy on HLA tissue typing. A new, extended policy is passed by the Authority on 21 July 2004, giving up the distinction between inherited and sporadic diseases.
<b>4 Aug 2004</b>	The new policy is communicated to clinics through Chair's Letter CH(04)05
<b>6 Sept 2004</b>	HFEA Licence Committee grants a licence to ARGC to provide HLA tissue typing for Mr and Mrs Fletcher whose son Joshua suffers from a sporadic form of Diamond Blackfan anaemia.
<b>March 2005</b>	CORE application on preimplantation tissue typing considered by House of Lords.

246. There are two strands evident in the development of the HFEA's policy and licensing decisions. (It should be noted that HFEA policy decisions are not necessarily informed by legal opinion and that licence committees are not bound by HFEA policy.) The first strand is the legal jurisdiction of the HFEA to license preimplantation tissue typing and the second is the HFEA's interpretation of the welfare of the child provision, which we discussed above in paragraphs 92–108. As we have stated, under the current Court of Appeal ruling, the HFEA can license PGD as means of identifying a "suitable" embryo for transfer. On 1 August 2001 the HFEA wrote to Mohamed Taranissi of the Assisted Reproduction and Gynaecology Centre, communicating its refusal to grant a licence to the Whitaker family. It gave two reasons. The first was that it was not consistent with the welfare of the child provision since (unlike in the case of the Hashmis) there was no risk of any of their embryos being born with the genetic disease in question. The second was that preimplantation tissue typing without PGD lay outside the terms of paragraph 1(1)d of Schedule 2 of the HFE Act, which states that the HFEA can issue treatment licences for "practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose" using the definition of treatment services in Section 2(1) which is "medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children". Mr Taranissi made this letter available to us.

247. HFEA licence committees are required to make their decisions in isolation from the rest of the Authority. The basis of this is that if there is an appeal against a decision a second licence committee may consider the application afresh. Also, licence committees cannot contain individuals with conflicts of interest and the Authority is likely to contain an individual with such conflict. In this case, for example, Professor Peter Braude, who is director of the biggest PGD programme in the country at Guy's and St Thomas' Hospital in London, was not able to sit on the licence committee.<sup>322</sup> This partially explains why, in questioning the HFEA on 21 July 2004, Angela McNab told us "My own recollection of the initial decision between the Hashmis and the Whitakers is that it was based on ethical and welfare of the child issues regarding the benefit to the embryo and the risks and benefits of the procedure itself, given that there might be no benefit to the embryo in one case and there would be in another case. It was not a legal issue."<sup>323</sup> Since the HFEA's letter to Mr Taranissi cited legal grounds and the legal advice provided by the solicitors Morgan Cole to the licence committee, which was subsequently made available to us, argued strongly that the HFEA could not license PTT alone, Ms McNab's recollections were not accurate. Since the Authority was not privy to the licence committee's legal opinion, her error would be forgivable if the letter to Mr Taranissi had not been signed by Dr Chris O'Toole, who was sitting alongside Ms McNab when she made this statement.

248. Our inquiry has tried to focus on the legislative and regulatory needs of the future, yet its policy and licensing decisions on PTT have undermined our confidence in the HFEA's understanding and/or use of the law. It has equally raised concerns about decisions of such importance—even controversy—being taken in this forum and the outcome determined solely on the basis of a Code of Practice generated by that same body. Indeed, on 19

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322 Q 624

323 Q 505

January 2005 Suzi Leather told us that the problems the HFEA had with PGD generally were partly attributable to the fact that it “does not appear on the face of the legislation”.<sup>324</sup> She admitted that “I certainly think that some of the decisions we have made [e.g. pre-implantation genetic diagnosis and tissue-typing] must have seemed rather confusing for many people, with seeming contradictions”.<sup>325</sup> While she professed herself “content with where we are now”, she should not be content with the process by which the HFEA arrived at its decisions.<sup>326</sup> The criteria now employed, following its change of policy in July 2004, are published by the HFEA in a revision to its Code of Practice (see Table 14).

**Table 14: HFEA’s decision-making criteria for the use of preimplantation tissue-typing.**

The condition of the existing child	The possible consequences for the child to be born	The family circumstances
(i) the degree of suffering associated with the condition of the affected child; (ii) the speed of degeneration in progressive disorders; (iii) the extent of any intellectual impairment; (iv) the prognosis for the affected child in relation to all treatment options available; (v) the availability of alternative sources of tissue for the treatment of the affected child, now and in the future; (vi) the availability of effective therapy for the affected child, now and in the future;	(vii) any risks associated with embryo biopsy for the child who may be born; (viii) the likely long-term emotional and psychological implications for the child who may be born; (ix) whether the treatment of the affected child is likely to require intrusive surgery for the child to be born (and whether this is likely to be repeated); (x) any complications or predispositions for the child who may be born associated with the tissue type to be selected;	(xi) the previous reproductive experience of those seeking treatment; (xii) the view of the people seeking treatment and of the affected child of the condition of the affected child; (xiii) the likelihood of a successful outcome, taking into account the reproductive circumstances of the patients <sup>327</sup> and the likely outcome of treatment for the affected child; (xiv) the consequences of an unsuccessful outcome; (xv) the demands of IVF/preimplantation testing treatment on the family whilst caring for an affected child; (xvi) the extent of social support available; (xvii) the family circumstances of the people seeking treatment.

249. It is instructive to dwell on some of the issues that weighed on the Authority when it drew up its policy in November 2001. We have commented on its use of the precautionary

324 Q 1239

325 Q 1281

326 Q1273

327 i.e. number of embryos likely to be available for testing in each treatment cycle, the number likely to be suitable for transfer, whether carrier embryos may be transferred, the number of cycles likely to be undertaken

principle above.<sup>328</sup> As a members of the ethics committee, Professor Peter Braude counted himself as a likely dissenter from its recommendation to allow treatment such as that sought by the Whitakers and he reported the reaction of horror of geneticists as a conference in June 2000, at which Dr Yuri Verlinsky, director of the Reproductive Genetics Institute in Chicago, reported the successful birth of Adam Nash, the first to be born following PTT. Most revealing is his statement that “There were other members who were not persuaded by the concerns that the public might have over this”.<sup>329</sup> This leaves us with the impression that while the Ethics Committee could deliberate in relative comfort, the Authority was more concerned with its write-up in the press than it was in coming to an informed and ethical judgement.

250. In our 2002 Report on *Developments in Human Genetics and Embryology*, we criticised the HFEA for not seeking recourse to Parliament, which, we argued, “does not need protecting and democracy is not served by unelected quangos taking decisions on behalf of Parliament”.<sup>330</sup> We recognise that, faced with a licence application, the HFEA had little choice but to make a decision, but while it was clearly recognised that PGD raised important legal issues for the Authority in 1999, we have no reason to believe that any advice was given to the Secretary of State to that effect. The Christian Medical Fellowship argues that the HFEA “must be the servant of primary legislation making decisions only within its bounds”.<sup>331</sup> Earlier in this Chapter, we accused the HFEA of pushing for legislative change. In this case, however, it has seemed content to rely on the courts’ judgements rather than pre-empt any challenge. Suzi Leather has invited Parliament to clarify the law regarding PGD. It is unfortunate that her predecessor did not do so six years ago. The PTT story, as Suzi Leather pointed out, does not end here as the Hashmi licence decision went before the House of Lords in March 2005 and its decision is awaited.

251. We have no evidence that the use of preimplantation testing would be used for “trivial” reasons to a degree that would harm the children born as the result of these procedures. By invoking the welfare of the child provision in its decisions on preimplantation tissue typing, the HFEA has tied itself in ethical knots trying to reach policy and licensing conditions. We are not sure how this has served the interests of the public, the profession and, most important, the patients themselves. **The development of the HFEA’s policy and licensing decisions on preimplantation tissue typing has been highly unsatisfactory. We share the Chair’s contentment with its current policy and agree that revised legislation must make it clear that preimplantation genetic diagnosis and preimplantation tissue typing can be undertaken within legal restraints .**

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328 see paragraphs 274-277

329 Q 628

330 para 18

331 Ev 217

## Use of research

252. As one would expect of an organisation of its kind, the HFEA has a “commitment to evidence based policy making”.<sup>332</sup> There are a number of issues that relate to the gathering and application of that evidence:

- a) What research, if any, it should conduct or commission;
- b) What data collection and analysis it should undertake of data generated by treatment centres;
- c) What its role should be in contributing to the research priorities of research funders;
- d) How it should apply research findings, published or otherwise, to its decision-making.

## Research function

253. The HFEA has no formal research function and does not “have the budget or the expertise to conduct high level academic research”.<sup>333</sup> Indeed it was an expressed recommendation by the Warnock Committee that the Authority would not have such a function.<sup>334</sup> It has been suggested that this should change. The Christian Medical Fellowship would like to see the HFEA have the “power and funding to commission research into relevant medical and social issues of the techniques they regulate. Regulation is not enough – society needs information on the results, far broader than just the number of babies born”.<sup>335</sup>

254. In considering the research that the HFEA conducts, it is worth drawing a distinction between scientific and social research, at least on cost grounds. A three-year grant awarded in October 2004 by the Biotechnology and Biological Sciences Research Council to Professor Peter Andrews from Sheffield University to work on human embryonic stem cells cost £208,000.<sup>336</sup> In contrast, the Economic and Social Research Council will fund grants from as little as £2,000 and considers anything over £45,000 to be a large grant.<sup>337</sup> Despite having no budget, the HFEA has engaged in a number of research projects. Many of these have been literature surveys but in 1993, they did commission academic social research into the attitudes of donors and treatment centres towards sperm donation. **If the HFEA is to retain its current functions, it is important that it has access to the best relevant data to support its decision-making. While research is not defined as part of its remit as such, it should have the budget to fund small scale unlicensable academic studies.**

255. We have recognised the limits of the HFEA’s ability to commission research to support policy formation. Nevertheless, this need not prevent it playing a proactive role in

<sup>332</sup> Ev 377

<sup>333</sup> Ev 377

<sup>334</sup> para 13.12

<sup>335</sup> Ev 219

<sup>336</sup> [www.bbsrc.ac.uk](http://www.bbsrc.ac.uk)

<sup>337</sup> [www.esrc.ac.uk](http://www.esrc.ac.uk)

influencing the research priorities of other funders. We are pleased to see that the HFEA has recognised the importance of this. It initiated the Medical Research Council working group on safety and assisted reproduction, which we discuss below, and supported an outline proposal from the National Perinatal Epidemiology Unit at Oxford to set up a National Assisted Reproductive Technology Research Centre.<sup>338</sup> We are pleased that it is “starting to establish sustained working relationships with both the ESRC and Wellcome Trust in order to increase the knowledge and evidence base for the HFEA’s policy making function”.<sup>339</sup> **The MRC Working Group contained a social researcher but the report gave little attention to the social impacts of assisted reproduction, despite being cited frequently in HFEA policy documents. We recommend that the HFEA ask the Economic and Social Research Council to set up a working group to look specifically at the social impacts of and attitudes to assisted reproduction .**

### **Data collection and analysis**

256. Section 31 of the HFE Act outlines the requirement of the HFEA to keep a Register and what information it should contain. This includes:

- a) the provision of treatment services for any identifiable individual, or
- b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
- c) or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.<sup>340</sup>

257. In theory, this should be a valuable resource in identifying any risks associated with assisted reproduction but for a number of reasons it is unclear what use it has been in this respect. A significant concern has been that the confidentiality requirements set out in Section 33, which states that no member or employee of the authority can disclose the information contained on the register, are excessive and reflect concerns that those undergoing or born as a result of IVF might be stigmatised as the technology was “unnatural and secretive.”<sup>341</sup> The result has been that the data are isolated from a person’s medical record and clinical databases such as the cancer registry. The RCOG describes this as “counter to the spirit of good preventive medicine” and sees “no purpose in maintaining this information indefinitely, unless the register is put to useful purposes”.<sup>342</sup>

258. While in theory a relaxation of the confidentiality provisions could allow the Register to be more useful for researchers, a more fundamental issue has been identified. Professor Richard Fleming from Glasgow Royal Infirmary contends that the data have little use: “If the database were intended to be a prospective research tool, then comprehensive training in information entry would have been an integrated part of the research design. This was

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338 Q 1228; this application was turned down by the MRC in December 2004

339 Ev 377

340 Section 31(2)

341 Ev 368

342 Ev 368

not the case.”<sup>343</sup> He comments that any grant application in which the researchers had no control over the primary source evidence would be rejected.<sup>344</sup> According to the MRC Working Group, the HFEA acknowledges variations in standards of data collection and missing data.<sup>345</sup> Despite this, Professor Catherine Peckham, who chaired the Working Group described the register to the Committee as “an incredibly rich, quite unique database, [which] is not being maximised and used to address new questions which perhaps were not asked in the same way previously. But there is huge opportunity to build on and strengthen rather than say that what is done now is not good.”<sup>346</sup> In contrast Professor Fleming concludes that the Register could only be used for crude analysis and points out the major cost to his centre incurred in conforming with the HFE Act’s requirements.<sup>347</sup> Alison Murdoch, Chair of the British Fertility Society, said that any “central collection of other clinical or laboratory data by the HFEA [...] would inevitably be a ‘fishing exercise’ for the data that may be relevant in the future”.<sup>348</sup> **The confidentiality provisions in the HFE Act have hampered efforts to establish the risks associated with assisted reproduction. We conclude that they are unnecessarily onerous and inconsistent with the widespread use of assisted reproductive technologies. We recommend that the data from the HFEA’s register should be applied as far as is possible to research studies.**

259. The MRC Working Group considered the database as part of its work. It suggested two options for making the Register available for research:

- a) A change in the law to the HFE Act section 33 to relax restrictions on consented data release direct from the HFEA database to a research database.
- b) Consented disclosure of information by licensed clinics rather than by the HFEA to a research database. Section 33 allows data transfer from the HFEA back to the clinics and the restrictions on disclosure of information from the clinics are less tight.

260. The Working Group pointed out that as a regulatory body, the HFEA is thus not best placed to maintain a research database or perform long-term follow-up studies and suggests that an independent group take on this function. It does not question whether these data need to be collected routinely on a national basis.

261. A distinction needs to be made between the data that already exist and future data collection. In theory, the Register contains 14 years of data which, even if of dubious quality, should be subject to analysis. It is less clear that the data should be added to for research purposes, still less that this should be a statutory obligation. ACE argues that in any case clinics are required to carry out regular audit of outcomes and records may be made available to external audit if necessary.<sup>349</sup> It seems reasonable that legislation should demand that certain basic data are maintained by treatment centres, but the removal of

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343 Ev 342

344 Ev 343

345 MRC Working Group, Draft technical report

346 Q 1059

347 Ev 343, 335

348 Ev 398

349 Ev 244



confidentiality provisions for treatment that does not involve gamete or embryo donation would enable the necessary follow-up studies to be undertaken. As the British Fertility Society suggests, only normal clinical records and routine birth registration are required. It says it is desirable for health and safety reasons that we monitor these children through adulthood and into the second generation but that this can be achieved through the existing health monitoring procedures and does not need the HFEA register.<sup>350</sup>

262. Our discussion is predicated on the assumption that the stigma of infertility and IVF is largely a thing of the past. However, we have received evidence from researchers at De Montfort University that confidentiality is extremely important for people from some ethnic groups who may object to certain forms of fertility treatment.<sup>351</sup>

**263. The confidentiality provisions in the HFE Act have hampered efforts to establish the risks associated with assisted reproduction. We conclude that they are unnecessarily onerous and inconsistent with the widespread use of assisted reproductive technologies. We recommend that the data from the HFEA’s register should be applied as far as is possible to research studies. We have criticised the excessive use of the precautionary principle in assisted reproduction. However, we recognise that there are public concerns about possible adverse risks associated with assisted reproduction. Treatment centres should, as a condition of their licence, maintain a database in a suitable form which is available for peer reviewed research projects. As result, there will be a justifiable burden on clinics.**

264. Maintaining the Register has been a headache for the HFEA. As Angela McNab put it with impressive understatement “there have been some difficulties with the IT system or the register system itself”, i.e. the database was found to be corrupted and much of the data lost.<sup>352</sup> The Authority has had to spend around £5 million to reconstitute the data as part of its Historical Audit Project, going back to data held by clinics, in order to fulfil its legal obligation to be able to respond to an inquiry in 2009 (when the first children to be born from HFEA-regulated services reach 18 years of age). The HFEA has also been unable to publish IVF data. **While the value of the Register for research has been open to question, it should have been able to provide data on the uptake of IVF and donor insemination and success rates to inform policy development on assisted reproduction and its provision. However, in recent years these data have not been published, which is unfortunate. We consider it to be a fundamental role of a regulator to provide information about the industry it is regulating.**

## *Use of evidence*

### *Safety of assisted reproduction*

265. Since 1978, over 1 million children worldwide have been born via assisted reproduction and 1–3% of live births in the developed world are now the products of ART.<sup>353</sup> Despite this there have been concerns that the risks to the mother and children

350 Ev 214

351 Ev 352

352 Q 534

353 MRC Working Group Draft Technical Report

born through assisted reproduction are poorly understood. This prompted the HFEA to approach the Medical Research Council (MRC) to set up a working group with the following aims:

- a) To take account of current knowledge of ART and its possible health effects, identifying the gaps in the basic science of human fertilisation and early embryo development, and heritable traits linked to subfertility;
- b) To provide broad scientific advice on research needed—whether retrospective or prospective—into ART, ranging from surveillance, epidemiology and data collection to biological mechanisms and hypotheses focusing on where the potential risks to offspring appeared to be greatest;
- c) To advise on how to meet research needs, taking account of the need for scientific quality, value-for-money and ethical and legal considerations.

The MRC's report concluded that "Although there is widespread acceptance, based on experience, that current ART procedures are generally safe, the evidence for this, particularly in terms of long-term safety, is relatively weak when compared to other similarly well-established clinical techniques". It identified a number of potential biological risks:

- a) In vitro manipulations might damage gametes or embryos. This damage might be mechanical, chromosomal or genetic, or result from changes in gene expression;
- b) Aspects of specific technologies, such as drugs (ovarian hyperstimulation syndrome), embryo culture, freezing, embryo biopsy or ICSI, may cause deviation from normal physiology; and
- c) The fact that conception occurs where at least one of the parents is infertile may pass on fertility problems or result in children with chromosomal abnormalities.

266. There have been suggestions that children born using assisted reproduction are more likely to have certain "imprinting disorders" such as Prader Willi syndrome, Angelman syndrome and Beckwith-Wiedemann syndrome. Other health risks seem to be associated with an increase in prematurity and low birth weight. Nevertheless, the Working Group was concerned by the lack of data and suggested that "all existing and emerging ARTs required careful evaluation as to their short-and long-term effects on the children produced". **We take seriously the possible risks of assisted reproduction technologies. For this reason, we encourage research in this area, both to inform professional practice and in order that intending parents can be adequately and appropriately informed of any risk to which they are considering providing consent.**

### *Multiple pregnancies*

267. Although there are specific risks associated with assisted reproduction, the Peckham Report concludes that "By far the greatest risks to both mother and child arise from the practice of implanting several embryos to increase the chances of having a baby, and the

consequences of a possible multiple pregnancy”.<sup>354</sup> Women with a multiple pregnancy are at higher risk of a range of conditions, including gestational diabetes, musculoskeletal problems, anaemia and hypertension. Multiple births also cause increased rates of parental stress, maternal depression and child abuse. On the children’s part, there is a higher risk of perinatal mortality and they are more likely to be born prematurely with a low birth weight, which is associated with problems such as chronic lung disease, adult-onset diabetes, coronary heart disease, high blood pressure, intellectual, physical and sensory disabilities, and psychological and emotional distress. As a result, multiple births are a significant strain on health service resources.

268. The HFEA likes to give the impression that its move to reduce the number of embryos per transfer from three to two embryos was a beacon of evidence-based policy when in fact it was dragging its heels behind the professional bodies.<sup>355</sup> This account of the HFEA driving forward good practice is not shared by the Professor Alison Murdoch, Chairman of the British Fertility Society, who told us that “For more than 10 years, both the RCOG and BFS have been arguing for and have published recommendations that a maximum of only 2 embryos be transferred during each IVF treatment. We have further argued that there should be no exception which is more restrictive than current HFEA regulations. A review of the HFEA reports of national data shows that a decrease in the number of 3 embryo transfer cycles has been steadily decreasing before any HFEA regulations changed.”<sup>356</sup> Looking around Europe, it is clear that some countries have done more than consider the change. For example, single embryo transfer is standard medical practice in many Nordic countries, notably Finland (see Table 15).<sup>357</sup>

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354 p.4

355 Ev 207, Q 1288, HFEA reduces maximum number of embryos transferred in single IVF treatment from three to two, HFEA press release, 8 August 2001.

356 Ev 396

357 Ev 372

Table 15: Percentage of embryos transferred in Europe in 2000.

	1	2	3	4+
<b>Finland</b>	27.0%	67.2%	6.0%	0.1%
<b>Hungary</b>	7.6%	19.2%	47.8%	25.5%
<b>Iceland</b>	9.4%	69.8%	20.9%	0.0%
<b>Ireland</b>	7.1%	40.4%	50.5%	2.0%
<b>Italy</b>	13.3%	33.4%	38.1%	15.2%
<b>Poland</b>	16.8%	56.9%	20.9%	5.4%
<b>Portugal</b>	10.8%	35.0%	48.2%	6.0%
<b>Russia</b>	10.6%	19.5%	33.1%	35.4%
<b>Slovenia</b>	20.4%	65.1%	14.4%	0.0%
<b>Spain</b>	27.0%	22.1%	44.4%	24.1%
<b>Sweden</b>	12.6%	83.6%	3.8%	0.0%
<b>Switzerland</b>	13.4%	57.8%	27.1%	1.7%
<b>UK</b>	8.0%	58.2%	33.8%	0.0%
<b>Ukraine</b>	9.2%	18.4%	29.1%	43.4%
<b>All</b>	12.1%	46.7%	33.3%	6.8%

Source: *The European IVF-monitoring programme (EIM) for the European Society of Human, Human Reproduction, Vol. 19, No. 3, 490–503, March 2004*

### Embryo biopsy and PGD

269. The safety of embryo biopsy has been at the heart of the HFEA's policy development on PGD and PTT. The problem has been that the available data are limited. Professor Peter Braude, from Guy's Hospital, told us: "What has not been established and could not be established other than by long-term follow-up is, has this any impact later in life".<sup>358</sup> On the face of it, removing one or two cells from an eight cell embryo sounds as if it should have a major effect on the embryo's survival and development but at this stage all eight cells can form any tissue or organ in the body, and half of them will, in any case, form the placenta. The data that suggest that biopsy may not be damaging come from the results of implanting frozen embryos. Professor Braude said that "you might lose half the embryo [...] [but] They will come out seemingly normal".<sup>359</sup> The MRC Working Group concluded that in humans the removal of one or two cells at the eight cell stage do not affect subsequent embryo growth and clinical data do not show reduced implantation rates.<sup>360</sup>

358 Q 613

359 Q 617

360 MRC Working Group Draft Technical Report

270. When the HFEA first considered preimplantation tissue typing in 2001, much was made of the theoretical harm to the embryo from the biopsy. Speaking to the Committee about the HFEA's anticipated change in policy on preimplantation tissue typing, Chief Executive Angela McNab said "What has changed in the area of PGD and HLA is that there is now two years' more data across the world of carrying out these kind of techniques. Therefore, there is information regarding outcomes, safety, and about the data, not just in this country because a relatively small number of these procedures are carried out worldwide, but there is collectively two years' worth of experience and in addition any update on the views of the public and on the wellbeing of the children."<sup>361</sup> It could be argued that the amount of data has not changed radically but the efforts of the HFEA in surveying that evidence has done.

### *Psychosocial risks*

271. Underpinning conclusions on assisted reproduction must be the findings of high quality social research. We are fortunate in the UK that we have excellent research teams looking at the social implications of assisted reproduction and genetics. Among these, Professors Susan Golombok and Martin Richards gave both written and oral evidence to this inquiry. Professor Golombok told us that while most studies had only looked at children born as a result of assisted reproduction in early childhood (Louise Brown is still only 26), studies had shown that "neither the quality of parenting nor the psychological well being of children is adversely affected by assisted conception".<sup>362</sup> There is particular concern for those couples wishing to conceive following donation. As well as the difficulties faced by the parents, it is important to discover how these families are functioning. Professor Susan Golombok from City University has undertaken research in this area, and her findings are reassuring: "the evidence is not there that there are particular problems for those concerned".<sup>363</sup>

272. In its discussion of the use of sex selection, the HFEA used the following welfare argument to support its recommendation that sex selection for social reasons should not be permitted:

"In our view the most persuasive arguments for restricting arguments for sex selection technologies, beside the potential health risks involved, are related to the welfare of the children and families concerned. There was considerable alarm among consultation respondents that children selected for their sex alone may in some way be psychologically damaged by the knowledge that they had been selected in this way as embryos."<sup>364</sup>

Thus the most persuasive argument was not that there was evidence of harm but that there was evidence of concern about harm. This is not a satisfactory use of evidence to support policy advice.

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361 Q 495

362 Ev 357

363 Q 972

364 para 139

### Precautionary principle

273. The origins of the precautionary principle lie in German environmental policy in the 1970s. Put simply, if there is only a risk of effects occurring, the possibilities of risk prevention have to be investigated and if the risk is high enough, preventive measures should be ordered. It has more recently been applied to advances in medical care, for which it implies that there should be proof of an absence or limited risk of harm, both physical and psychosocial, before treatments should be permitted. Several witnesses have invoked the precautionary principle in their evidence. The Rev Chris Johnson, a contributor to our e-consultation, wished to apply the precautionary principle as “the science is well ahead of the legislation” and this could avoid us taking decisions that we would later regret. Nothing should be permitted, he said, unless it had been thought through.<sup>365</sup> Dr Neville Cobbe, another contributor to our online consultation, applies the principle to stem cell research, arguing “I think we need to be exceedingly cautious. One thing I would be concerned about is why we want to rush ahead with human embryonic stem cells before the mouse studies have properly eliminated risk”.<sup>366</sup>

274. The HFEA invoked the precautionary principle in its 2001 policy decision on preimplantation tissue typing. As we set out in Table 13 the Authority decided at the time not to allow preimplantation testing when the child to be born had very little chance of developing the disease, yet its decision was contrary to the advice of its Ethics Committee.<sup>367</sup> Professor Tom Baldwin, Deputy Chair of the Authority, was a member of the Committee at the time: “When that went to the whole authority, in my opinion, unfortunately they disagreed. Why did they disagree? Because [...] of risks arising from embryo biopsy and it was felt that the Ethics Committee *had not taken proper account of the absence of evidence of no risk* [our italics]”.<sup>368</sup> Another example can be found in its 2004 report on Sex Selection. It argued that “It is not possible to discount a theoretical risk to health” in relation to the use of flow cytometry for sperm sorting.<sup>369</sup> The BMA is concerned that the application of the precautionary principle leaves open the possibility of extending the licensing role of the HFEA to incorporate a range of additional treatments including GIFT (gamete intra-fallopian transfer) and ovulation induction both of which have been associated with high order multiple births and expose the mother and the children to an element of risk. The BMA believes, however, that a “theoretical risk to health” is not an appropriate level at which to set the requirement for licensing since this would encapsulate vast areas of medical practice that do not raise the type of sensitivities referred to above.

275. The Genetic Interest Group is critical of the use of the precautionary principle and does not believe that “current or near-future practice in these areas [PGD and embryo research] threatens to undermine humane values or carries with it any obvious risks that are not already under consideration. Indeed, if caution is required, it is in giving weight to

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365 Qq 130, 133

366 Q 230

367 Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors, HFEA Ethics Committee, November 2001, para 3.14

368 Q 622

369 Sex selection report

speculative risks, backed up by little or no evidence, when benefits for parents making choices are clear, and research has only just begun.”<sup>370</sup>”.

276. Often the argument comes down to what weight you are prepared to give to existing evidence and this tends to betray attitudes to the technologies. In expressing their concerns about the application of the principle of reproductive freedom, Dr Alexina McWhinnie and Professor Alastair Bissett-Johnson from the Department of Law at Dundee University state that “Research and follow up studies are increasingly showing that there are potential risks for such children and the stability of their families and that they can experience psychological problems in childhood, at adolescence and as adults directly related to the methods used in their creation.”<sup>371</sup> In considering the use of new reproductive technologies, Dr Elizabeth Allan informs us that “The psychological damage alone from [...] abnormal parentage (unborn foetus as a mother; unborn embryo as a father or mother; no genetic father; mother and grandmother being identical, etc) could be profound.”<sup>372</sup> These comments sound eerily like the concerns back in 1978 about IVF, which have, according to Professor Golombok, failed to materialise. Indeed, she says “I just think the evidence is not there that there are particular problems for those concerned.”<sup>373</sup> The Epan management consultancy describes the HFEA’s invoking of the precautionary principle as an inevitable consequence of its separation from risk assessment: “In the absence of any information about the risks associated with the procedures they are licensing, they usually exercise caution,” it argues.<sup>374</sup> **No-one wishes to expose patients and children to physical harm or psychosocial stresses, but all medical practice has inherent risks and the only solution is a rational approach to risk assessment and management, coupled with strategies to undertake and apply the results of medical, scientific and social research.**

## Conclusion

277. We have identified serious shortcomings in the HFEA’s use of evidence in informing its policy development. However, the picture is not all bleak. We recognise that the change in its policy on preimplantation tissue-typing owes a lot to better use of evidence. The joint MRC/HFEA working group has done some valuable work and should help to build better links between these organisations. In addition, the HFEA’s international Horizon Scanning Expert Panel, set up in December 2004, is a welcome initiative. This panel aims to provide an expert assessment of upcoming scientific and technical developments and to identify priority areas for further scrutiny. We were surprised, however, that of its 17 members, none is a social researcher. Given the HFEA’s fondness for citing welfare issues in its policy decisions, it is peculiar that it did not see the need to build up its social research knowledge base. **We welcome the setting up of an international Horizon Scanning Expert Panel as a positive step in improving the HFEA’s use of evidence. We are unclear why there is not even one social researcher on the panel and urge the HFEA to rectify this.**

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370 Ev 277

371 Ev 410

372 Ev 268

373 Q 972

374 Ev 347

278. The Warnock report concentrated on the social, ethical and legal implications of the technology and the HFE Act placed little emphasis on the need to create a framework in which safety concerns about existing and new reproductive technologies can be identified. Indeed, there have been concerns that the Act is a major obstacle to attempts to establish the risks associated with assisted reproduction. The MRC Group concluded that “The current infrastructure in the UK allows AR technologies to be licensed and introduced with limited evidence of safety”. We welcome the MRC’s efforts to identify some of the safety issues facing assisted reproduction. It is unfortunate, however, that it has been unable to fund the proposal from the National Perinatal Epidemiology Unit at Oxford to set up a National Assisted Reproductive Technology Research Centre. We also understand that proposals to study the risks of ICSI and the effectiveness of blastocyst transfer have also failed to get MRC funding in recent years.<sup>375</sup> We would not wish to interfere with the MRC’s peer review process but we hope that the MRC will give further consideration to how it can enable some of the research needs it identifies to be funded. **By most standards, the safety of IVF lies within the boundaries of acceptability. Nevertheless, any risks must not be underplayed and patients should be made fully aware of them before treatment. We hope the Medical Research Council will look favourably on proposals to undertake national studies to establish the safety and effectiveness of assisted reproduction techniques.**



## Funding and licence fees

279. The HFEA generates income by charging fees to in-vitro fertilisation centres holding licences. In the past it was set an expenditure limit (£1,575,000 in 2000–01). The Department of Health and the devolved administrations funded the difference between the levied charges (£1,242,000 in 2000–01) and this expenditure limit. The funding mechanism ensured that the HFEA's income remains the same whatever the income raised by fees, and therefore that it has no direct incentive to award licences. In June 2002, the HFEA issued a consultation document on its future funding. It stated that the HFEA needs "ongoing operating funding of at least £4.5 million" to perform its licensing and regulatory functions. It cited scientific and clinical developments, public expectations and government policy as justifications for the increase. We were cautious in our 2002 report:

“The HFEA is asking for its income to be more than doubled. We accept that its activities have increased in recent years but, for such a large increase, it needs to make a more detailed financial case than its consultation document provides. If it can prove the need for such a large increase, it should be met by increased contributions from Government as well as from licensees. We are concerned that the Government's insistence that any increase in funding should be met from licence fees alone undermines the principle that the HFEA should have no incentive to award licences”.

In the Government's reply, it announced that it had agreed with the HFEA's request to raise the further funds it had requested from licence fees. The Department has since ended the claw-back and provides a block grant to support activities such as policy formation and public consultation which are not integral parts of the HFEA's regulatory function. **We welcome the changes in the funding arrangements for the HFEA, which recognise that the HFEA, as presently constituted, has a wider duty to the public beyond its role as a regulator.**

280. A further issue is the extent to which the costs of regulation are passed on to clinics and thus to patients. The British Fertility Society is concerned that “The burden of funding of the regulatory process falls to those that are being regulated (the providers) and those that are the subjects of the regulation (the patients). Patients and public are not made aware of this burden. The cost far exceeds any similar levy that is applied by other quangos on a per capita basis and, in its scope, has no parallel in the health care setting. With the major shift to the NHS setting likely with the implementation of the NICE guideline, it is time to fund the HFEA adequately from exchequer resources and remove this iniquitous and anomalous burden from the provider and patient.”<sup>376</sup> There are two issues here. First, should we provide free regulation of private treatment? We are aware that for some it is an extremely lucrative business and it is not clear that the State should further subsidise this. The second point is that for NHS-funded services, the costs of regulation ultimately have an impact on the funding available for services so the issue is largely to do with the transparency of license fees. The problem may be that for other areas of health care regulation, the costs of regulation are not so transparent for clinicians and are less aware that these are being incurred in the course of treatment.

### Research licence fees

281. In March 2004, the HFEA published a consultation on human embryo research licence fees and proposed changes in the application process. It stated that since the HFEA was established in 1991, most of the costs of research regulation have been met from grant-in-aid and from fee income from licensed treatment and storage centres. It pointed out that the HFEA is subject to Treasury rules, which do not allow for this kind of cross subsidy and that the costs of research licensing should be met from licence fee income paid by those being regulated. Furthermore, there was no prospect of the costs being met from other sources. The research licence fee had been set at £200 and the HFEA proposed that this was raised to an average of £6000. This horrified numerous witnesses, not least Anne McLaren, a distinguished embryologist and former member of the Authority, who told us that the questions on the consultation were of the “Have you stopped beating your wife?” variety”. In consequence of this “gargantuan increase in fees”, “The UK’s research reputation in this field would suffer, patients would suffer, basic understanding of early human development would suffer”.<sup>377</sup>

282. When the Authority met in July 2004 to make a decision, the minutes reported that “The DH agreed this work should be included in the list of items funded by their grant in aid” and that “The Authority agreed to propose an increased fee of £500 for all small projects and a fee of £750 for large, complex projects”. In other words, having undertaken a consultation on the basis that cross-subsidy was not an option, the HFEA discovered that it was an option at the last minute. We have no way of knowing whether the fault for this farce lies in the HFEA or the Department. Either way, they have succeeded in angering the research community and the HFEA’s reputation has been damaged as a result.

### Principles of good regulation

283. The Government’s Better Regulation Task Force, established in 1997, has set out five basic principles of good regulation:<sup>378</sup>

- a) Proportionate: Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
- b) Accountable: Regulators must be able to justify decisions, and be subject to public scrutiny.
- c) Consistent: Government rules and standards must be joined up and implemented fairly.
- d) Transparent: Regulators should be open, and keep regulations simple and user friendly.
- e) Targeted: Regulation should be focused on the problem, and minimise side effects.

284. We agree that these principles provide a sound basis for regulation and it is worthwhile to consider how the HFE Act and the HFEA itself stand up to these principles.

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377 Ev 200

378 [www.brtf.gov.uk](http://www.brtf.gov.uk)

We are aware that the HFEA has discussed these principles in relation to its policy on Dewar safety.

### **Proportional**

285. The degree to which the HFEA's regulation is proportionate depends largely on the perceived risks of not regulating. The HFEA receives around £3½ million a year in licence fees from close to 100 treatment centres. The size of the executive has increased rapidly on recent years. In 2002–03 there were 57 part-time and full-time employees and in 2003–04 there were 91. We understand that the figure is now over 100. We are aware that the HFEA has been stretched in recent years, as we discussed in our 2002 Report, although it has been argued that this was a result of expanding its own activities beyond its statutory duties rather than an increase in the workload imposed on the organisation. We asked the Minister whether she felt that the size of the HFEA's secretariat was appropriate. In her view, the HFEA was "a very tiny organisation these days".<sup>379</sup> We do not dispute that there are many much larger organisations than the HFEA but the issue is whether it is a suitable size for the job it is required to do by statute. We discuss parallels with the regulation of animal experimentation and abortion clinics, both of which are contentious issues in paragraphs 239 and 327.

### **Accountable**

286. One of the reasons for this inquiry was Ruth Deech's comment to us in 2002 that Parliament should be protected from making decisions on developments in assisted reproduction such as PGD. The current regime has shown a greater willingness to consult with the public and professionals and interact with Parliament, which is welcome. We will discuss the role of these groups in respect of the functioning of the regulator in Chapter 9.

### **Consistent**

287. We have discussed the consistency of the HFEA both in relation to its policy function and in the deliberations of licence committees. We argued that consistency could not be achieved unless the HFEA developed policy. A problem has been the dispute over the scope of the legislation (with regard to preimplantation tissue-typing) and high staff turnover. We have been told about the HFEA's short corporate memory, which irrespective of the calibre of the current executive (which by most accounts is high), has meant that contradictory statements have been made. We have heard particular complaints over the inconsistency of licensing and inspections.

### **Transparent**

288. This is an area that has improved since we last looked at the HFEA in 2002. The website is more comprehensive and the minutes and agendas of Authority meetings are available, if not always promptly. However, we have concerns that the activities of HFEA committees, and in particular the licence committees, are opaque. We feel this has eroded

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379 Q 1305

confidence in the HFEA. On the positive side, the Authority's policy formation is being more fully presented.

### ***Targeted***

289. We have heard concerns that the inspection processes being employed by the HFEA have not been effective in identifying poor practice. This has been chronicled in detail by the Toft Report.

290. **The principles of good regulation adopted by the Better Regulation Task Force are appropriate and valuable. We regret that in many areas the HFEA falls short of these ideals. We recognise that the HFEA has improved its performance but it has been stretched by too much poorly targeted regulation. This needs to be addressed by refocusing its efforts. We will discuss our solutions in Chapter 9.**

## 6 Provision of infertility services

291. There has been a rapid growth in the number of people in the UK seeking assisted conception since the HFE Act was passed. The HFEA reported in 2000 that 50,000 babies had been born using IVF since 1978 and that a third of these had been in the previous three years. The Warnock Committee decided against considering this approach in the light of increases in world population as “the number of children born as a result of techniques to assist in the treatment of infertility will always be insignificant in comparison with the naturally increasing population”.<sup>380</sup> Given that population growth in developed countries, where most IVF, is undertaken, is modest, this seems a reasonable position, although it should be noted that in some countries IVF accounts for more than 3% of live births (see Table 15). Despite being responsible for the first IVF birth, the UK is by no means a leader in its provision. Figures from abroad suggest that demand will become greater as a result of the NICE guidelines since IVF is responsible for a higher proportion of babies born where there is widespread state funding.<sup>381</sup> Table 13 provides figures for the rest of Europe.

**Table 15: Assisted reproduction in 2000 in those European countries where all clinics reported to the national register**

	Cycles	Population	Cycles/million	ART deliveries	ART infants	National births	ART infants (%)
<b>Denmark</b>	9,682	5.29	1,830	2,457	2,457	67,081	3.7
<b>Finland</b>	7,489	5.18	1,446	1,184	1,293	56,742	2.3
<b>France</b>	56,754	59.08	961	8,357	10,334	744,791	1.4
<b>Iceland</b>	364	0.28	1,300	102	166	4,315	3.8
<b>Netherlands</b>	15,062	15.93	946	N/A	N/A		
<b>Norway</b>	4,340	4.47	971	860	1,223	59,234	2.1
<b>Sweden</b>	9,205	8.87	1,038	1854	2,253	90,441	2.5
<b>Switzerland</b>	4,644	7.21	644	783	809	78,458	1.0
<b>UK</b>	34,634	59.76	580	5,553	7,677	679,029	1.1
<b>All</b>	142,174	166.07	856				

*Number of reported cycles, deliveries and infants in relation to the population and the national number of live born. ART = assisted reproduction technologies.*

<sup>380</sup> para 2.4

<sup>381</sup> HC Deb, 26 Jan 2005, Cols 96 WH-115WH

## The fertility “industry”

292. While 75% of UK IVF provision is currently in the private sector, this can give a slightly misleading impression, since some IVF patients in the NHS are self-funded and some centres in the private sector offer treatment at similar rates to the NHS. In addition, some primary care trusts (PCTs) have contracts with private sector clinics. In 2000–01 there were about 25,000 ART treatment cycles in the UK, each costing between £2000–£5000 per cycle.<sup>382</sup> Professor Margaret Brazier from Manchester University argues in her written evidence that regulation should be extended to cover the market in infertility services: “Fertility treatment is a highly lucrative business. Patients/clients are willing to mortgage their homes, forfeit their lifesavings and borrow thousands of pounds. Just as financial services such as pensions and life insurance need specialist regulation so does the fertility industry”.<sup>383</sup> The Department of Health has rejected a role for the HFEA here, declaring that “the Government does not see the role of the HFEA as being that of a financial regulator”.<sup>384</sup> **We have heard concerns that some of the services being offered to patients in IVF clinics are not justified by evidence of their value. We believe that clinics, private and NHS, must make it clear when they are offering services and treatments that lie outside the NICE guidelines. Practitioners need to be aware that their patients are desperate for a child and vulnerable to exploitation. We recommend that the Healthcare Commission prioritise its activities in this area.**

## Success rates

293. Section 8 of the HFE Act 1990 obliges the HFEA to provide information to the public about ‘services provided in pursuance of a licence’ and to provide information and advice to persons who are receiving treatment services’. The HFEA has taken this to include outcome data from all licensed clinics.<sup>385</sup> The professional bodies have been critical of the policy. Dr Richard Kennedy from the British Fertility Society argued that IVF procedures were standardised in Western Europe and North America and cited evidence from the US that concluded that the single most important factor was variation among the patients rather than differences in individual practices.<sup>386</sup> We heard during our visit to Guy’s and St Thomas’ Hospital that it had three PCT contracts yet despite the fact that all patients received the same treatment, there were significant differences in the success rates for each contract. It is well established that maternal age is a major factor in the success rate and cultural and financial factors may have a bearing in the age at which infertility treatment is sought.<sup>387</sup> Dr Sue Avery of the Association of Clinical Embryologists told us that the results from the vast majority of clinics are not statistically different from each other, but that “You have outliers at the top and the other concern is the outliers at the bottom”.<sup>388</sup> Professor Alison Murdoch, Chair of the British Fertility Society, has expressed concern that

382 Medical Research Council: Assisted reproduction: a safe, sound future, 2004

383 Ev 367

384 Ev 428

385 Ev 377

386 Q 4

387 NICE, Fertility assessment and treatment for people with fertility problems, February 2004

388 Q 26

the league tables that were inevitably produced created competition between clinics which was not conducive to collaborative clinical trials.<sup>389</sup>

294. However undesirable Dr Richard Kennedy, Secretary of the British Fertility Society, thinks it is for league tables to be published, it will take place and as Dr Simon Thornton from the Park Hospital in Nottingham told us, “One of the main issues that patients do look at when they are selecting clinics – both in the independent sector and in the state sector – are the results”.<sup>390</sup> The important issue is that patients are not misled by the information presented to them and it is presented in such a way as to drive good practice rather than bad practice, as Dr Kennedy suggests they do at present.<sup>391</sup> We see a clear role for the regulator in providing useful data that help patients make choices. If all clinics were the same then we could understand Dr Kennedy’s argument, but the presence of “outliers” in the data does not bear him out. Furthermore, we fail to see any merit in withholding this information from patients. The British Fertility Society should share everyone’s concern that some centres are not performing and not seek to protect them. Robert Winston, Professor of Fertility Studies at Imperial College, London is concerned that the HFEA seems to have no explanation for why some centres are obtaining very good results (“is this because some clinics are giving untruthful statements or because some clinics are surprisingly skilful at what they do?”) and why others are much worse.<sup>392</sup>

295. The HFEA has made a welcome recognition of the concerns of professionals and set up a Clinical Information Working Group, consisting of representatives from centres, the professional bodies, patients and counsellors. This group decided that publishing outcome data should be continued, but that a single unified comparator (a ‘success rate’) should not be calculated for 2004 because it would reflect the wide range of embryo transfer practice before the introduction of the two embryo transfer policy.<sup>393</sup> **The issue to be resolved is not whether there should be league tables but how to ensure that the data are sound and provide useful information to patients. Not all of the factors that influence the success of IVF are clearly understood but we see an important role for the regulator in developing metrics. We welcome the HFEA’s work on developing better comparators but it should resist publication of success rates for different clinics until it is satisfied that they are not misleading.**

### *International comparisons*

296. Table 16 shows the number of transferred embryos needed to achieve a live birth using data from the European Society of Human Reproduction and Embryology’s European IVF Monitoring programme. This measure is commonly used as a “parameter of excellence”. It shows that despite having tight regulatory regime, IVF in the UK is not the market leader. One can argue whether live births per embryo transfer would be a more meaningful measure or that the data from other countries may not be complete.<sup>394</sup>

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389 Ev 398

390 Q 12

391 Qq 4-7, 12, 14

392 Ev 425

393 Ev 377; see also para 269

394 Q 1175

However, the picture may be slightly misleading since it would be reasonable to expect larger clinics to have better success rates (since they would have a greater body of expertise and ability to train staff) and the UK may have a larger number of small clinics by virtue of the fewer number of cycles being undertaken. We have also heard that the inconsistency of reporting standards and criteria vary across Europe, but the overall picture, particularly in relation to the Nordic countries, is undeniable.<sup>395</sup>

**Table 16: Number of embryos needed to achieve a live birth across Europe.**

Country	Number of Embryos
Iceland	5.6
Finland	6.2
Sweden	7.1
Norway	8
Denmark	8.5
Europe	9.6
UK	10.6

Source: see Arne Sunde

**297. Despite being a pioneer in IVF, the UK lags behind many of its European neighbours in quality of the treatment it offers. We believe that, while regulation is not necessarily an appropriate tool to improve standards, the Healthcare Commission has a role in identifying the reasons why some other countries perform better than we do as a means of underpinning changes in UK practice.**

298. We have concluded that one of the most important rationales for the regulation is the protection of the patient. This has two inter-related, elements to it: protection from dishonest practitioners and unsafe procedures; and promotion of the highest clinical standards. In other words, eliminating the bad and promoting the good. While there is a danger that undue attention is given to the first of these, it is not clear what regulation can do to promote best practice. The RCOG defines clinical standards as “standards of clinical care which the College would expect units and hospitals to adopt in relation to the quality of patient services, training opportunities and participation in national data gathering of relevance to clinical accountability and effectiveness”.<sup>396</sup> Dr Kennedy told us that “it is up to the professional bodies, such as the Royal Colleges and other professional organisations, to ensure that the clinical standards and laboratory standards of practice are such that they strive to produce the highest standards of care and the best possible results of practice”.<sup>397</sup>

299. National comparisons paint only a crude picture of the state of assisted reproduction across Europe, not least because of the variation that is likely to exist within countries. It is reasonable, however, to ask what external mechanisms could be employed to close this

395 Q 1286

396 Royal College of Obstetricians and Gynaecologists, *Clinical Standards: Advice on Planning the Service in Obstetrics and Gynaecology*, July 2002

397 Q 1176



perceived gap. Dr Arne Sunde, Chairman of the European Society of Human Reproduction and Embryology, told us that “you cannot use regulation to achieve excellence. Regulations can of course determine what type of treatment is available, prevent the worst cases of malpractice, and define a minimum standard of treatment. To discover the reason for the relative success in countries like Belgium and the Nordic countries, you will have to look at the way infertility treatment is funded and organised”.<sup>398</sup> He suggested that “there is a good case for making economic incentives rather than raising regulatory hurdles if you want to improve treatment”.<sup>399</sup> An alternative perspective is to look at what regulation might be doing to obstruct the promotion of good practice. It is hard to find examples of where the HFEA has been obstructive. Professor Allan Templeton said that there had been “inappropriate inhibitions” on egg freezing but that in general the response to new techniques has “been fair and has been balanced”.<sup>400</sup> This is not the same as saying that the regulatory environment is conducive to the introduction and spread of good practice. The Code of Practice has become the practitioner’s “bible” prompting concerns that by being provided with such explicit guidance, the profession has become passive in its outlook, waiting to be told what to do. Another perspective is provided by the RCOG, which suggests that Code has strayed further into technical matters to fill a void left by the professional bodies.<sup>401</sup> These are not mutually exclusive concerns. It seems likely that in this new area of medicine, assisted reproduction practitioners initially lacked the confidence to push forward change in what was, and still is, a controversial area. The HFEA, in turn, was only too keen to fill the gap, and thus inhibited the profession from developing a proactive approach to best practice. There are welcome signs that this is changing. The HFEA has asked the British Fertility Society and the Association of Clinical Embryologists to develop technical standards as a basis for accreditation and comprehensive draft standards have now been drawn up. **We welcome the increased responsibility taken by professional bodies to draw up and maintain guidelines on clinical and laboratory standards.**

300. One should be cautious in drawing a link between the regulatory regime and the standard of medical practice, since cultural differences between patients and the medical professions could contribute to perceived differences. However, the UK has tighter regulation than many other countries and yet it appears to have failed to match the best practice of neighbouring countries. Of the Scandinavian countries only in Sweden is the practice of single embryo transfer formally promoted through regulation. According to Dr Arne Sunde from the University of Trondheim and Chairman of ESHRE, “To my opinion, there is a correlation between success parameters and the legal situation in the country[...]A strict law and strict regulation is not necessarily beneficial in this respect”.<sup>402</sup>

301. This does not necessarily reflect badly on the HFEA. Nowhere in the HFE Act does it indicate explicitly that the Authority should work to improve clinical standards. Section 8(c) states that the HFEA should “provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply” and Section 25(1) stipulates

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398 Ev 372

399 As above

400 Q 1212

401 Ev 369

402 Presentation to Royal College of Obstetricians and Gynaecologists, 8 October 2004

that its Code of Practice should give “guidance about the proper conduct of activities carried on in pursuance of a licence”. It could be argued, however, that the Authority’s obligation to consider the welfare of the child should require it to promote the highest medical standards. As we discussed above, in Finland the move to single embryo transfer has occurred without direction from a regulator or funder. In these cases practitioners, possibly responding to the well-informed demands from their patients, have taken the decision themselves. In the UK too, it is possible that the professional bodies could have encouraged further change unilaterally. The reasons for their failure to do so may be complex but it may be attributable to the culture that has developed in an emerging sub-specialty as a result of the heavy regulatory burden and intense public interest. Professionals took a passive role in setting standards as everything that governed their practice was contained in their “bible”, i.e. the Code of Practice.

### NICE Guidelines

302. The National Institute for Clinical Excellence (NICE) published guidelines on *Fertility: assessment and treatment for people with fertility problems* in February 2004.<sup>403</sup> The report identified seven “key priorities for implementation”, and four of these relate to IVF provision (see Box 11). The first of these, that within certain criteria, women should be offered three cycles of IVF on the NHS, is the most significant. This has clear resource implication and, in responding to the guidelines, Secretary of State of Health John Reid, stated that he wanted all PCTs to offer at least one cycle of treatment by April 2005 but that he wished the NHS to make progress towards full implementation of the NICE guidelines.<sup>404</sup>

#### Box 11: NICE Guidelines on provision of in vitro fertilisation

- Couples in which the woman is aged 23–39 years at the time of treatment and who have an identified cause for their fertility problems (such as azoospermia or bilateral tubal occlusion) or who have infertility of at least 3 years’ duration should be offered up to three stimulated cycles of in vitro fertilisation treatment.
- Human menopausal gonadotrophin, urinary follicle-stimulating hormone and recombinant follicle-stimulating hormone are equally effective in achieving a live birth when used following pituitary down-regulation as part of in vitro fertilisation treatment. Consideration should be given to minimising cost when prescribing.
- Couples should be informed that the chance of multiple pregnancy following in vitro fertilisation treatment depends on the number of embryos transferred per cycle of treatment. To balance the chance of a live birth and the risk of multiple pregnancy and its consequences, no more than two embryos should be transferred during any one cycle of in vitro fertilisation treatment.
- Embryos not transferred during a stimulated in vitro fertilisation treatment cycle may be suitable for freezing. If two or more embryos are frozen then they should be transferred before the next stimulated treatment cycle because this will minimise ovulation induction and egg collection, both of which carry risks for the woman and use more resources.

403 Clinical Guideline 11, February 2004, Developed by the National Collaborating Centre for Women’s and Children’s Health

404 “Health Secretary welcomes new fertility guidance”, Department of Health press release 2004/0069, 25 February 2004

303. We welcome the more equitable availability of assisted reproduction services and the promotion of best practice in this area by NICE. Comment on the nature of the guidelines is beyond this inquiry but there are implications for regulation. It has been estimated that implementation of the NICE guidelines will result in an 80% increase in the number of live births resulting from IVF (5,400 births) and substantial changes in the IVF industry. However, we note concerns that many PCTs will not be able to meet the NICE recommendations.<sup>405</sup>

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<sup>405</sup> HC Deb, 26 January 2005, Cols 96WH-115WH; NHS Funded IVF: Is It Really So Nice Out There?, Dr Brian Lieberman, St Mary's Hospital, Manchester, BioNews, 14 February 2005

## 7 Review of the Act

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304. On 21 January 2004, the Parliamentary Under Secretary for Public Health announced at the Human Fertilisation and Embryology Authority's annual conference that the Government had decided to review the Human Fertilisation and Embryology Act 1990. The review will be undertaken by the Department of Health, and will include a full public consultation exercise in 2005. The extent of the changes needed to update the Act will not be determined until after the consultation. The Department does not intend that its review will address fundamental aspects of the legislation that are generally accepted in our society, such as the creation of embryos through IVF. Nor is the review intended to address issues that Parliament has recently debated and approved, such as embryo stem cell research and the creation of embryos by cell nuclear replacement for research purposes ('therapeutic cloning').

305. We are pleased at the Department's belated recognition that the HFE Act needed urgent attention. The Minister's recognition of the value of our inquiry is sensible and welcome. We have several comments about the process and scope of the review. First, the fact that the review will not consider fundamental aspects of the legislation. We believe that the Minister is correct that IVF and embryo research are generally accepted in our society; nevertheless we see dangers in conducting a review in which around 20% of the population feel that their view that the embryo is entitled to full human rights at conception is ignored. We have found the comments made by those with a principled opposition to assisted reproduction stimulating and valuable, even when we have not agreed with them. Furthermore, the Government is naïve if it thinks it will not need to address the concerns of a significant number of Parliamentarians. The House divided 366 to 174 in favour of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 on 19 December 2000 and while the composition of Parliament may well have changed by the time the House votes on revised legislation after the next General Election, the Review of the Act will be a more robust process if views on all aspects of the legislation are welcomed.

### Abortion

306. The basis for UK abortion law is the Abortion Act 1967. The issue's inclusion in this report stems from an amendment to the Act in Section 37 of the 1990 HFE Act, which changed the criteria on which abortions could be offered, principally limiting abortions beyond 24 weeks to cases where the mother is at risk of serious injury or death or if the child would have severe abnormalities. Its inclusion here – however briefly – stems from the fact that the status of the human embryo is at the heart of debates about abortion, assisted reproduction and embryo research. At the beginning of this Inquiry, we decided to keep an open mind as to whether to include an assessment of current legislation on abortion. In July 2004, we decided that addressing the abortion issue could hamper our ability to give adequate consideration to reproductive technologies.<sup>406</sup> Nonetheless, discussion of abortion does give a valuable reference point to discussions on preimplantation genetic diagnosis, which was discussed in paragraphs 118–120.

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<sup>406</sup> Science and Technology Committee, Press Notice No. 58 of Session 2003-04, 8 July 2004

307. Our decision not to include abortion should not be seen as a reluctance for Parliament to discuss the issue again. It would also be wrong to assume that pressure to review legislation on abortion comes exclusively from those with a principled opposition to assisted reproduction. The Family Planning Association argues that it is “inappropriate for law in this area to be primarily governed by legislation laid down over thirty-five years ago”. It advocates several changes to the 1967 Act, principally loosening the requirements on those who control access and undertake abortions and the environment in which they take place.

308. The Department of Health is under the impression that revision of the HFE Act would not require it to address abortion. It told us:

“the position as the Department sees it is that section 37 of the 1990 Act does not deal substantively with abortion. It took effect by deleting the existing section 1(1)(a) and (b) of the Abortion Act 1967 and inserting four new grounds for abortion into section 1(1) instead. This happened immediately that section 37 came into force.”

It is not yet clear before the Bill is published that the Department’s view is correct. In any event, we anticipate well supported amendments to any new legislation unless the Government indicates that it is prepared to give Parliamentary time to an abortion bill. There have been no votes on abortion since 1990, yet this is an issue about which many people, on both sides, feel very strongly about. Given that both sides of the debate wish to see change, it is regrettable that this issue will not be considered. It would also be unfortunate if Parliamentary debate was a polarised battle between entrenched positions. **We call on both Houses in the new Parliament to set up a joint committee to consider the scientific, medical and social changes in relation to abortion that have taken place since 1967, with a view to presenting options for new legislation. This committee should be broadly based and should include nominees from the Commons Select Committees for Science and Technology and Health and the Lords Science and Technology Committee.**

309. We started on this Inquiry with the recognition that legislation on assisted reproduction and embryo research needed more regular Parliamentary scrutiny. Professor Allan Templeton, President of the Royal College of Obstetricians and Gynaecologists, told us that abortion law should be decoupled from assisted reproduction and embryo research.<sup>407</sup> We agree that legislating for these activities together, however convenient it may have seemed in 1990, was a mistake and has led to an even greater disincentive to reopen legislation. **We recommend that any new legislation introduced to amend the HFE Act should not include abortion, which should be dealt with in a separate Bill.**

## Surrogacy

310. Existing legislation covering surrogacy arrangements – the Surrogacy Arrangements Act 1985 as amended by the Human Fertilisation and Embryology Act 1990 – is based in part on the conclusions of the 1984 Warnock Report. The Warnock committee took the view that although surrogacy arrangements were to be discouraged because of the potential difficulties, where they did take place, there could be no question of the surrogate mother

being forced by any contractual obligation to give up her child. It is illegal to advertise for surrogates or intended parents. Thus surrogacy is legal in the UK. The main proviso is that no money other than 'reasonable expenses' should be paid to the surrogate. There is no strict definition as what constitutes "reasonable expenses", thus it is left up to the individuals involved in a surrogate arrangement to come to an agreement regarding these expenses. Any costs incurred by a surrogate that are as a result of the pregnancy would be regarded as expenses. The law does not recognise surrogacy as a binding agreement on either party. There is very little that the intended parents can do to secure their position prior to the birth, even in the case of gestational surrogacy where the baby is genetically related to both intended parents and not the surrogate.

311. Professor Margaret Brazier was asked to chair a review of surrogacy arrangements in 1997. The terms of reference covered three specific aspects. First, should surrogate mothers be allowed to receive payment; second, should an agency be established to regulate surrogacy arrangements; and third, do the findings on these issues suggest that existing legislation needs to be changed. Among its recommendations were:

- a) Payment to surrogate mothers should be restricted to legitimate and documented expenses – including loss of earnings;
- b) Any payment over and above legitimate expenses would result in ineligibility for parental orders;
- c) Surrogacy agencies should be registered by the Department of Health;
- d) A code of practice should be drawn up setting out good practice for surrogacy arrangements and this should be binding on all agencies;
- e) The Government should consider introducing new legislation.<sup>408</sup>

These recommendations were not acted upon by the Government. She told us that "I would certainly like to see the question of the regulation of surrogacy looked at again. The report that Alastair Campbell, Susan Golombok and I issued was in 1998, and a great deal has changed" "It would be equally regrettable, I think, now just to pick it up six years later and say, "Let's do something about it," because everything has moved at such a pace."

312. The Government hints in its evidence that surrogacy arrangements will be considered as part of its review of the Act: "The legislative framework for assisted reproduction includes other primary legislation, such as the Surrogacy Arrangements Act 1985 and the Human Fertilisation and Embryology (Deceased Fathers) Act 2003, and several statutory instruments (see Annex A). A number of these are likely to fall for consideration within the Department's review of the Human Fertilisation and Embryology Act."<sup>409</sup> A key concern of COTS (Childlessness Overcome Through Surrogacy), a voluntary surrogacy organisation, has been the payment issue. It claims that the expenses paid to surrogates are significantly higher than the figures declared and argues that payment should be permitted to avoid illegal surrogacy arrangements. It wishes to see binding contracts between the

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408 Department of Health, Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation. Report of the Review Team, Cm 4068, October 1998, pp 71-73

409 Ev 197

commissioning family and the surrogate. **We recommend that the Department includes with its review of the HFE Act an assessment of surrogacy arrangements. This should use the Brazier Report as a starting point and consider what developments there have been since 1998. We regret the Government's inaction. Consideration should be given to introducing separate legislation covering surrogacy.**

### Prelegislative scrutiny

313. Revised legislation will be complex and must be subject to intense scrutiny. Professor Margaret Brazier has concerns about the nature of the 1990 Parliamentary debates. She argues in her written evidence that “The limited nature of the debate on the original Human Fertilisation and Embryology Bill in 1990 meant that some of the basic questions relating to the regulation of fertility treatments were never fully addressed. An emphasis on the legitimacy, or otherwise, of research on embryos distorted debate on the bill as a whole [...] The compromise of “respect” for embryos embodied in the 1990 Act helped to create a philosophical limbo which (in my view) hampered the HFEA in engaging with the tough moral and legal questions that arose between 1990 and 2004”.<sup>410</sup> Parliamentary debates will focus on the more controversial issues and these are not necessarily the most important ones from a legal perspective. This problem cannot easily be resolved but a first step should be to submit a draft Bill to prelegislative scrutiny. The Government will be acutely aware of the problematic passage of the Human Tissue Bill through Parliament. **We recommend that the Government publish any revised Bill on assisted reproduction and embryo research in draft. We recommend that this Bill, and any new Abortion Act, be subject to pre-legislative scrutiny.**

### Free vote

314. The passage of the 1990 Human Fertilisation and Embryology Bill and the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 were characterised by passionate and informed debates in both Houses. A further common feature was that in both cases there was a free vote. This was sadly lacking in the First Standing Committee on Delegated Legislation on 18 May 2004, at which the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 were approved. We asked the Minister whether the Government would allow a free vote on any future legislation. She replied that “it is a matter for the usual channels to decide whether there are free votes on things at the time that the business is being put to the House [...] I do not think we can pre-judge that here”.<sup>411</sup> The Government would do well to reflect on the commitment made by the Conservative Government in 1987 its White Paper that there would be a free vote, over two years before the Bill was introduced.<sup>412</sup> We do not think it unreasonable to ask for such a commitment now for any future legislation. **We recommend that the Parliamentary parties should give a clear undertaking that Members will be given a free vote on any new legislation concerning assisted reproduction and embryo research.**

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410 Ev 367

411 Q 1300

412 See Lords Hansard 7 December 1989

## New legislation

315. The HFE Act is a fairly short piece of legislation, with 48 Sections and four Schedules. Apart from defining a handful of prohibitions, this leaves a large amount of discretion to the HFEA. During the Second Reading debate in 1990, the then Secretary of State for Health said:

“It has been argued that, rather than having a completely independent authority, Ministers should be responsible for these matters. We decided against that, because it would place Ministers and the House in a permanently difficult position if, as a semi-political issue, it was said that Ministers should take this or that view on medical or scientific matters . . . The code of practice of the authority will have to be submitted to the Secretary of State and laid before the House, but some independence in medical and scientific matters is in the interests of Parliament and the Secretary of State.”<sup>413</sup>

The HFEA’s room for manoeuvre can be seen as both its major strength and its biggest weakness. We have seen that by giving the HFEA jurisdiction over what is a “suitable condition” for an embryo to be transferred, it has been able to license PGD despite legal challenge. Professor Kenyon Mason told the committee that “the very real problem is that there is too much in this act that is not in the act but is in the Code of Practice”.<sup>414</sup> The drawback to consolidating more of the code of practice in legislation is that it is less able to respond to changing circumstances. Schedule 2 of the HFE Act sets out the activities for which licences may be granted. Suzi Leather suggested to us that she would like to see permitted purposes of PGD set out in legislation in a similar way to research.<sup>415</sup> These could reflect the eight criteria that the Code of Practice suggests should be considered when deciding the appropriateness of PGD.<sup>416</sup> In paragraphs 73–79 we discuss the development of HFEA policy-making on preimplantation testing. It is instructive to consider what might have happened since 2001 if the purposes for which PGD could be licensed had been set out in the legislation. Let us assume that the list of purposes clearly brought the Hashmi case within the Act but made the treatment for the Whitakers not permissible. The advantage would be that the law was explicit and neither family would have had to suffer the trauma of legal proceedings while looking after a sick child. The disadvantage would be that if the Government wished, on the basis of evidence, to remove the distinction between these cases in law, it would have been necessary to introduce draft Regulations, which in itself is a time-consuming process. Depending on how explicit revised legislation was and the degree to which it permitted regulation-making powers, it is not impossible that new Regulations would be needed on at least an annual basis. Given that many of these would warrant debate in the House, there might be problems in securing sufficient Parliamentary time. While statutory instruments can be used to update legislation, it would be foolish not to acknowledge that in such a contentious area with rapid technical advance in the context of social change, legislation will inevitably date rapidly. We have heard that the HFE Act’s longevity is attributable to the degree of flexibility it allows the HFEA. We have

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413 HC Deb, 2 April 1990, cols 915-20

414 Q 850

415 Q 1241

416 6th edition, para 14.23



recommended that the scrutiny of Parliament is sufficiently important to reduce that freedom. **In our view, Parliament's ability to revisit contentious issues relating to the creation of new life and the permissible uses of human embryos is vital. We recommend that new legislation is more explicit and provides Parliament with greater powers to debate and amend legislation. We propose mechanisms for achieving this in Chapter 9.**

## 8 Legislative and regulatory models

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316. In Chapter 3 we discussed some of the reasons why the state has interest in regulating assisted reproduction. However, a key question for this inquiry has been whether assisted reproduction requires special attention and whether any concerns can or should be addressed by generic regulation. A 2004 report by the Better Regulation Task Force states:

“Classic regulation, in the form of prescriptive rules, is the most common response to a policy problem. Sometimes, this is the best and most direct way to protect people from harm, or it may be a necessary element in implementing an EU Directive. In many cases, however, an alternative form of implementing policy – either on its own, or in conjunction with other methods – may be the better approach. It is often best not to intervene at all.”<sup>417</sup>

317. One reason for close regulation is that the state has some interests in assisted reproduction, as we concluded in Chapter 3, in restricting reproductive freedom if there are demonstrable harm or negative impacts on society. A further reason would be to ensure high standards of treatment. In Finland, which has the highest success rates in the world and had the highest use of single embryo transfer in Europe in 2000, there is effectively no regulation in place.<sup>418</sup> It could be concluded that the single most important factor in determining clinical standards is not regulation as such but the self-imposed standards of the profession. To draw conclusions on the effect of deregulation in the UK requires an analysis of the culture of medical practitioners in these countries.

318. In giving evidence to us, Dr Simon Fishel said that regulation should avoid ethics and focus on the safety of the procedures; the appropriateness of the technology; the efficacy of the technology; and the information given to patients.<sup>419</sup> We have accepted that there needs to be some mechanism for having controls to provide safeguards to individuals and society. However, we accept that the distinction between regulating reproductive decision-making and clinical standards is important.

### Clinical and technical standards

319. We have identified four approaches to regulation in this area:

- a) The extension of the current regime to ensure that all assisted reproductive technologies (including those currently excluded) are covered;
- b) The separation of the scientific or clinical from the ethical or policy aspects of regulation, with the inspection and quality assurance aspects retained by the regulator but questions of ethics and policy placed under the responsibility of a separately constituted body which would advise Parliament;
- c) Deregulation of certain aspects of the provision of services. The regulator would have no policy function but would have a policing and monitoring role. Reproductive

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417 Better Regulation Task Force, *Alternatives to Regulation*, January 2004

418 This is the last year for which comparative data are available.

419 Q 651

medicine would be subject to the usual controls on medical interventions. Embryo research would not require local ethical review and scientific peer review before it was allowed to proceed;

d) Complete deregulation.

320. Professor Martin Johnson from Cambridge University has concluded that some sort of regulation is inevitable so that the starting point for any discussion should be a justification of regulation in terms of its objectives and the ethical principle on which they are based and should allow the expression and creativity of doctors and scientists while allowing responsible choice and self-determination by patients. Professor Johnson draws attention to the formal and informal self regulation that already exists in medical practice. While this has advantages, there is a danger that it is viewed with suspicion by the public. We have also heard concerns that self-regulation could be more conservative, perhaps for this reason. Professor Johnson identifies three deficiencies in the way that the professionals currently operate:

- a) They must be more open and honest about how they conduct and disseminate their findings and recommendations;
- b) They must develop better relationships with their members and improve their ethical and attitudinal education;
- c) They must deal better with mavericks in their ranks.

321. He argues that external regulation should be limited to discrete areas and should follow three principles:

- a) There should be a positive culture between the regulator and professionals
- b) The regulator should work to outcome-based objectives
- c) The regulator should avoid excessive bureaucracy.

### ***Regulation of other medical practice***

322. Since the HFE Act was passed, the regulatory environment for medical practice has changed substantially. Large numbers of bodies have been set up by Government to regulate clinical standards, medicines and healthcare products and equipment and the conduct of healthcare professionals. The current vogue is to merge these bodies and the key organisations are described below.

### ***Medicines and Healthcare Products Regulatory Agency***

323. From 1 April 2003, the Medicines and Healthcare Products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA). It is an executive agency of the Department of Health which aims to protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

324. The draft technical standards produced by the professional bodies demand that: “All procedures shall be validated for their intended use prior to introduction, and the methods used and results obtained shall be recorded.”<sup>420</sup> This requires a process by which new techniques can be introduced. The MHRA’s brief does not currently include medical procedures but we see little fundamental difference between a new drug and a new surgical technique.

### *Commission for Healthcare Audit and Inspection*

325. The Commission for Healthcare Audit and Inspection (the Healthcare Commission) was set up on 1 April 2004 under the Health and Social Care (Community Health and Standards) Act 2003. It replaces the work of the Commission for Health Improvement, takes over the private and voluntary healthcare functions of the National Care Standards Commission and covers the elements of the Audit Commission’s work which relate to efficiency, effectiveness and economy of healthcare.

The Inspectorate will:

- a) Encourage improvement in the quality and effectiveness of care, and in the economy and efficiency of its provision;
- b) Inspect the management, provision and quality of health care services and tracking where, and how well, public resources are being used;
- c) Carry out investigations into serious service failures;
- d) Report serious concerns about the quality of public services to the Secretary of State;
- e) Publish annual performance ratings for all NHS organisations and produce annual reports to Parliament on the state of healthcare;
- f) Collaborate with other relevant organisations including the CSCI;
- g) Carry out an independent review function for NHS complaints.

326. Professor Allan Templeton, President of the Royal College of Obstetricians and Gynaecologists told us that abortion regulation could be usefully compared to assisted reproduction. He suggested that its hands-off, more focused approach, informed by a more professional input into the accreditation system standards with a professional inspectorate had merits.<sup>421</sup> Abortion clinics are inspected and registered by the Healthcare Commission on a 4-yearly basis, although they are charged an annual fee, which might typically be around £3–5k. We understand that the Government wishes the Healthcare Commission to pass on the full costs of regulation to healthcare providers and that the figures currently charged reflect about one third of the full costs. While it might be unwise to make too much of the relative costs of regulating abortion and assisted reproduction facilities, a large IVF clinic could face regulatory bills in excess of £100,000.

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420 February 2004, para E 2.2

421 Q 1165

### *Relationship of the HFEA with other regulators*

327. The HFEA says it is its aim to minimise duplication and to pool efforts and resources wherever practicable. It says it is doing this by:

- a) Working closely with professional bodies and associations linked to assisted reproduction and developing agreed protocols on the conduct of inspections.
- b) Agreeing a memorandum of understanding with the GMC and working towards similar agreements with other regulatory bodies (such as MHRA and CHAI).
- c) Close liaison with the HGC through mutual co-optation of members and exchange of information.
- d) Active involvement in the MRC's development of protocols for the use of stem cells.

328. The extent of overlap with the Healthcare Commission is the most problematic. The HC has published an agreement between the main healthcare inspection, review and audit bodies in England, aimed at reducing the burden of inspection on frontline healthcare staff. The Concordat commits each organisation to a set of principles which aim to support improvement in health services while minimising disruption and duplication, ensure that information is shared appropriately and encourage joint inspections. The HFEA reveals in its 2003–04 Annual Report that it is holding discussions with the HC to eliminate duplication.

### **Ethical oversight**

329. It is important to establish what we mean by ethics in this context. As the Warnock Committee pointed out, medical ethics can be used to describe professionally acceptable practice or the principles upon which these practices are based. The distinction is important since the former could be considered to be an element of good medical practice, such as the way consent is achieved or description of the duty of care owed to patients. However, ethics can also be evaluated from the perspective of the principles which underpin the enterprise itself, and we have been concerned to engage with the latter interpretation. Ethical oversight of assisted reproduction and embryo research can take place at several levels. Legislation can set out boundaries, national guidelines can then be set out by the HFEA. The conduct and scope of clinicians' and researchers' work can also attract the attention of local ethics committees, of which there are two forms, for research and for the consideration of clinical cases. Currently, national guidelines are drawn up by the HFEA.

### **Research oversight**

330. A research project involving human embryos has three bureaucratic obstacles it must overcome before it can proceed. It must have an HFEA licence, it must satisfy a local ethics committee and it must have funding. The HFEA has the power to grant research licences for up to three years for individual research projects. All licence applications, renewals and progress reports are evaluated by an HFEA Licence Committee. Research ethics approval must have been sought from a properly constituted research ethics committee (REC)

before an application is made. The HFEA then initiates peer reviews which determine whether the application:

- a) Comes within the statutory purposes of the HFE Act;
- b) Requires human embryos to fulfil its aims and objectives;
- c) Requires the numbers and types of embryos described in the application;
- d) Meets the requirements of the HFEA's Code of Practice.

331. In theory, the HFEA Research Licence Committee does not give ethical approval, merely decides whether the proposed research comes within the eight purposes set out in Schedule 2 of the HFE Act and conforms to its provisions in Section 15 on the conditions of research licences and consent (Schedule 3). As the HFEA's Chair, Suzi Leather, put it, "There are ethical dimensions, of course, to the work we do; but essentially we implement the wishes of Parliament. The legislation does not contain any explicit ethical principles".<sup>422</sup> We asked the HFEA for what reasons research licences had been refused. It gave three examples:

- a) Because there was no "research" angle, and the application was effectively about training ICSI or embryo biopsy practitioners (not within the law to grant such a licence, but we have flagged up that we would like to be given power to give such licences).
- b) Because the applicants couldn't demonstrate the required ability to select spermatids reliably.
- c) Because the Committee felt that the proposal was of "poor experimental design".<sup>423</sup>

332. Research ethics committees are well established in the UK and an English network now operates under a central committee called the Central Office for Research Ethics Committees (COREC) (see Box 12).

**Box 12: Functions of the Central Office for Research Ethics Committees (COREC)**

co-ordinates the development of operational systems for local and multi-centre Research Ethics Committees (LRECs and MRECs), on behalf of the NHS in England;  
 Maintains an overview of the operation of the research ethics system in England, and alerts the Department of Health and other responsible authorities if the need arises for them to review policy and operational guidance relating to Research Ethics Committees;  
 Manages the MRECs in England;  
 Develops and manages a national training programme for REC members and administrators in England;  
 Maintains close contact with officials in the Department of Health with policy responsibility for wider issues of research ethics and with colleagues from Northern Ireland, Scotland and Wales;  
 With appropriate advice, develops, implements and maintains operating procedures and standards for RECs that will be consistent across the UK;  
 Establishes and manages regional Offices of Research Ethics Committees (ORECs) to oversee the activity of LRECs;  
 Provides advice to the Department of Health on the implications and practicalities of transposing the European Clinical Trials Directive in the UK.

422 Q 1270

423 Ev 431

333. Professor Robert Edwards highlighted the importance of RECs during his work: “When IVF started there were hardly any ethical committees in hospital. It was a sort of American invention that was entering our practice, and when I started working with Patrick Steptoe we had to strengthen the ethical committee. It was doing nothing. We had to make it much stronger, and we had to tell someone else to appoint the people otherwise we were biasing it towards ourselves. I think in those days you talked to your colleagues and your friends and your doctors and you decided things were safe and you had to make a lot of decisions by yourself, and this is what we had to do, but at every step we took immense advice from everybody.”<sup>424</sup>

334. Professor Neil McClure from Queen’s University Belfast told us that “the whole ethics structure within the United Kingdom has changed so much there is no need any more to have the HFEA regulating basic research projects. They will be very tightly regulated by the local ethics committees and by the research governance societies”.<sup>425</sup> Dr Veronica van Heyningen, a geneticist who contributed to our online consultation, also suggested that there was too much oversight: “the levels at which the barriers are drawn should be different for laboratory science and for putting it to practical use and there should be a very rigorous barrier of testing before something is taken from the lab to the clinical side”.<sup>426</sup>

335. However, there are a number of concerns about the way RECs operate. There are around 200 in the UK and they are not universally admired, perhaps not surprisingly since they are likely to impose a burden on clinical researchers. There are a number of criticisms that have been levelled at them:

- a) There are major variations in the way they operate.
- b) Delays in approval may inhibit research
- c) Committees are risk averse and fail to recognise the benefits to patients

336. These issues cannot be ducked and in recognition of this, Lord Warner of Brockley, Parliamentary Under Secretary of State (Lords) has asked Michael O’Higgins, a managing partner of PA Consulting Group Ltd, to review the systems that support NHS Research Ethics Committees in England, and make recommendations for further steps to improve their operation, building on changes already under way. It is due to report to Health Ministers by the end of March 2005.<sup>427</sup> We look forward to reading Mr O’Higgins’s conclusions.

337. During our visit to Sweden we heard that in January 2004 an Ethics Review of Research Involving Humans Act came into force. It created a new organisation of six independent regional boards for research ethics review, each chaired by a judge, as well as a Central (National) Board for research ethics review. The only requirement on researchers wishing to undertake research using human embryos is that their proposal is accepted by

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424 Q 1057

425 Q 31

426 Q 227

427 Lord Warner, Written Ministerial Statement, 17 November 2004

their local committee, and even here the emphasis is on the protection of the donor, since this is not required if the donor cannot be traced. The research ethics committee has to judge whether the project is scientifically sound and defensible in terms of the knowledge it will generate and to make certain that subjects are given enough information about what participation entails and give their consent to participate in a satisfactory manner.

338. If an embryo research project requires external funding it is likely that it will have to go through the scientific peer review process. The major funder in the UK is the Medical Research Council. The MRC's assessment of any research proposal is based on three core criteria:

- a) Importance: how important are the questions, or gaps in knowledge, that are being addressed?
- b) Scientific potential: what are the prospects for good scientific progress?
- c) Resources: are the funds requested essential for the work, and do the importance and scientific potential justify funding on the scale requested?

In addition, MRC Research Boards are asked to identify any ethical issues or risks to human participants, that need further attention.<sup>428</sup> We presented some of the reasons why the HFEA had refused embryo research licences. These are problems that we would expect peer reviewers to pick up. Indeed, it is likely that this exactly what happened, thus in these cases, the HFEA licensing process apparently added nothing to the refusal of the application.

339. It is worth considering whether the combination of scientific peer review and local ethical oversight could fulfil the Warnock Committee's desire that embryos should not be used frivolously for research. An obstacle would be that the research purposes currently in Schedule 2 of the HFE Act are open to interpretation, particularly with regard the use of the term "serious disease" and the extent to which basic research can be licensed. In this respect, the licensing process places compliance with the legislation in the lap of the HFEA. As Suzi Leather put it, "There are very complex issues that our licence committees have to look at. The lawyers would do terribly well if you asked local ethics committees to do our job".<sup>429</sup> This supposes that the law remains the same. A problem with the eight research purposes listed in Schedule 2 is that they are open to interpretation – by lawyers. The issue here is whether legislation needs to specify the purposes for which research on embryos can be undertaken. The aim of Schedule 2(3) is to spell out what Parliament considers to be the ethical use of embryos, yet this should not be beyond the abilities of a properly constituted local ethics committee. The Act, as amended by the 2001 research purposes regulations, effectively says you can do research on embryos if you have a good reason for doing so, provided that they are allowed by the prohibitions in Sections 3 and 4. The MRC's guidance to its review panels makes it quite clear that it will not fund research unless there is a good reason for doing so.

340. Rather than demand that a research project conforms to certain research purposes, legislation could instead specify the processes used by ethical committees with regard to

428 [www.mrc.ac.uk](http://www.mrc.ac.uk)

429 Q 1268



embryo research and the issues they need to consider. It is worth remembering that the vast majority of RECs will never see an embryo research proposal. The HFEA currently lists 30 licensed research projects and some are held by the same institution (the most recent annual report says that there are 24 centres holding research licences, of which 17 also provide treatment and storage). Thus the embryo research community is not large, notwithstanding the growth in embryonic stem cell research.

341. There are, however, advocates of the present system in the scientific community. Professor Alison Murdoch described the current system as the single most important reason why we have taken a lead worldwide in stem cell research and Professor Roger Pederson thinks that “the HFEA works and that it is a huge part of the engine that drives forward stem cell research”.<sup>430</sup> Nevertheless, any mechanism that can offer a less bureaucratic approval process is worth further consideration. **We recognise that there need to be some prohibitions on research in law, as we set out in Chapter 9, but we think there is much merit in a system of local oversight to provide faster, more proportionate, oversight of research on human embryos.**

### ***Oversight of treatment***

342. Clinical ethics committees (CECs) are less established than their research equivalents. While there has been a rapid growth in recent years, there are currently only 68 in the UK, most of which are in acute trusts. They have three principal functions:

- a) Provide advice to health professionals on individual cases;
- b) Provide ethical input into trust policies and guidelines;
- c) Facilitate ethics education for health professionals within the trust.

Professor Doyal from Queen Mary, University of London says that CECs can play a valuable role in disseminating national guidance, which has been presented in long documents and may not be readily assimilated by busy clinicians. He has considered some of the reasons why CECs are less prevalent than their research counterparts:

- d) Concerns that the collective character of CECs will contaminate the doctor-patient relationship because of its dependence on the trust patients place in their individual clinicians;
- e) Concerns that individual clinicians might abnegate personal responsibility for difficult ethicolegal decisions through becoming overly reliant on CECs;
- f) Concerns that “decision making by committee” may be ineffective; and
- g) Opposition from senior clinicians who resent the idea that they might need ethicolegal support and advice from colleagues who are in different specialisations or have no medical training at all.<sup>431</sup>

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430 Q 1112

431 Len Doyal, Clinical ethics committees and the formulation of health care policy, *Journal of Medical Ethics*, 2001; 27:i44-i49

343. Many assisted reproduction clinics have their own dedicated ethics committee. While the HFEA provides no guidance in its current Code of Practice on what form CECs should take, Professor Henry Leese, a former member of the Authority, told us that “we would always look at the constitution of the ethics committee. It was one of the questions. ‘Do you have a properly formulated ethics committee?’”<sup>432</sup> Anne Slowther and Tony Hope from the Ethox Centre at Oxford, which has been awarded an NHS grant to set up network of CECs, argue that “Ethics support at unit level is valuable despite the existence of a national statutory body (the HFEA)”<sup>433</sup> Professor Doyal says that in assisted reproduction CECs can advise on how best to implement professional and legal guidance on all forms of treatment and genetic screening.

344. It is possible that clinical ethics committees could be valuable in aiding clinical decision-making. However, their national provision is uneven and there would need to be a national framework for committees, setting out their composition and working practices. Professor Len Doyal has concluded that “Provided that CECs work to such principles and their members are trained to do so then there is every reason to believe they can make an extremely positive contribution to improving clinical practice and the general quality of health care”. This view, however, is not universally shared, and research is currently under way to evaluate the impact of CECs on the delivery of healthcare services. Funded by the Wellcome Trust, the outcome of this research will not be available until 2007.

345. It would be tempting to seek to combine local research and clinical committees but Dr Slowther and Professor Hope explain that CECs have distinct functions and should therefore remain distinct.<sup>434</sup> While RECs are decision-making bodies, preventing or allowing research, CECs are constituted to help clinicians make decisions. **There are merits in the creation of a nationally coordinated network of clinical ethics committees to parallel the arrangement for local research ethics committees. Should the evaluation of these committees demonstrate their value, they should be provided with national guidelines for their conduct in the area of assisted reproduction but their decisions should be directed needs of patients and the families and the concerns of health care professionals.**

### **National committees**

346. The creation of a national bioethics committee is favoured by many with a principled opposition to assisted reproduction, who feel that they have no national forum to express their views since successive Secretaries of State for Health have refused to appoint Authority members who are not sympathetic to the HFEA’s aims. Cardinal Cormac Murphy-O’Connor, the head of the Roman Catholic Church in England and Wales, was reported in the Daily Telegraph as saying: “I am hearing from all sides a growing demand for major bioethical decisions to be subject to greater scrutiny by Parliament, and for there to be proper public discussion and awareness of what is at stake.” He said that the HFEA was “not an adequate body” for dealing with the implications of many of the latest technological advances. “Many of the HFEA’s rulings are causing deep public disquiet.

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432 Q 1088

433 Ev 402

434 Ev 401

People do not understand the thinking behind them. They see them as contradictory and perplexing". The Cardinal said he would like to see a national bioethics committee of the sort that exists elsewhere in Europe and the United States. He said it could be made up of moral philosophers, theologians and ethicists, as well as scientists and IVF clinicians.<sup>435</sup>

347. CORE argues that the UK should set up such a national bioethics council, with a focus on philosophers, theologians and qualified ethicists rather than scientists: "Such a group, far removed from any possible accusations of conflict of interest, would address the ever-increasing ethical issues arising in the field of reproductive technology and stem cell research, and report its conclusions for the benefit of Westminster and the country at large." CORE cites the President's Council on Bioethics, set up by George W Bush in November 2001, as a model for such a council (see Box 13 for examples of national bioethics committees).

**Box 13: National bioethics committees**  
**US President's Council on Bioethics**

The Council is composed of not more than 18 members appointed by the President from among individuals who are not officers or employees of the Federal Government. The Council includes members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences. Its functions are:

to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioural science and technology;

to explore specific ethical and policy questions related to these developments;

to provide a forum for a national discussion of bioethical issues;

to facilitate a greater understanding of bioethical issues; and

to explore possibilities for useful international collaboration on bioethical issues.

Unlike the HFEA it has no statutory powers. Since members are appointed directly by the President there have been accusations of political and ideological bias.

**French National Consultative Ethics Committee for Health and Life Sciences**

French National Consultative Ethics Committee for Health and Life Sciences's mission is to give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine, and health. The National Consultative Ethics Committee is now an independent authority and is composed as follows: the President, nominated by the President of the Republic, an Honorary President, and 39 members. Five of these members are drawn from the main philosophies and religious faiths and are designated by the President of the Republic. Nineteen members are chosen because of their qualifications, competence, and their interest in ethical issues. Fifteen members are engaged in scientific research. The Committee publishes around five "opinions" a year. Opinions in 2004 include: Composite tissue allotransplantation of the face; the generalised prenatal screening for cystic fibrosis; and Opinion on education in medical ethics.<sup>436</sup>

348. It has emerged that there were discussions as part of the review of arms' length bodies on the creation of a national bioethics committee because some of the functions of arms' length bodies could have been vested in such a committee. The Nuffield Council on Bioethics wrote to Lord Warner at the Department of Health setting out its concerns that it might be asked to form part of a National Bioethics Commission.<sup>437</sup> It argues that national bioethics commissions can often be asked to tackle "short term issues of narrow scope" and

435 Cardinal demands tougher scrutiny over fertility research, *Daily Telegraph*, 20 December 2004

436 [www.ccne-ethique.fr](http://www.ccne-ethique.fr)

437 This private letter was sent to the Chairman. The Nuffield Council did not wish to make this public but instead made a written submission to the Committee (Ev 394) outlining their concerns on this issue.

“tend to be heavily politicised”. The Government ultimately concluded that the current distributed system remains the best option as it provides for specific bioethical issues to be addressed by dedicated groups who are able to concentrate on the relevant field in question.

349. It is not possible to present simple arguments for and against a national bioethics committee. As Sarah Elliston from Glasgow University pointed out, “there are very many different models of a bio-ethics committee and a bio-ethics commission that we could actually follow and each of them would have different implications.”<sup>438</sup> Professor Margaret Brazier from Manchester University, while indicating that she thought a national bioethics committee should be considered by the Government, but that there should be substantial research into how such committees and commissions operate in other jurisdictions where they have been set up. She told us that there were a number of holes into which they can fall:

- a) They can simply be talking shops;
- b) They can be hugely expensive bureaucracies; or
- c) They can become extremely politicised.<sup>439</sup>

350. Professor Brazier’s first point can be addressed by clearly defining the role of the committee. If they are simply left to operate detached from practice and regulation then there must be a danger that well meaning reports will be considered as worthy and inconsequential and dutifully filed. Alternatively, if these committees have statutory powers then their output will be highly relevant. If this is the case then it is likely that there will be fewer concerns about cost.

351. The suggestion that appointments are heavily politicised has been an accusation levelled at the US President’s Council on Bioethics, which is seen as weighted towards those with a principled opposition to assisted reproduction and “thereby lost all credibility in the medical and bioethics community”.<sup>440</sup> This can, however, be overcome by removing the political control over appointments. We have heard that members of the HFEA are no longer appointed by the Secretary of State for Health but by the NHS Appointments Commission.<sup>441</sup> If a bioethics committee were appointed in this way we would consider this sufficient protection against political interference.

352. Professor Donna Dickenson from Birkbeck College argues that even if a national bioethics committee were set up, “an updated regulatory authority, accompanied by a national bioethics committee but not replaced by it, is absolutely essential to deal with the rapid evolution of new reproductive technologies”. She points out that in France a new statutory national biomedicine regulatory authority has been set up to work alongside its 20-year-old national ethics committee.<sup>442</sup> This system may have advantages. In the UK, the

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438 Q 899, Ev 394

439 Q 899

440 Ev 400

441 Q 1257

442 Ev 399

regulator could be left to deal with technical and quality management issues, the “boring bits”, while an ethical committee with teeth sits above it and provides direction on ethical policy issues. This would satisfy the demands of the British Fertility Society that policy be separated from policing. A drawback would be that the role of a wide ranging bioethics committee with executive functions would not sit easily with a number of other regulatory bodies that might fall within its remit, e.g. Gene Therapy Advisory Committee (GTAC), the UK Xenotransplantation Interim Regulatory Authority (UKXIRA) and the Unrelated Live Transplant Regulatory Authority (ULTRA). While this could be addressed by limiting the jurisdiction of the ethics committee, **we believe that the Government is correct that smaller advisory committees with specific briefs would be more effective. Nevertheless, we favour the rationalisation of these committees where there is clear overlap and human genetics and embryology fall into this category. We recommend the formation of a single commission to develop policy issues relating to the assisted reproduction, embryo research and human genetics.**

### *Local vs national oversight*

353. Decisions made at a local level have the advantages of speed and proximity to the clinical setting. National deliberation has the advantages of consistency and of being placed in the context of national debate. We have favoured the first approach as long as there is a national forum where ethical issues can be discussed. There are two major drawbacks of local decision-making, however. The first is that judgements will be inconsistent and the second is that the threat of legal challenge will paralyse research and treatment services. Inconsistency is already a concern among clinical researchers.

354. Both of these can be tackled by specifying in law the processes that local committees work by but not including provisions that are open to interpretation. For example, the legislation could demand that research proposals have been peer reviewed but not that the research must be for a particular purpose. In the clinical setting, a local committee could be asked to consider the wider implications of the treatment but would not be asked to make subjective judgements, for example as to what constituted a serious disease. The consistency and transparency of operations, should ensure the confidence of clinicians, patients and the public. A charge that has been levelled at research ethics committees is that they are inconsistent and bureaucratic. However, the Department of Health, COREC and the Association of Research Ethics Committees are working to improve standards. The solution is not necessarily one or the other but their roles would need to be clearly defined. They can have distinct roles or they can be hierarchical whereby difficult cases can be referred upwards for national consideration. Professor Donna Dickenson believes that the later approach can cause difficulties since it can introduce lengthy delays to decisions that need to be taken as soon as possible. **Any national policy-making committee should not attempt to interfere with individual clinical decisions. If the value of local clinical ethics committees can be established, they should be given a defined brief that clearly distinguishes their role from the Commission, which should issue guidelines for their operation .**

## Role of Parliament

355. In our Report *Developments in Human Genetics and Embryology* in 2002, we took issue with the assertion by Ruth Deech (the outgoing chair) that the HFEA's decision on PGD "protects Members of Parliament from direct involvement in that sort of thing".<sup>443</sup> We argued that Parliament does not need to be protected and democracy is not served by unelected quangos taking decisions on behalf of Parliament.<sup>444</sup> During this inquiry, our view of a strengthened role for Parliament has been widely supported. Professor Kenyon Mason of Edinburgh University argued that "the great deal of thrust really ought to be by parliamentary decisions, if it could be done; but it would be a matter of parliamentary technique rather than anything else."<sup>445</sup> Dr Sue Avery of ACE said that sex selection and cloning "are not issues to be decided by a committee; they are issues for Parliament" and Ms Philippa Taylor, a contributor to our online consultation, told us that "there are some obvious weaknesses in the HFEA and I would want to see Parliament's role superseding that of the HFEA in difficult cases".<sup>446</sup> The All-Party Parliamentary Pro-Life Group argues that Parliament needs to do more to engage in debate on sensitive bioethical issues: "It is simply not good enough for Parliament to legislate in this field and then wash its hands of the matter for a decade or so".<sup>447</sup>

356. The problem remains of the level and type of intervention. An arms' length body such as the HFEA has certain advantages. It is insulated against political pressures and vagaries and, as Professor Kenyon Mason commented, it can make changes fairly rapidly. Dr Richard Fleming, a contributor to our online consultation, agreed: "There is a comfort zone about having some level of framework within which all of these things operate and I think that is right".<sup>448</sup> Professor Margaret Brazier argued that "It would be entirely impossible for Parliament to intervene at every possible stage. [...] it is very difficult, even with hindsight, to identify a particular time and think, "Ah, that is the boundary that never should have been crossed."".<sup>449</sup> The Chair of the HFEA, Suzi Leather, told us that "We have [...] a quieter environment, in a sense, for the cutting edge research, embryonic stem cell research, in this country than, for instance, in the United States. I think that some of that can be put down to regulation".<sup>450</sup> We are not convinced that comparisons with the US are useful. We have no separate authority for abortion clinics yet the UK "climate" is considerably cooler than in the US. We are also aware that public support for embryonic stem cell research in the US is similar to that in the UK.<sup>451</sup> **We remain convinced that a larger role for our democratically accountable Parliament would give the public greater confidence that the big ethical issues of the day are being given adequate attention.**

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443 HC (2001-02) 791

444 As above

445 Q 851

446 Qq 47,128

447 Ev 222

448 Q 225

449 Q 851

450 Q 1241

451 [www.pollingreport.com/science.htm](http://www.pollingreport.com/science.htm); [www.mori.com/polls/2003/amrc.shtml](http://www.mori.com/polls/2003/amrc.shtml)

## Role of the public

357. One of our starting points for this inquiry was the change in social attitudes to assisted reproduction. Professor Martin Richards from Cambridge University comments that any novel technology which artificially intervenes in the natural process of human reproduction will usually be resisted initially and only becomes generally accepted when social benefits are demonstrated in practice and familiarity with its use increases. He cites the birth of Louise Brown in 1978 as an obvious example.<sup>452</sup>

358. One reason for caution in using attitude surveys is that views can change rapidly. The HFEA's 1993 consultation on sex selection reported that 93% of the 165 responses opposed sex selection using PGD for non-medical reasons. In the opinion poll commissioned by the HFEA and conducted in January 2003, 69% did not agree with the suggestion that any parent should be able to choose the sex of their child. While only the more recent survey was an opinion poll using recognised methodology, there is a suggestion that attitudes have become more liberal. This is in line with the comments from Professor Martin Richards, a social researcher from Cambridge, who told us that in the same way that IVF had become more socially acceptable, the same would be likely for other reproductive technologies such as sex selection and cloning. Dr Sarah Parry, a social researcher from Edinburgh, told the Committee that in the case of reproductive cloning, it was possible that public attitudes were not as clear cut as one might expect: "The people I have spoken to were able to think it through and came to the conclusion that maybe it would not be such a bad thing".<sup>453</sup>

359. As pollsters are keen to point out, the answers you get to depend on the phrasing of the question, and also the circumstance. We commented above in paragraph 143 that we did not doubt the accuracy of the HFEA's polls on sex selection, but we were interested to hear the Mastertons tell us they were surprised by the results of the public opinion polls conducted by the HFEA as people they met were universally supportive of their stance. We do not doubt the accuracy of their reports but we suspect that family's tragedy has influenced the local response to their campaign. It would not surprise us that faced with abstract questioning on the uses of sex selection, these same people would offer similar views to those elicited for the HFEA. The HFEA has recently allowed the subjects of treatment licences to make representations should their initial application fail. We will be interested to see what effect this has on their decisions on difficult cases.

360. In our 2003 Report on Developments in Human Genetics and Embryology, we welcomed Suzi Leather's declaration that "[...]". Public consultations are not difficult processes to undertake given experience and good advice. More problematic is how the results are used, and seen to be used. The Christian Medical Fellowship says that "Public consultations must not be just a listening exercise to satisfy the critics [...] the HFEA must respect and be seen to take on board the concerns of individuals and groups who invest huge amounts of time and resources in contributing to the debate, and yet often feel marginalised and excluded from the decision-making process".<sup>454</sup> Comment on Reproductive Ethics (CORE) is concerned about the way the HFEA uses public

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452 Ev 363

453 Q 1026

454 Ev 221

consultation to inform policy. CORE was founded in response to serious dissatisfaction with a 1994 HFEA consultation on donated ovarian tissue, which “having recorded public opinion then virtually ignored it”. Its dissatisfaction has increased over the years and was reinforced following the recent consultation on sex selection.<sup>455</sup> Similarly, the Christian charity, CARE, states that “it has never been entirely clear to us what note is taken of consultations and to what extent they do actually influence decision-making within the HFEA or other bodies”.<sup>456</sup>

361. The HFEA’s consultation on sex selection makes a good case history. As well as disappointing groups such as CORE for having ignored the opinion it elicited, it has been criticised for giving it too much weight. We were aware of these pitfalls in planning our own online consultation and hope we have been able to show how we have used the views put to us to reach our conclusions. At the same time, we made no efforts to quantify the views submitted. We commented above that when the Department sought the HFEA’s view on sex selection, it was not necessarily asking for the public’s view. We believe that the HFEA would have been well-advised to adopt our approach, for having found that a large majority did not wish to see sex selection for social reasons it would have been very brave to conclude otherwise, unless serious ethical debate was engaged in and principles could be identified which justified proceeding on the basis of these rather than the numbers opposed. The Medical Research Council has suggested that the HFEA should consider setting up a citizens council to help guide it through ethical decision-making. This has the attraction of providing ongoing public input. Surveys and opinion polls provide useful input to policy development, but are essentially anecdotal and represent the views of a self-selecting group of individuals; often activists. Additionally, we would caution about using the weight of response to determine the outcome of any policy review.

362. It is instructive to look at the roles that the HFEA does or could conceivably have as a regulator:

- a) Development of technical guidelines
- b) Policy development and ethical oversight
- c) Policing the legislation
- d) Licensing/accreditation
- e) Risk assessment
- f) Collating data on clinical practice
- g) Oversight of new technologies
- h) Providing information to patients
- i) Consulting professionals and the public
- j) Advising central Government

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455 Ev 265

456 Ev 276



k) Providing a forum for public debate

### **Policy and advice**

363. We have discussed above how the combination of the HFEA's advisory role could conflict with its statutory duty to enforce the HFE Act.<sup>457</sup> Similar conflicts arise with HFEA's policy role, according to the British Fertility Society. The BFS wishes to see the separation of the HFEA's policy and regulatory function and its Secretary, Dr Richard Kennedy, suggested to us that the policy function of the HFEA could be merged with the Human Genetics Commission (HGC).<sup>458</sup> We have discussed criticisms of the HFEA from the Lawyers' Christian Fellowship that in making policy the HFEA has strayed beyond its statutory remit.<sup>459</sup> We argued that the HFEA had little choice but to develop a policy function given its brief. This is not the same as concluding that the regulator should be in a position where it has to develop policy. If the regulator was charged with ensuring that technical standards were maintained and that quality management systems were satisfactory then it would have no need to deliberate on, for example, the welfare issues associated with sex selection or PGD. Merely it would check that the processes were in place to ensure that patients were provided with a service that embraced the wider implications of clinical care.

364. Dr Kennedy's view that the HFEA's policy function should be merged with the HGC is shared by Professor Margaret Brazier from Manchester University.<sup>460</sup> The HGC is a well respected advisory body that has made valuable contributions in this area and is currently undertaking a consultation on reproductive decision-making.<sup>461</sup> In the area of PGD in particular there is common ground between the two organisations and the HFEA's Chair is an ex-officio member of the Commission. However, there is an important difference between the HFEA and the HGC. While both may develop policy in similar ways, the HFEA's conclusions become enshrined in its Code of Practice, on which clinics are obliged to comply; the HGC can only recommend, however persuasively. As the HGC is an advisory body, it did not form part of the Department of Health's Review of Arm's Length Bodies in 2004. (The HGC, despite being a joint body of the DoH and the Office of Science and Technology, is not at arm's length, being firmly embedded in the Department.). The Department's basis for its exclusion was because the review "considered primarily those stand-alone national organisations sponsored by the Department of Health undertaking executive functions, which normally have boards, employ staff and publish accounts".<sup>462</sup>

365. It is worth considering whether a statutory policy function is necessary at all. We have declared that the foundation of legislation is to protect as far as possible the reproductive freedom of people wishing to have children. Any declared statutory policy can only erode the freedom of patients to make decisions in consultation with their doctors. Much of the

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457 See paras 209–218

458 Q 40

459 See paras 219–221

460 Q 899

461 Human Genetics Commission, *Choosing the future: genetics and reproductive decision making*, July 2004; [www.hgc.gov.uk](http://www.hgc.gov.uk)

462 Ev 427

HFEA's policy centres around the welfare of the child provision in Section 13(5), yet we have concluded that this is fundamentally discriminatory and should not be part of any future legislation. **There is sufficient overlap between the policy and advisory functions of the HFEA and the Human Genetics Commission to provide a strong case for merger.**

### *Policing and accreditation*

366. At present the HFEA's Code of Practice embraces both technical standards and directions to treatment centres on its interpretation of the HFEA. It is debatable whether the HFEA was ever intended to police the Act and impose technical standards. The fact that it has is not a criticism of the Authority. The assisted reproduction subspecialty was embryonic in more ways than one in 1990 and, while the British Fertility Society (BFS) was formed in 1972, the Royal College of Obstetricians and Gynaecologists (RCOG) comments that "there has been a dearth of any clear standards from either the British Fertility Society or the Association of Clinical Embryologists (ACE) against which inspections could take place. Therefore the HFEA had to draw up its own Code of Practice in this vacuum".<sup>463</sup> ACE commented that "there exists no accreditation body for embryology laboratories. The Clinical Pathology Accreditation scheme (CPA) has expanded its portfolio to include andrology, but does not accredit embryology laboratories as the field is considered "too controversial".<sup>464</sup>

367. In 2004, on the instigation of the HFEA, the BFS worked with the ACE, the British Andrological Society, the Royal College of Nursing and the British Infertility Counselling Association to develop Standards for Assisted Conception Units. These standards reflect a desire to move from a system of licensing to an accreditation process. ACE says that the current HFEA inspection process does not amount to accreditation since insufficient time is spent on inspection and inspector training is inadequate and inappropriate.<sup>465</sup> The development of these standards coincides with the 2004 EU Tissue Directive, which will be transposed to UK law by April 2006.<sup>466</sup> The Directive introduces a skeleton framework for inspection and accreditation, incorporating amongst other things the establishment of a register of accredited establishments, guidelines for inspectors, and the requirement of a notification system for adverse incidents. The BFS is concerned about the duplication of regulation, but concludes that implementation of the Directive "gives an opportunity to ensure that we have robust, consistent and effective regulation".<sup>467</sup>

368. The BFS believes that the professional bodies' standards incorporate and should replace the current HFEA Code of Practice. It recommends that inspection should be carried out by professional inspectors with guidance from the professions and patient groups. During this inquiry the RCOG has undertaken to set up a committee under its auspices (to include the Royal College of Pathologists, the college responsible for embryologist accreditation) to draw up professional guidelines ready for the introduction

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463 Ev 369

464 Ev 244

465 Ev 244

466 Existing licensing centres in the UK have been given a year's grace to comply with the Directive and must comply by April 2007.

467 Ev 214

of any new legislation.<sup>468</sup> The professional bodies' model would require them to be responsible in law for maintaining quality standards in compliance with the EU Directive. We supported the introduction of a professional inspectorate in paragraph 238. **We see great merits in the professional bodies taking control of the technical and management standards and welcome the offer of the Royal College of Obstetricians to take responsibility under the auspices of the regulator in drawing up and maintaining these standards for centres concerned with the provision of storage or treatment services in compliance with the EU Tissue Directive.**

### *ISO accreditation*

369. The international standard for quality measurement is ISO 9001. Its application to assisted reproduction is widespread in Germany and is increasing in the UK, largely since the drug company Serono is funding the compliance by treatment centres. In the UK, ISO accreditation is awarded by BSI, which employs its own inspectors. It has been suggested that ISO accreditation can improve standards of care, including the safety of the procedures and success rates. This route of accreditation offers an alternative to that proposed by the professional bodies. The Department of Health says it has not encouraged or supported clinics to achieve ISO accreditation specifically, although it recognises that the EU Tissue Directive's emphasise on the importance of a 'quality systems' approach is "inspired by and has much in common with relevant ISO accreditation".<sup>469</sup> **If the regulator can be assured that external forms of accreditation such as ISO 9001 comply with legislation following the transposition of the EU Directive into UK law, then such accredited facilities should be free to operate without additional scrutiny.**

### *Risk management*

370. The Epan consultancy, which provides risk management, training and public affairs services to those working in reproductive and genetic technologies, states that risk management in assisted reproduction is of fundamental importance, both for the protection of patients and for progress and the development of good practice in treatment and research. Epan argues that "no-one has accepted responsibility for risk in ART in the UK [...] the HFEA, was never intended to take responsibility for risk management and has consistently maintained that it does not have the resources to conduct the necessary follow-up studies and reviews that constitute an essential part of the process". It compares the HFEA with Canada's Assisted Human Reproduction Agency. Health Canada commissioned a review of all risk in ART (including psychosocial risks) reported in peer reviewed journals around the world. They then used this information to develop a risk management tool which will be used by the regulatory body in policy making, in regulation, and in advising the centres they licence. The tool will be updated so as to assess the risks associated with new reproductive technologies as and when they emerge.<sup>470</sup>

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468 Ev 370

469 Ev 430

470 Ev 347

**Box 14: Risk management and the Incident Alert System**

Epalan believes that “The ‘quality control’ model proposed by the Directive is also more closely related to risk management and risk assessment so the transition would be easily made.”<sup>471</sup> In response to the Toft Report on adverse incidents in Leeds, the HFEA announced an Incident Alert System in September 2003 to warn clinics about any incident which could have an adverse effect on patient care and staff safety. It will be the duty of the Person Responsible in each clinic to check their equipment or procedures and take avoiding action so that mistakes are not repeated. The warning system came in response to a number of incidents involving either equipment failure or human error. It is hoped that the alert system will reduce the risk by enabling clinics to change the way they work. The type of incidents that would trigger an alert include equipment failure such as the freezer malfunction in the Western General Hospital in Edinburgh which led to the destruction of some sperm samples and human error such as the misreading of patient’s name labels on sperm samples which happened at Leeds General Infirmary in the twins mix up case. The HFEA requires Persons Responsible to ensure that any incident is reported to the HFEA without delay. An adverse incident means anything relating to treatment services which is potentially harmful or actually causes harm to any person, embryos, gametes or staff. In an average month about five incidents are reported to the HFEA. Typically these relate to equipment failure or breaches of protocol which cause serious concern but haven’t done any actual harm. The Alert will be sent to all 110 licensed centres, HFEA inspectors and professional bodies such as British Fertility Society (BFS) and Association of Clinical Embryologists (ACE).

**Role of clinicians**

371. Opinion polls conducted by MORI on behalf of the British Medical Association have been tracking public trust in the professions for 20 years. Trust in the medical profession has risen steadily since 1983 from 82% 20 years ago, to 91% in 2003. This is higher than for any other professions that have featured in the polls.<sup>472</sup> Nevertheless, we have heard concerns from within and without the profession. Mr John Ford, a contributor to our e-consultation told us that “I do not know exactly what they are doing and were we to leave it up to them to regulate themselves I think they would decide to do what they wanted to do”. It is interesting that he drew a distinction between the medics on the ground, who described as “superb” and those working in the “background”.<sup>473</sup>

372. There are concerns from within the profession too. Vivian Nathanson of the BMA told us that “the fact that there is a strong regulatory framework helps to encourage public support for people who would otherwise, perhaps, sit on the fence”.<sup>474</sup> Dr Martin Briggs is concerned that doctors do not always have an objective view of patients’ quality of life, arguing “our ‘expert’ view as doctors of patients quality of life is heavily biased through being based mainly on our meeting them at the lowest points in their life i.e. when they are very ill and suffering[...] doctors should not be regarded as having ‘expert knowledge’ of the day-to-day reality of patient’s lives such as to justify ‘authoritative pronouncements’ on the subjective quality of life of our patients”.<sup>475</sup> An interesting feature of the evidence we have received from three medical bodies – the British Fertility Society, the Royal College of Obstetricians and Gynaecologists and the British Medical Association – is that the broader the remit of the body, the more cautious and conservative their views on assisted reproduction.

471 Ev 349

472 [www.mori.com/polls/2003/bma.shtml](http://www.mori.com/polls/2003/bma.shtml)

473 Q 153

474 Q 816

475 Ev 206

373. Jayson Whitaker, who sought preimplantation testing to conceive a child who was a tissue match for a sick sibling, told us “I think that, to a certain extent, [clinical decisions] should be left to the patient and the doctor but there does need to be some voice of reason in there. What I am not advocating is *carte blanche* to go off and have PGD for anything you fancy. There should be some voice of reason but not as regulated as it is at the moment.”<sup>476</sup> Mr Tony Gilland, a contributor to our online consultation, told us that that responsibility for decision-making should shift away from the public and the experts to the individuals concerned.<sup>477</sup>

374. The independence of doctors to respond to the problems of their patients is at the heart of the welfare of the child debate. We have heard concerns that there is a danger that doctors, in feeling sympathetic to patients’ fertility problems, lose sight of the bigger picture. Dr Alexina McWhinnie and Professor Alastair Bissett-Johnson from Dundee University quote Peter Brinsden, Medical Director at the Bourne Hall Clinic:

“It is impossible for us as caring individuals not to be strongly influenced by a couple’s particular needs, and yet there may be a conflict between what we believe may be the best option for them and what is ‘right’ or ‘ethical’ to society [...] It is possible for us clinicians in particular to become so ‘wrapped up’ in what we perceive to be best for the couple that we do not see the wider picture’.”<sup>478</sup>

Dr McWhinnie and Professor Bissett-Johnson use this to counter arguments for reproductive freedom. In our view this provides a strong argument for the use of clinical ethics committees to provide a broader input into clinical decision-making.<sup>479</sup>

## Review of arms length bodies

375. The Department of Health undertook a review of its arms-length bodies including the HFEA. The review is aimed at reforming the arms-length body sector to achieve the objectives of:

- a) maximum devolution of responsibility to front line NHS and social care
- b) improved efficiency across the sector with minimal bureaucratic overhead
- c) closer working across boundaries between health and social care; and
- d) minimised burden of inspection and regulation on health and social care services without reduced effectiveness.

The Secretary of State has decided that, against a baseline year of 2003/04, the parameters for the review should be:

- e) a 50% reduction in the number of arms-length bodies
- f) a saving in expenditure by arms-length bodies of £0.5 billion by 2007/08; and

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476 Q 589

477 Q 155

478 Ev 409

479 Ev 408

g) a reduction in posts of 25% in the same period.

The Department of Health's Report on Reconfiguring the Department of Health's Arm's Length Bodies concluded that the HFEA should be merged with the proposed Human Tissue Authority to form RAFT (Regulatory Authority for Fertility and Tissue).<sup>480</sup> According to the Report, the merger reflects the many similarities between the HFEA and the HTA, both of which are designed to:

- h) be competent authorities under the EU Tissues and Cells directive
- i) regulate ethically sensitive areas
- j) focus on technical matters of safety and quality
- k) set standards
- l) enforce compliance
- m) cover research as well as therapy
- n) cover settings outside healthcare, e.g. sperm banks (HFEA) and university anatomy schools (HTA)
- o) operate UK wide

376. The creation of RAFT requires primary legislation. The aim is to start up RAFT by 1 April 2008, merging HFEA and HTA in the process. In the meantime a minimalist HTA (shadow board by April 2005 and an ENDPB by April 2006) will be set up using HFEA accommodation and corporate services. HTA Chair and members will be recruited for the period 2005–2008. A shadow RAFT will be set up in 2007–08. The merger has not been universally popular. The solicitor James Lawford Davies told the Committee “I think it was a moment of reckless abandonment to suggest that the HFEA and the Human Tissue Authority should be joined together”.<sup>481</sup> According to Professor Margaret Brazier, this is “profoundly misguided” and “RAFT will either have to be so large that it cannot function effectively or any expertise in its diverse subject matter will be so dilute as to be useless. Lay representation will become tokenism. The subject matter which the proposed partners in RAFT will address is entirely different”.<sup>482</sup> She told the Committee “I think it would be disastrous to merge the two authorities.”<sup>483</sup> Suzi Leather, Chair of the HFEA, wrote to the Department of Health on 7 June expressing the Authority's concern at the review, citing the HFEA's “vital, highly specialised functions in an area of acutely sensitive and highly contested public policy” and setting out 10 reasons for retaining the status quo. If there was to be radical change, she said, “the best option would be to merge the HFEA with the Human Tissue Authority”. Ms Leather is now more in favour, describing the merger as “sensible”.<sup>484</sup> We have argued for the rationalisation of advisory bodies in the past as they

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480 Department of Health, Reconfiguring the Department of Health's Arm's Length Bodies, July 2004

481 Q 891

482 Ev 367–368

483 Q 892

484 Q 1278

have a habit of springing up to plug holes without proper consideration.<sup>485</sup> Our concern here is that the exercise has more to do with the political need to portray Government as lean and efficient. More specifically, we have concerns that the merger will hamper any progress in reforming the regulation of assisted reproduction and embryo research. **The creation of the Regulatory Authority for Fertility and Tissue seems to be the result of political pressure to be seen to be reducing bureaucracy rather than a logical move . Nevertheless, we share the Department’s wish to see fewer appendages to central Government and recognise that the merger of the regulatory functions of the HFEA and the HTA has its merits as long as its implementation recognises that there are big differences in the activities they regulate, as well as similarities. However, its activities should be restricted to the oversight of assisted reproduction to technical standards and quality management.**

### International dimension

377. The Warnock Committee recognised that the problems it faced were not confined to the UK and accepted that there was “an obvious attraction” in pursuing an international approach but noted that “Different countries [...] have different cultural, moral and legal traditions, influencing the way a problem is tackled and the ways in which it might be resolved”.<sup>486</sup>

### Harmonisation of legislation

378. There are two reasons why one might wish to harmonise legislation in assisted reproduction and embryo research on a regional or global basis. First, for practical reasons to ensure common standards and definitions and, second, to develop common ethical standards. At a European level the problem is what competence the EU has to pass such laws. Clearly the Tissue and Cells Directive will have an impact<sup>487</sup> but it is doubtful if that could or should be replicated in relation to, say, treatment services.

### International monitoring programmes

379. Sweden has established two permanent and independent systems to monitor assisted reproductive technology outcomes. Furthermore, several national ad hoc research projects have been conducted using information from these two national databases.<sup>488</sup> A World Health Organization conference in 2001 identified the need for more national and international IVF registries. The Medical Research Council says that harmonising international monitoring programmes would provide the “maximum statistical power particularly for the analysis of putative adverse events”.<sup>489</sup> In the UK such a registry would require changes to the HFE Act. Section 33 demands that no member or employee of the HFEA disclose any information held on its register. **We have recommended that the**

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485 HC (2001–02) 791

486 para 1.8

487 See paras 84, 89, 236–238, 368–370, 386

488 Karl Nygren, The Swedish experience of assisted reproductive technologies surveillance, *In Current Practices and Controversies in Assisted Reproduction*, WHO, 2002, Section 6

489 Ev 436

**confidentiality provisions in the HFE Act need to be relaxed. This should be accompanied by efforts to use UK data to inform the international monitoring of the risks of assisted reproduction.**

### *Trade in gametes*

380. Professor Donna Dickenson from Birkbeck College, London has drawn our attention to the global trade in oocytes as a result of their shortage for IVF purposes and their value in stem cell research. She states that payments of up to \$50,000 per cycle have been reported, with up to 70 oocytes being extracted in some cases. It seems highly likely that poor women in the Third World and in Eastern Europe will be the targets of this trade. Professor Dickenson points out that the HFEA has taken some steps towards attempting to regulate this international trade, for example by overseeing procedures under which ova are imported from Romania, but it is clear that some international oversight will be necessary.

**381. We see major advantages in creating international standards in the handling and export of human gametes and embryos to improve the consistency and quality of procedures, protect those at risk of exploitation and improve the monitoring of treatments and risks.**

### *Reproductive tourism*

382. The lack of international legislation means that individuals can and do seek treatment abroad that they cannot in their own country. Cheaper treatment can also provide an incentive to what is often termed reproductive tourism. While the HFEA has control over the import and export of gametes and embryos, it has no powers to prevent patients seeking treatment abroad nor clinicians from assisted patients going overseas. Examples of seeking treatment abroad have been for sex selection (often to Spain or the USA) and preimplantation tissue typing (often to the USA). It has been suggested that the removal of donor anonymity will lead to patients going abroad to seek donated sperm (quite likely to Denmark).<sup>490</sup> PROGAR, a multidisciplinary body under the auspices of the British Association of Social Workers says that “for many people, the biological drive and social pressure to have children will cause them to try to get round any perceived restrictions. People will always devise their own reproductive strategies whatever the prevailing culture’s official view.” As Jayson Whitaker, who went with his wife to the US for preimplantation tissue-typing put it, “let us be totally honest and totally brutal. If I decide that I want to have a girl next time and you cannot do it in the UK, then I can go to a European country or I can go to an American country or I can go to all sorts of other places and have it done. To me, it does not matter whether I have boys or girls but people may have an overwhelming desire to have one sex or another.”<sup>491</sup> Professor Margaret Brazier from Manchester University told us that “No system of regulation can eliminate or effectively control procreative tourism. One basic question needs to be addressed. The provisions of the HFEA concerning parental status are important in securing the welfare of the child once born. Amendment to the HFE Act should make provision for status rules

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490 Ev 435

491 Q 584



concerning the recognition of the status of children born after fertility treatment outside the UK.”

383. We have heard demands to limit the ability of patients to circumvent UK legislation and regulation. The Christian Medical Fellowship would like to see clinics licensed by the HFEA prevented from importing embryos obtained from abroad using techniques illegal in the UK, nor export embryos created here by techniques that are illegal abroad.<sup>492</sup> A Report commissioned by the Department of Health and published in 1998 also recommended that the export provision of the 1990 Act should be clarified to ensure that gametes obtained unlawfully in the UK could not be exported for treatment in other European countries. Dr David King, a contributor to our online consultation, points out there is a precedent for making it an offence in the UK to either refer people to abroad or to go abroad oneself to do something which would be illegal in the UK.<sup>493</sup> Professor Brazier said that “Extra-territoriality is a very difficult area of criminal jurisdiction. For a very long time we limited our extra-territorial jurisdiction to offences such as homicide and offences against the Crown: sedition and treason. I do not believe that such extensive invasions of personal freedom would be compatible with either the European Union treaties in relation to freedom of movement and freedom of services or the human rights provision.”

384. The Sexual Offences Act 2003 tightened up the regulation of sex offenders. Registered sex offenders must notify their local police before they travel abroad, where the trip exceeds three days. The local Police then decide whether to notify the country concerned on the basis of a risk assessment and knowledge of the individual. Extra-territorial legislation can be used to prosecute UK nationals or residents for sex offences committed against children overseas.<sup>494</sup> However, extraterritorial legislation can only be applied if the behaviour is illegal in the country where it is being committed, thus it could not be used to prevent people from travelling overseas to use cloning technology unless it was illegal in that country. Professor Brazier did argue that there was value in introducing certain common standards in the EU to combat procreative tourism, to harmonise the status of children born as a result of assisted reproduction and to ensure common competency”.<sup>495</sup>

385. A paper presented at a recent meeting of the European Society of Human Reproduction and Embryology indicated that the availability of cheaper IVF in some Eastern European countries may lead to an increase in “reproductive tourism”.<sup>496</sup> The HFEA has issued a press release warning of the dangers of unregulated clinics. Suzi Leather repeated this warning in giving evidence[...]. We are not sure what evidence she has to support this statement other than the notion that regulation necessarily leads to safer practice. The EU Tissue Directive will come into force in 2006 in 25 European nations. Given that the standards this imposes on the handling of gametes in treatment centres is higher than that required by the HFEA, we would see no reason to discourage UK citizens to seek cheaper treatment in these countries. The Department of Health told us that they gave no guidance to patients thinking of seeking treatment abroad but the HFEA has

492 Ev 218

493 Q 166

494 [www.fco.gov.uk](http://www.fco.gov.uk)

495 Q 864

496 ESHRE European IVF Monitoring report, 20th annual conference of the European Society of Human Reproduction and Embryology, July 2004

produced a leaflet entitled “Thinking of going abroad for fertility treatment or using donor material from abroad?”<sup>497</sup> It declares that “IVF treatment in the UK is the safest in the world. No other country has this system of independent regulation”. We have discussed above the weaknesses in the HFEA’s inspection processes and the high standards of treatment in some other European countries. It makes the mistake of believing that tight regulation is good regulation. As we stated in Chapter 5, there are good grounds for concluding that the HFEA’s regulation has not been good regulation. **We believe that any attempts to curtail reproductive tourism would not be justified by the seriousness of the offence. Moreover, it would be impossible to enforce if the treatment was legal in the country concerned. Nevertheless, anyone considering such a course of action should be aware of any risks involved. It would be inappropriate for the HFEA to encourage patients to go overseas for treatments that were either prohibited or prevented in the UK; however, we consider the HFEA’s guidance to be misleading and complacent. We recommend that it provide more detailed guidance on treatment overseas based on evidence not on prejudice.**

### *International science*

386. The issue of reproductive tourism has its parallels in scientific research. The UK has been the beneficiary of the USA’s conservative federal stance on embryonic stem cell research. Of course this is a feature in many scientific fields, with researchers moving to countries where they can best undertake the research they wish to do (even if the motive is often financial). This has implications for the development of reproductive technologies. Dr Richard Fleming, a contributor to our online consultation, told us that “Progress is going to happen whether it happens here or not. If it happens in a country where we are not happy with their ethical approach, does that mean we are not going to take any notice of it and is our community not going to benefit from some of this other work?”<sup>498</sup>

### *International treaties*

387. It is extremely difficult to introduce international or harmonised legislation. In some areas, there may be little justification for harmonisation and it is reasonable for national legislation to reflect the traditions of the relevant country, even if it results in the reproductive tourism (see above in paragraphs 383–386). In other areas, there are good reasons for achieving a consensus at a European or global level. This may be to establish fundamental ethical guidelines or to remove legal anomalies that may arise if people seek treatment overseas. It is therefore necessary to consider our legislative proposals in the international context. It was suggested by Josephine Quintavalle during the Committee’s launch of its e-consultation on 22 January 2004 that the UK had a responsibility in setting a good example for other countries. It has certainly been suggested that the UK is seen as being highly influential its approach to regulation of assisted reproduction and embryo research, although, as we have discussed above, we suspect this is exaggerated. We recognise there are practical constraints to any regulatory proposals but ultimately the UK Government should do what it thinks is best for the those who receive and deliver these services and for the wider public in the UK. The Centre for Bioethics and Public Policy has

497 Issued 12 July 2004

498 Q 228

drawn our attention to the UK's apparent "international isolation of the UK in permitting the creation of cloned human embryos".<sup>499</sup> However, being in a minority does not necessarily make you wrong. As the BioIndustry Association puts it, "it is essential that the principle of subsidiarity is maintained".<sup>500</sup> It is right that we should learn what we can from the example of others and we should offer what advice we can to other nations. We accept they will do what best reflects their culture and traditions. **Charters, declarations and treaties no doubt keep diplomats busy and fulfilled but there are some ethical issues which are the domain of nation states and cultures. We should respect the cultures and desires of others and not seek to impose our own ideas. Such charters can only produce vague, lowest common-denominator agreements that are of questionable clarity and dubious effectiveness. Further attempts should be resisted until legislation and regulation are more widespread and the common threads can be identified.**

### **Legislation around the world**

388. The first IVF legislation in the world was enacted in Victoria, Australia in 1984 and must countries where it is widely practised now have legislation. A noteworthy exception is Finland, which by most measures has the highest quality treatment in the world and 2.3% of live births are as a result of IVF or ICSI in 2000.<sup>501</sup> We have been struck by how little comparative information there is about the approach to legislation and regulation in other countries. We understand that the Progress Educational Trust approached the Department of Health in August 2004 for funding to undertake a comparative study of international approaches to legislation and regulation, but this was refused. However, Progress has been able to assemble some preliminary information, which it has generously agreed to share with us.

389. Whatever the Department's reasons, it is unfortunate that this information is not available. In our 2002 report on *Developments in Human Genetics and Embryology* we expressed surprise that the House of Lords Stem Cell Research Committee referred to the esteem with which the HFEA was held overseas without any supporting evidence.<sup>502</sup> As Professor Robert Winston comments, "Over the last 15 years, many countries have looked at the British system of regulation and rejected it. Indeed, there is not a single member of the European Union with a precisely similar body."<sup>503</sup> The HFEA unwittingly concedes this in declaring IVF in the UK as the safest in the world as "No other country has this system of independent regulation".<sup>504</sup> Despite this, the Minister maintained that "we are regarded very highly internationally as a result of the arrangements we have here".<sup>505</sup> From our discussions in Sweden, it seems that the UK system is seen as being rather burdensome. Perhaps the only country where the regulatory model show strong similarities to the UK's is in Canada, where the Assisted Human Reproduction Act 2004,

499 Ev 237

500 Ev 279

501 Assisted reproductive technology in Europe, 2000. Results generated from European registers by ESHRE, Human Reproduction Vol.19, No.3 pp. 490-503, 2004

502 HC (2001-02) 791

503 Ev 424

504 HFEA, Thinking of going abroad for fertility treatment or using donor material from abroad?, July 2004

505 Q 1328

passed after years of deliberation, creates the Assisted Human Reproduction Agency of Canada. A new bioethics law, passed in France in July 2004 created a new agency, which will have a similar remit to the HFEA to regulate embryology and reproduction. **The Government claims that our regulation of assisted reproduction is highly regarded with little substance to support this view, which betrays a worrying complacency. We recommend that the Government, as a first step in its review of the HFE Act, conduct a review of regulatory models overseas and their effectiveness in maintaining public confidence, protecting patients and promoting safe and effective treatment. Given that the Progress Educational Trust has made a start, it would be well placed to continue this work, with appropriate funding, on behalf of the Department of Health.**

**Box 15: Canada's Assisted Human Reproduction Act 2004**

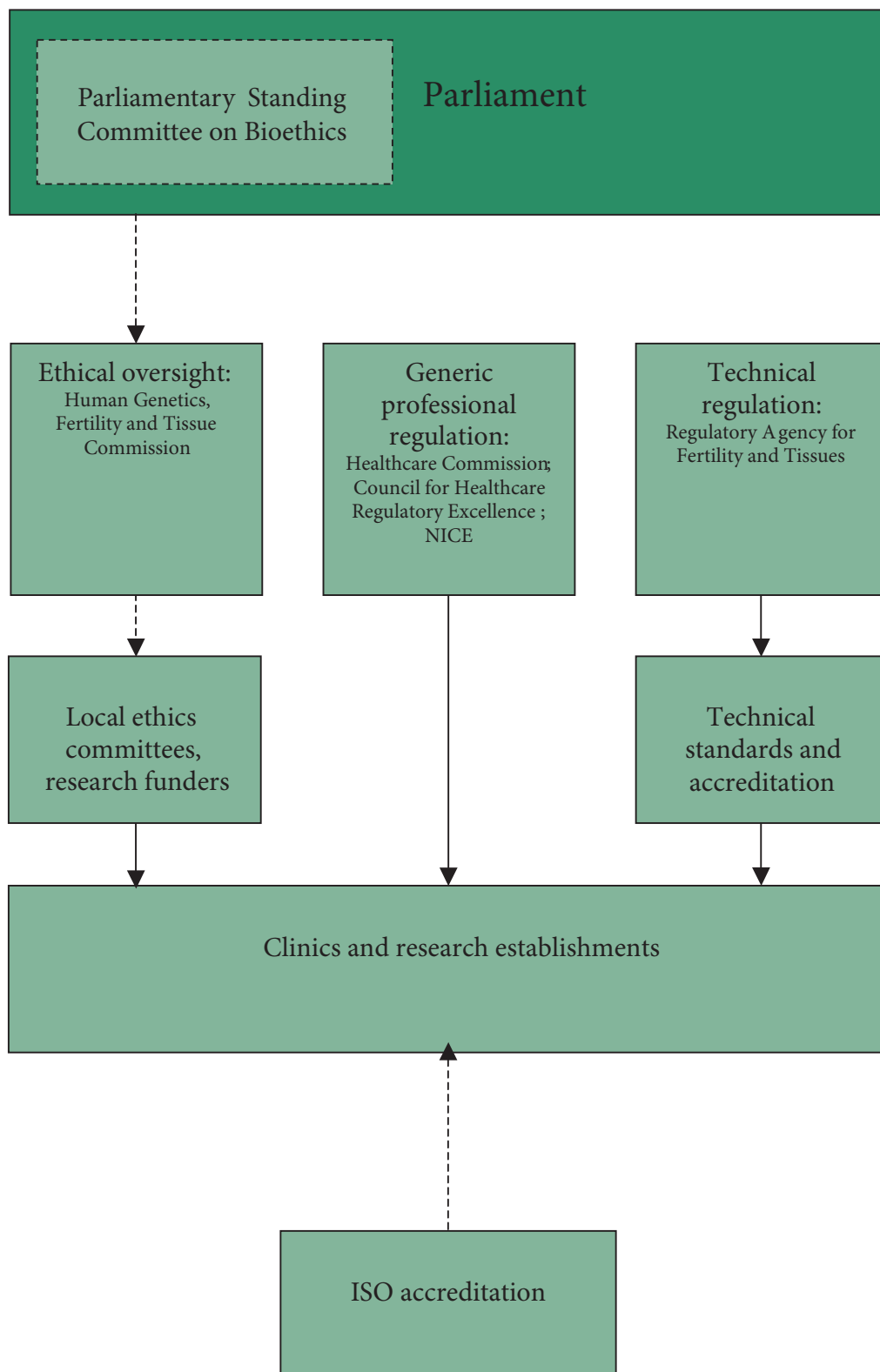
The Assisted Human Reproduction Agency of Canada has a Board of Directors, analogous to the Authority but while the Act specifies that a range of backgrounds should be represented, a person is not eligible to be a member of the board of directors if they hold a licence or are an applicant for a licence or a director, officer, shareholder or partner of a licensee or applicant for a licence.<sup>506</sup> Canada has recently established a regulatory body to oversee the area of assisted human reproduction and related research. The Assisted Human Reproduction Agency of Canada will be separate from Health Canada, but will report to Parliament through the Minister of Health. The body is similar to the HFEA and it employs a system of prohibited and controlled activities. There are important differences in the legislation. It is based on a system of risk management and therapeutic cloning is expressly forbidden.

## 9 A new approach

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390. We have argued that there should be balance between the freedom of individuals to make their own reproductive choices and the legitimate interests of the state, but that any intervention into reproductive choice must have a sound ethical basis and also take into account evidence of harm to children or to society. We propose that the current regulatory model, which provides the HFEA with a large amount of policy-making flexibility, should be replaced with a system which devolves clinical decision-making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight. This system has three strands: a dedicated Government regulator to ensure high standards of treatment; professional regulation to ensure the highest level of conduct by practitioners; and a system of ethical oversight.

Figure 2: Regulation of assisted reproduction and embryo research in the 21<sup>st</sup> century.



## Legislation

391. Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety. Intending parents should be able to seek appropriate services, subject to the professional regulation of safety and quality. This would ensure that reproductive decisions remain primarily in the private domain, governed by professional ethics and the law of consent. However, legislation will be needed to offer appropriate protection for the human embryo and to accommodate status and other legal issues.

### *Status and protection of the embryo and gametes*

392. The legislation will not define the embryo, although it will not come under the protection of the law until it has reached the two cell stage after around 36 hours. It will introduce a definition of gamete to encompass all haploid human cells but a distinction will be made between mature gametes on one hand and immature and artificial gametes on the other. Only embryos created through the union of human sperm and egg can be implanted in a woman, unless otherwise specified. Embryos formed by any process identified in the legislation must be destroyed at a specified stage of development if they are not implanted in a woman. This stage should be set at 14 days but this should be capable of amendment by Parliament. Research on any embryo containing human chromosomal material is permissible up until the specified stage of development if it has received approval from a local research ethics committee and—where appropriate—peer review from a public research funding agency. These provisions are intended to prohibit human reproductive cloning or indeed assisted reproduction using any procedure that does not involve the union of mature gametes. However, legislation should be sufficiently flexible to enable Parliament to reconsider these prohibitions as technology advances.

### *Consent and confidentiality*

393. Issues of consent to receiving assisted reproduction techniques will continue to be governed by the common law on information disclosure and consent to treatment. The legislation's treatment of confidentiality will permit the appropriate sharing of information and high quality research.

### *Regulatory agency*

394. Legislation will create the Regulatory Agency for Fertility and Tissues funded by fees from accredited facilities. It would have an advisory body drawn from the relevant professional bodies. The Agency will:

- a) Ensure that clinics using procedures covered by the Act are appropriately accredited, through the use of an in-house inspectorate or recognised external accreditation bodies;
- b) Regulate gamete and embryo donation and donation services, including the maintenance of a national database;

- c) **Set maximum limits for multiple pregnancies for treatment centres using procedures falling within the legislation;**
- d) **Collect and analyse outcome data;**
- e) **Validate new materials or processes for the handling or embryos of gametes;**
- f) **Provide information to patients, including the cost of treatment. It could intervene to ensure that patients were not charged excessive costs by private clinics;**
- g) **Ensure that research proposals have received adequate ethical and scientific review and publish a lay summary of all approved research projects covered by the legislation;**
- h) **Be supported by an advisory body for technical standards under the auspices of the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists.**
- i) **Undertake the role currently envisaged for the Human Tissue Authority. There should be provision for secondary legislation to bring regulation of non-reproductive tissues into line with that for assisted reproduction and embryo research in consultation with relevant professional bodies and accreditation services.**

### *Technical standards*

395. **Professional bodies under the auspices of the Royal College of Obstetricians and Gynaecologists would draw up technical standards for clinics offering assisted reproduction and undertaking embryo research as a basis for accreditation. The guidelines should set out how assisted reproduction techniques should be undertaken but would not specify what those techniques would be used for. These standards should be consistent with the EU Tissue and Cells Directive and cover:**

- a) Organisation and quality management system
- b) Personnel
- c) Premises and environment
- d) Equipment, information systems and reagents
- e) Procedures
- f) Evaluation and quality assurance.

396. There will be no welfare provisions in the standards beyond the requirement that the risks to any child conceived from treatment as a result of the procedures are minimised within the constraints of available knowledge. To take the example of preimplantation genetic diagnosis, the professional bodies would set out the technical standards to undertake the procedure but not what genetic conditions could be diagnosed. This body would also specify which techniques could be accredited and which could only be undertaken as part of a clinical trial. The technical standards would cover the requirements



for training staff. The standards would specify that treatment centres must maintain clinical records in a form that would enable their use for future targeted analysis. Funding would be provided by grant-in-aid.

### Professional regulation

397. Medical practice is well covered by generic regulation. The professional bodies under the Council for Healthcare Regulatory Excellence are charged with maintaining the professional standards of conduct of healthcare professionals. The Healthcare Commission has a statutory obligation to monitor the performance in the private and public sectors. The National Institute for Clinical Excellence makes recommendations on treatments and care using the best available evidence. Combined, we believe that they provide sufficient statutory weight to ensure that clinical standards are maintained and decisions are supported by the best available guidance. Guidance in the field of assisted reproduction is provided by the professional bodies, notably the Royal College of Obstetricians and Gynaecologists, the British Fertility Society and the Association of Clinical Embryologists.

### Parliamentary Standing Committee on Bioethics

398. **We have argued for greater Parliamentary oversight over issues relating to assisted reproduction and embryo research. To achieve this we propose a new Parliamentary Standing Committee on Bioethics. This would undertake annual scrutiny of the Regulatory Agency for Fertility and Tissues, make recommendations on the need to amend or introduce legislation and scrutinise draft legislation brought before Parliament within its remit.** All statutory instruments under the new Act would automatically be referred to this Committee instead of the Joint Committee on Statutory Instruments. As with human rights, this is an issue that requires collaboration of MPs and Peers and the Committee would be made up of members of both Houses, unlike the Stem Cell Research Committee set up by the House of Lords in 2001. It would appoint a panel of advisers and have a specialist secretariat. Any lack of consensus on statutory instruments would trigger a debate in both Houses.

### Human Genetics, Fertility and Tissue Commission

399. **We propose the creation of a new Human Genetics, Fertility and Tissue Commission would expand the remit of the Human Genetics Commission to include the issues currently the domain of the HFEA and the relevant areas from the Human Tissue Authority. The bodies would provide advice and recommendations on issues which it considered that there were societal implications, such as selection for social reasons and preimplantation tissue typing, but would not provide clinical guidance. It would be informed by public consultations and could commission social science research.**

### Research

400. Embryo research would need to be undertaken in an accredited facility, have been scrutinised by a local or regional research ethics committee, which would ensure that adequate consent had been sought from donors, and have been scientifically peer

**reviewed.** We believe that the MRC's guidelines would be sufficient to ensure that research projects involving embryos were of real clinical benefit and suggest that it take on the peer review process for applications even if they do not involve a request for MRC funds.

## Conclusions and recommendations

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1. While it has been argued that there have been many scientific developments and changes in social attitudes, the Warnock Committee's approach to the status of the embryo remains valuable. While this gradualist approach to the status of the embryo may cause difficulties in the drafting of legislation, we believe that it represents the most ethically sound and pragmatic solution and one which permits in vitro fertilisation and embryo research within certain constraints set out in legislation. (Paragraph 28)
2. We accept that a society that is both multi-faith and largely secular, there is never going to be consensus on the level of protection accorded to the embryo or the role of the state in reproductive decision-making. There are no demonstrably "right" answers to the complex ethical, moral and political equations involved. We respect the views of all sides on these issues. We recognise the difficulty of achieving consensus between protagonists in opposing camps in this debate, for example the pro-life groups and those advocating an entirely libertarian approach to either assisted reproduction or research use of the embryo. We believe, however, that to be effective this Committee's conclusions should seek consensus, as far as it is possible to achieve. Given the rate of scientific change and the ethical dilemmas involved, we conclude, therefore, that we should adopt an approach consistent with the gradualist approach, of which the Warnock Committee is one important example. This does not mean that we will shy from criticism of regulation to date, where we believe it warranted. But it does mean that we accept that assisted reproduction and research involving the embryo of the human species both remain legitimate interests of the state. Reproductive and research freedoms must be balanced against the interests of society but alleged harms to society, too, should be based on evidence. (Paragraph 46)
3. We do not see why the area human reproductive technologies should do anything other than proceed under a precautionary principle currently prevalent in scientific, research and clinical practise. This means – as specified in paragraph 46 above – that alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded. (Paragraph 47)
4. We believe that the research on human embryos can be undertaken without compromising their special status but that this research should have proper ethical oversight as set out in Chapter 8 and 9. We further conclude that, where necessary, embryos can be created specifically for research purposes. (Paragraph 51)
5. We are concerned that any legal definitions of the embryo based on the way it was created or its capabilities would either be open to legal challenge or fail to withstand technological advance. The attempt to define an embryo in the HFE Act has proved counter-productive, and we recommend that any future legislation should resist the temptation to redefine it. We consider that a better approach would be to define the forms of embryo that can be implanted and under what circumstances. Using this approach, only those forms of embryo specified by the legislation, such as those created by fertilisation, could be implanted in the womb and thereby used for

reproductive purposes. Other forms of embryo would be regulated insofar as they are created and used for research purposes. (Paragraph 54)

6. We see little value in regulating the use of an egg in the process of fertilisation. A unique genetic entity is only formed at the union of the male and female pronuclei and this seems the most appropriate point at which to bring the creation under the protection of legislation. (Paragraph 56)
7. We have been told that the 14-day rule is an arbitrary cut off point. For many, even those who support assisted reproduction and embryo research, an extension to the 14-day rule would be unacceptable. We accept that there is no case at present for an extension, or indeed reduction. However, we believe that, if scientists or clinicians were able to provide convincing justification for any change, this should be determined by Parliament. (Paragraph 59)
8. In considering the subject comprehensively we should not shy away from addressing difficult subjects which may widely be considered 'taboo'. In this instance, however, we have heard no evidence which would lead us to conclude that there is any merit in relaxing the HFE Act's prohibition on placing human embryos in an animal for research purposes. Should the government receive expert advice to the contrary, given the ethical issues involved, any such change should be a matter for Parliament and primary legislation. (Paragraph 63)
9. The ethical status of hybrids and chimeras is complex. While there is revulsion in some quarters that such creations appear to blur the distinction between animals and humans, it could be argued that they are less human than, and therefore pose fewer ethical problems for research than fully human embryos. We recognise concerns that hybrids and chimeras could be used for reproductive purposes and recommend that new legislation a) defines the nature of these creations, b) makes their creation legal for research purposes if they are destroyed in line with the current 14-day rule for human embryo cultures, and c) prohibits their implantation in a woman. (Paragraph 67)
10. We recognise that human reproductive cloning, if possible at all, is not currently safe and that no clinician could legitimately pursue it under existing professional regulation. In addition, we recognise that research in developing reproductive cloning would very likely involve experimentation that is highly unethical. Nonetheless, the patchy legislation around the world suggests that the research will take place somewhere and someone may be able to demonstrate a technique that is safe, effective and reliable. (Paragraph 70)
11. Even if human reproductive cloning were shown to be safe, effective and reliable we would still have grave concerns about many of its applications. However, there are clear examples where the situation is not so clear cut and the ethical debate is highly complex. Professor Ian Wilmut has described a scenario in which the aims are therapeutic and no clone is created of an individual who has ever been born. If there is to be a total prohibition of any form of reproductive cloning, it is important that it is supported by principled arguments why such a technique should be banned even if it were shown to be safe, effective and reliable. Without such arguments, an

indefinite absolute ban could not be considered rational. The Minister's refusal to enter into any discussion of reproductive cloning is not an encouraging starting point for an open-minded review of the adequacy of existing legislation. (Paragraph 72)

12. As with cell nuclear replacement, the risks of implanting a split embryo are high, but a distinction needs to be made between safety of the treatment and the fundamental ethical principles. If embryo splitting for treatment purposes is to be prevented, as with reproductive cloning, this should be based on coherent ethical argument, such as the right not to be purposefully created with a specific genetic identity. (Paragraph 76)
13. We regret that the use of parthenogenesis to derive stem cells was not considered by either the Donaldson report or the House of Lords Stem Research Committee. This gives the impression that inadequate consideration has been given to these ethical issues before research projects were licensed by the HFEA. Nevertheless, we are pleased that this line of research is possible under the current legislation as we take the view that parthenogenesis raises fewer ethical issues than creating an embryo created using CNR, provided that it is not cultured for longer than 14 days. (Paragraph 78)
14. Regardless of whether cell nuclear replacement is undertaken on eggs or embryos for the purposes of research on mitochondrial diseases, the aim of the research is the same. Given that we permit experimentation on embryos to investigate heritable diseases, we see no need to distinguish between the techniques in law. (Paragraph 81)
15. Effective and safe germline therapy to treat serious genetic diseases would result in reduced child mortality and morbidity and fewer abortions and destroyed embryos. (Paragraph 82)
16. We conclude that the absolute prohibition on genetic modification of the pre-14 day human embryo be removed for research purposes and recommend that future legislation, while prohibiting the modification of chromosomal DNA for reproductive purposes, should provide for regulations to be made to relax this ban under tightly controlled circumstances if and when the technology is further advanced. (Paragraph 83)
17. If the purpose of regulation in assisted reproduction is to protect patients, there is no justification for exempting GIFT and IUI with partner sperm from the legislative framework. However, given our acceptance of the position that the state should intervene only in carefully defined and justified circumstances, where there are specific harms, in reproductive decisions, the common law rules of consent are sufficient to protect patients in the face of these risks. It is consistent with our ethical approach that, rather than adding to the list of regulated fertility treatments, we should be decreasing the level of state intervention. We accept that GIFT and IUI pose similar risks to IVF, but we have already concluded that these risks lie within accepted legal boundaries on what people can consent to. We have not been persuaded, therefore, that regulation should demand anything more than that the highest technical standards are observed. (Paragraph 84)

18. The risks to users and their offspring from an internet sperm donation service need to be established. There is a case for regulating such services to ensure their quality. It is not clear whether they would be covered by the EU Tissue Directive. If not, we conclude that revised legislation should ensure that such commercial services are subject to the highest technical and safety standards. We would also consider it anomalous if gamete donation that is undertaken in a clinical setting required identifying information to be held in a central database but did not if the donor and recipient were “introduced” over the internet. Our concern is to ensure that the safety and quality standards expected of all assisted reproduction technologies are equivalent. (Paragraph 86)
19. We conclude that while it is appropriate that commercial services involving fresh gametes should be subject to regulation, this should not extend beyond seeking to ensure that there are as few anomalies as possible between different options for donor insemination. (Paragraph 89)
20. Subject to their safety, we recognise that artificial gametes have potential to treat infertility and reduce the need for gamete donors. It is important that, in the use of any cell cultures for reproductive purposes, the original donors must be traceable and their informed consent obtained. (Paragraph 91)
21. The requirement to consider whether a child born as a result of assisted reproduction needs a father is too open to interpretation and unjustifiably offensive to many. It is wrong for legislation to imply that unjustified discrimination against “unconventional families” is acceptable. (Paragraph 102)
22. The State employs social services to protect children from harm. If it has reason to believe that children born as a result of assisted reproduction are at increased risk then healthcare professionals can alert social services at an early stage. Indeed, the law has declined to intervene to protect the welfare of a child not yet born, being satisfied that the foetus in utero cannot be made a ward of court, and that appropriate action could be taken if required following live birth. (Paragraph 104)
23. The exclusive requirement to consider the welfare of the child for fertility treatments where fertilisation takes place outside the woman or involves donated sperm is illogical. If the legislation aims to regulate the treatment of infertility or subfertility then it should cover all forms of interventions. If it wishes to do both then this needs to be clearly stated and justified. (Paragraph 106)
24. The welfare of the child provision discriminates against the infertile and some sections of society, is impossible to implement and is of questionable practical value in protecting the interests of children born as a result of assisted reproduction. We recognise that there will be difficult cases but these should be resolved by recourse to local clinical ethics committees. The welfare of the child provision has enabled the HFEA and clinics to make judgements that are more properly made by patients in consultation with their doctor. It should be abolished in its current form. The minimum threshold principle should apply but should specify that this threshold should be the risk of unpreventable and significant harm. Doctors should minimise the risks to any child conceived from treatment within the constraints of available

knowledge but this should be encouraged through the promotion of good medical practice not legislation. (Paragraph 108)

25. If ensuring that your child is less likely to face a debilitating disease in the course of their life can be termed eugenics, we have no problem with its use. State programmes that impose a genetic blueprint are another matter. They should be outlawed as part of any regulation of assisted reproduction. Use of the word eugenics must not be used as an emotive term of abuse to obscure rational debate. (Paragraph 117)
26. It is possible to sex a child using ultrasound and seek a termination and if PGD reduces the demand for abortion then this is a good thing. While we recognise that abortion legislation recognises the right of the woman, our gradualist approach to the status of the embryo leads us to conclude that there is a mismatch between the protection afforded an embryo created in vitro before it is implanted and one at a later stage of development in a woman's uterus. (Paragraph 120)
27. We have concerns about the criteria imposed by the HFEA. PGD is limited in that it can only be used to screen out disorders and thus it cannot be used to create "designer babies". We see no reason why a regulator should seek to determine which disorders can be screened out using PGD. Nevertheless, clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements. (Paragraph 125)
28. We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament. (Paragraph 130)
29. The UK should carefully consider the current evidence there available now about such imbalances and harms before allowing blanket changes our laws and regulations on sex selection. (Paragraph 141)
30. The onus should be on those who oppose sex selection for social reasons using PGD to show harm from its use. However, the use and destruction of embryos does raise ethical issues and there are grounds for caution. The issue requires greater analysis than has been afforded it by the HFEA and we urge greater efforts to establish the demographic impacts across all sectors of society and the implications for the creation and destruction of embryos in vitro before new legislation is introduced. On balance we find no adequate justification for prohibiting the use of sex selection for family balancing. (Paragraph 143)
31. We recommend that the Government clarify the position relating to any financial obligations of donors before 1990. It would be regrettable if such donors did not come forward under the mistaken impression that they would become financially liable for the upbringing of children born as a result of an altruistic donation. (Paragraph 151)
32. We have sympathy with the view that if children born following donor insemination have a right to know their genetic parents, donors have some the rights to non-identifying information about any children born as a result of their donation. We

recommend that the Government address this anomaly in its review of the HFE Act. (Paragraph 152)

33. We regret the Department's poor use of evidence in policy-making and its failure to commission and have published the necessary research underpinning its decision on the removal of donor anonymity. (Paragraph 155)
34. Given the threat to donor supply, it would have been better to have attempted to conduct research on parental attitudes to secrecy in the context of anonymity versus identifiable donors before changing the system entirely to one where anonymity is ended. (Paragraph 158)
35. While the arguments for and against changing the status of donors are complex, opinions seem to centre on the relative weight given to the pain of infertility and the welfare of the offspring. Despite this, most would agree that, in principle, openness is a good thing. The task is to promote as much openness as possible without sacrificing the availability of donated gametes. In our view the benefits from the removal of anonymity are not such that the change justifies the likely impact on the number of donors. We therefore favour a twin track approach. While patients and donors should be aware of the benefits of openness and the regulator should provide for those who wish to adopt this strategy. (Paragraph 159)
36. We have been told that, the earlier the child is told that they were born from donor gametes the better, yet parents wishing to tell their child that he or she was born using donor gametes may wish to avoid telling them if they then are unable to know anything about the donor. We recommend that certain non-identifying information is available to the child so that they can request it upon being told by their legal parents that they were conceived using donor insemination. (Paragraph 160)
37. In recognition of concerns about the supply of donors, the Department of Health has launched a PR campaign to recruit new donors. By the time revised legislation is placed before Parliament, data should be available that give an indication as to whether the removal of anonymity will have a long-lasting effect on the supply of donors. With this information, Parliament can decide to what extent the removal of anonymity is a price worth paying. (Paragraph 161)
38. We look forward to the results of the HFEA's consultation on the remuneration of embryo and gamete donors. We are concerned that the HFEA should be placed in a position in which it is forced to make decisions that could provide an incentive or disincentive to donors. This is a political decision best left to Parliament. (Paragraph 163)
39. While we believe that clinicians should adopt a more sympathetic attitude to infertility counselling, counsellors must work harder to develop an evidence base to support their practice. Only in this way can they hope or deserve to receive the respect of their clinical colleagues. We see no role for legislation or regulation in facilitating this process. (Paragraph 169)
40. The HFEA is able to attach conditions to any licence that it awards and it could already use its existing licensing system to ensure that certain techniques were only



used as part of a clinical trial. We recognise that powers to award a clinical trials licence might have advantages for the HFEA but we would be nervous about the creation of any further bureaucratic hurdle introduced to the setting up of clinical trials. (Paragraph 173)

41. It is not appropriate that embryos donated for research should be used to train staff and it could be argued that the HFEA is acting illegally by awarding research licences in the knowledge that the primary purpose is training. Furthermore, training in the handling of embryos should not be limited to those centres that are undertaking research. Training staff to handle embryos for the purposes of providing treatment should be possible under treatment licences as long as it is made clear to donors of embryos what they will be used for. (Paragraph 174)
42. The budget allocations for the 2004 Spending Review were published in March 2005 without any specific reference to stem cell research. We recognise that the Research Councils have no interest in investing in research teams if they have no interest in sustaining them in the medium term. However, we recommend that they monitor the success of applications in this area made in open competition and bid for ring-fenced funds in future Spending Reviews if funding in stem cell research projects declines (Paragraph 182)
43. That the embryo only gradually acquires human rights is a widely accepted view. In this light, the maximum sentence of 10 years for breaching some of the prohibitions in the HFE Act seem unduly harsh. (Paragraph 184)
44. The legal role of the person responsible is outdated. While the law did not confer liability on the person responsible for the misdemeanours of a member of staff, it still seems sensible to separate responsibility in respect of compliance with the HFE Act and compliance with technical standards. Standards would become the responsibility of the Trust Chief Executive (or equivalent in the private sector) while responsibility for compliance with the provisions of the HFE Act would be retained by a senior member of the clinic. (Paragraph 185)
45. We agree that the regulator needs a wider range of sanctions but we are concerned that the emphasis is on penalty and not on improving standards and systems. The incompetent and the unethical needs to be closed down but the vast majority in the middle need to operate in a regulatory environment which encourages them to improve. There should be no deterrent to self-reporting. (Paragraph 187)
46. The primary aim of healthcare regulation should be to protect patients. We believe that this can best be achieved by creating a culture in which good practice is encouraged rather than the focus being on penalising poor service. If individual practitioners have performed below acceptable standards, the professional regulators should act in a manner that protects patients. We recognise the Government's efforts to improve professional regulation through the creation of the Council of Healthcare Regulatory Excellence. While these changes need to "bed down", we welcome the commitment to strengthen regulation. (Paragraph 193)
47. We share the widespread concerns about the extent of the scientific and clinical expertise of Authority members, but recognise that the principle of the lay majority is

important and should not easily be discarded. We believe that ultimate authority on issues of public concern should lie outside of the scientific and medical communities. At the same time, it is important that any decisions are informed by the science and medicine. (Paragraph 199)

48. We have sympathy with the view that those with principled opposition to assisted reproduction should have been unreasonably excluded from a place at the principal forum for debates on assisted reproduction and embryo research. It cannot, however, be a simple matter of reworking the job description for Authority members, since the presence of those opposed to assisted reproduction and embryo research would change the very nature of the organisation. The representation of views needs to be considered as part of a thorough assessment of the regulatory and advisory structures operating in this field. The composition of the regulator must either be substantially reformed or mechanisms found to improve the range and quality of advice it receives. (Paragraph 208)
49. We have heard that membership of the HFEA has so far been reserved for proponents of assisted reproduction and embryo research. It is therefore not surprising that its individual members would wish to see greater availability of licensable activities. Nevertheless, by promoting gamete donation in its corporate publications it has acted outside its statutory remit and crossed a boundary that risks compromising public trust. (Paragraph 217)
50. It is reasonable for the Authority to draw attention to problematic areas in legislation, indeed it would be negligent if it were not to do so, but there is a clear distinction between drawing attention to problems and inconsistencies and espousing solutions. (Paragraph 218)
51. We conclude that the HFEA could not have discharged its statutory duty without developing a policy-making function; nevertheless, any revised legislation should more clearly define the presence or absence of a policy-making role for the regulator. (Paragraph 219)
52. The HFEA must be aware that many individuals and organisations will pore over its statements for evidence of misdeeds. It is unfortunate that it has provided so much ammunition to its critics. As the Science and Technology Committee, we are pleased that the HFEA sees the value of scientific research; however, we accept that it is not its role to encourage licensable embryo research, merely to consider whether applications that it receives conform to the wishes of Parliament. (Paragraph 221)
53. It is right and proper that the HFEA should seek to update the protocols set out in the Code of Practice, which is, in effect, a rule book for centres licensed under the Act. The HFEA has not so far employed the internet to its full potential and we believe that its policy decisions should be consolidated in a single document as far as possible and as quickly as possible into a single digital entity. (Paragraph 226)
54. Advocates of the role of the HFEA have argued that it has succeeded in maintaining public confidence in a highly contentious area. If this is the case, it is hard to see how this can be maintained if its inspection processes are attracting sustained criticism. (Paragraph 234)

55. The EU Tissue Directive will provide a welcome impetus to improve and maintain the technical standards in treatment centres. However, we urge the Government and the HFEA to ensure that the standards applied are appropriate and proportionate (Paragraph 236)
56. We welcome the HFEA's decision to appoint an in-house professional inspectorate. However, it is important that these inspectors have the confidence of the assisted reproduction community and we recommend that its views are taken into account before appointments are made. (Paragraph 238)
57. It is unacceptable for the HFEA to attempt to withhold information relating to licence applications if it has no legal basis for doing so. Information relating to licence applications and licence committees should be made available on the internet as a matter of course. (Paragraph 240)
58. There may have been good reasons why licence committees were unable to hear directly from the patients, but cases must be dealt with sensitively and without needlessly erected bureaucratic walls. We are pleased that the HFEA has decided to adopt a more open policy in the future. (Paragraph 241)
59. We welcome the efforts that the HFEA has made to improve its research licensing procedures and we hope that these prove effective. However, we believe that there needs to be a thorough analysis of the process by which research involving embryos is approved so that we do not lose sight of what the process is trying to achieve. (Paragraph 243)
60. The regulation of preimplantation testing is highly unsatisfactory. We recognise that the HFEA has legal jurisdiction but this does not mean that it has a duty to regulate its use beyond ensuring that it is performed to the highest standards within statutory boundaries. (Paragraph 245)
61. The development of the HFEA's policy and licensing decisions on preimplantation tissue typing has been highly unsatisfactory. We share the Chair's contentment with its current policy and agree that revised legislation must make it clear that preimplantation genetic diagnosis and preimplantation tissue typing can be undertaken within legal restraints . (Paragraph 252)
62. If the HFEA is to retain its current functions, it is important that it has access to the best relevant data to support its decision-making. While research is not defined as part of its remit as such, it should have the budget to fund small scale unlicensable academic studies. (Paragraph 255)
63. The MRC Working Group contained a social researcher but the report gave little attention to the social impacts of assisted reproduction, despite being cited frequently in HFEA policy documents. We recommend that the HFEA ask the Economic and Social Research Council to set up a working group to look specifically at the social impacts of and attitudes to assisted reproduction . (Paragraph 256)
64. The confidentiality provisions in the HFE Act have hampered efforts to establish the risks associated with assisted reproduction. We conclude that they are unnecessarily

onerous and inconsistent with the widespread use of assisted reproductive technologies. We recommend that the data from the HFEA's register should be applied as far as is possible to research studies. (Paragraph 259)

65. The confidentiality provisions in the HFE Act have hampered efforts to establish the risks associated with assisted reproduction. We conclude that they are unnecessarily onerous and inconsistent with the widespread use of assisted reproductive technologies. We recommend that the data from the HFEA's register should be applied as far as is possible to research studies. We have criticised the excessive use of the precautionary principle in assisted reproduction. However, we recognise that there are public concerns about possible adverse risks associated with assisted reproduction. Treatment centres should, as a condition of their licence, maintain a database in a suitable form which is available for peer reviewed research projects. As a result, there will be a justifiable burden on clinics. (Paragraph 264)
66. While the value of the Register for research has been open to question, it should have been able to provide data on the uptake of IVF and donor insemination and success rates to inform policy development on assisted reproduction and its provision. However, in recent years these data have not been published, which is unfortunate. We consider it to be a fundamental role of a regulator to provide information about the industry it is regulating. (Paragraph 265)
67. We take seriously the possible risks of assisted reproduction technologies. For this reason, we encourage research in this area, both to inform professional practice and in order that intending parents can be adequately and appropriately informed of any risk to which they are considering providing consent. (Paragraph 267)
68. No-one wishes to expose patients and children to physical harm or psychosocial stresses, but all medical practice has inherent risks and the only solution is a rational approach to risk assessment and management, coupled with strategies to undertake and apply the results of medical, scientific and social research. (Paragraph 277)
69. We welcome the setting up of an international Horizon Scanning Expert Panel as a positive step in improving the HFEA's use of evidence. We are unclear why there is not even one social researcher on the panel and urge the HFEA to rectify this. (Paragraph 278)
70. By most standards, the safety of IVF lies within the boundaries of acceptability. Nevertheless, any risks must not be underplayed and patients should be made fully aware of them before treatment. We hope the Medical Research Council will look favourably on proposals to undertake national studies to establish the safety and effectiveness of assisted reproduction techniques. (Paragraph 279)
71. We welcome the changes in the funding arrangements for the HFEA, which recognise that the HFEA, as presently constituted, has a wider duty to the public beyond its role as a regulator. (Paragraph 280)
72. The principles of good regulation adopted by the Better Regulation Task Force are appropriate and valuable. We regret that in many areas the HFEA falls short of these ideals. We recognise that the HFEA has improved its performance but it has been

stretched by too much poorly targeted regulation. This needs to be addressed by refocusing its efforts. We will discuss our solutions in Chapter 9. (Paragraph 291)

73. We have heard concerns that some of the services being offered to patients in IVF clinics are not justified by evidence of their value. We believe that clinics, private and NHS, must make it clear when they are offering services and treatments that lie outside the NICE guidelines. Practitioners need to be aware that their patients are desperate for a child and vulnerable to exploitation. We recommend that the Healthcare Commission prioritise its activities in this area. (Paragraph 293)
74. The issue to be resolved is not whether there should be league tables but how to ensure that the data are sound and provide useful information to patients. Not all of the factors that influence the success of IVF are clearly understood but we see an important role for the regulator in developing metrics. We welcome the HFEA's work on developing better comparators but it should resist publication of success rates for different clinics until it is satisfied that they are not misleading. (Paragraph 296)
75. Despite being a pioneer in IVF, the UK lags behind many of its European neighbours in quality of the treatment it offers. We believe that, while regulation is not necessarily an appropriate tool to improve standards, the Healthcare Commission has a role in identifying the reasons why some other countries perform better than we do as a means of underpinning changes in UK practice. (Paragraph 298)
76. We welcome the increased responsibility taken by professional bodies to draw up and maintain guidelines on clinical and laboratory standards. (Paragraph 300)
77. We call on both Houses in the new Parliament to set up a joint committee to consider the scientific, medical and social changes in relation to abortion that have taken place since 1967, with a view to presenting options for new legislation. This committee should be broadly based and should include nominees from the Commons Select Committees for Science and Technology and Health and the Lords Science and Technology Committee. (Paragraph 309)
78. We recommend that any new legislation introduced to amend the HFE Act should not include abortion, which should be dealt with in a separate Bill. (Paragraph 310)
79. We recommend that the Department includes with its review of the HFE Act an assessment of surrogacy arrangements. This should use the Brazier Report as a starting point and consider what developments there have been since 1998. We regret the Government's inaction. Consideration should be given to introducing separate legislation covering surrogacy. (Paragraph 313)
80. We recommend that the Government publish any revised Bill on assisted reproduction and embryo research in draft. We recommend that this Bill, and any new Abortion Act, be subject to pre-legislative scrutiny. (Paragraph 314)
81. We recommend that the Parliamentary parties should give a clear undertaking that Members will be given a free vote on any new legislation concerning assisted reproduction and embryo research. (Paragraph 315)

82. In our view, Parliament's ability to revisit contentious issues relating to the creation of new life and the permissible uses of human embryos is vital. We recommend that new legislation is more explicit and provides Parliament with greater powers to debate and amend legislation. We propose mechanisms for achieving this in Chapter 9. (Paragraph 316)
83. We recognise that there need to be some prohibitions on research in law, as we set out in Chapter 9, but we think there is much merit in a system of local oversight to provide faster, more proportionate, oversight of research on human embryos (Paragraph 342)
84. There are merits in the creation of a nationally coordinated network of clinical ethics committees to parallel the arrangement for local research ethics committees. Should the evaluation of these committees demonstrate their value, they should be provided with national guidelines for their conduct in the area of assisted reproduction but their decisions should be directed needs of patients and the families and the concerns of health care professionals. (Paragraph 346)
85. We believe that the Government is correct that smaller advisory committees with specific briefs would be more effective. Nevertheless, we favour the rationalisation of these committees where there is clear overlap and human genetics and embryology fall into this category. We recommend the formation of a single commission to develop policy issues relating to the assisted reproduction, embryo research and human genetics. (Paragraph 353)
86. Any national policy-making committee should not attempt to interfere with individual clinical decisions. If the value of local clinical ethics committees can be established, they should be given a defined brief that clearly distinguishes their role from the Commission, which should issue guidelines for their operation . (Paragraph 355)
87. We remain convinced that a larger role for our democratically accountable Parliament would give the public greater confidence that the big ethical issues of the day are being given adequate attention. (Paragraph 357)
88. There is sufficient overlap between the policy and advisory functions of the HFEA and the Human Genetics Commission to provide a strong case for merger. (Paragraph 366)
89. We see great merits in the professional bodies taking control of the technical and management standards and welcome the offer of the Royal College of Obstetricians to take responsibility under the auspices of the regulator in drawing up and maintaining these standards for centres concerned with the provision of storage or treatment services in compliance with the EU Tissue Directive. (Paragraph 369)
90. If the regulator can be assured that external forms of accreditation such as ISO 9001 comply with legislation following the transposition of the EU Directive into UK law, then such accredited facilities should be free to operate without additional scrutiny. (Paragraph 370)

91. The creation of the Regulatory Authority for Fertility and Tissue seems to be the result of political pressure to be seen to be reducing bureaucracy rather than a logical move. Nevertheless, we share the Department's wish to see fewer appendages to central Government and recognise that the merger of the regulatory functions of the HFEA and the HTA has its merits as long as its implementation recognises that there are big differences in the activities they regulate, as well as similarities. However, its activities should be restricted to the oversight of assisted reproduction to technical standards and quality management. (Paragraph 377)
92. We have recommended that the confidentiality provisions in the HFE Act need to be relaxed. This should be accompanied by efforts to use UK data to inform the international monitoring of the risks of assisted reproduction. (Paragraph 380)
93. We see major advantages in creating international standards in the handling and export of human gametes and embryos to improve the consistency and quality of procedures, protect those at risk of exploitation and improve the monitoring of treatments and risks. (Paragraph 382)
94. We believe that any attempts to curtail reproductive tourism would not be justified by the seriousness of the offence. Moreover, it would be impossible to enforce if the treatment was legal in the country concerned. Nevertheless, anyone considering such a course of action should be aware of any risks involved. It would be inappropriate for the HFEA to encourage patients to go overseas for treatments that were either prohibited or prevented in the UK; however, we consider the HFEA's guidance to be misleading and complacent. We recommend that it provide more detailed guidance on treatment overseas based on evidence not on prejudice. (Paragraph 386)
95. Charters, declarations and treaties no doubt keep diplomats busy and fulfilled but there are some ethical issues which are the domain of nation states and cultures. We should respect the cultures and desires of others and not seek to impose our own ideas. Such charters can only produce vague, lowest common-denominator agreements that are of questionable clarity and dubious effectiveness. Further attempts should be resisted until legislation and regulation are more widespread and the common threads can be identified. (Paragraph 388)
96. The Government claims that our regulation of assisted reproduction is highly regarded with little substance to support this view, which betrays a worrying complacency. We recommend that the Government, as a first step in its review of the HFE Act, conduct a review of regulatory models overseas and their effectiveness in maintaining public confidence, protecting patients and promoting safe and effective treatment. Given that the Progress Educational Trust has made a start, it would be well placed to continue this work, with appropriate funding, on behalf of the Department of Health (Paragraph 390)
97. We have argued that there should be balance between the freedom of individuals to make their own reproductive choices and the legitimate interests of the state, but that any intervention into reproductive choice must have a sound ethical basis and also take into account evidence of harm to children or to society. We propose that the current regulatory model, which provides the HFEA with a large amount of policy-

making flexibility, should be replaced with a system which devolves clinical decision-making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight. This system has three strands: a dedicated Government regulator to ensure high standards of treatment; professional regulation to ensure the highest level of conduct by practitioners; and a system of ethical oversight. (Paragraph 391)

98. Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety. Intending parents should be able to seek appropriate services, subject to the professional regulation of safety and quality. This would ensure that reproductive decisions remain primarily in the private domain, governed by professional ethics and the law of consent. However, legislation will be needed to offer appropriate protection for the human embryo and to accommodate status and other legal issues. (Paragraph 392)
99. The legislation will not define the embryo, although it will not come under the protection of the law until it has reached the two cell stage after around 36 hours. It will introduce a definition of gamete to encompass all haploid human cells but a distinction will be made between mature gametes on one hand and immature and artificial gametes on the other. Only embryos created through the union of human sperm and egg can be implanted in a woman, unless otherwise specified. Embryos formed by any process identified in the legislation must be destroyed at a specified stage of development if they are not implanted in a woman. This stage should be set at 14 days but this should be capable of amendment by Parliament. Research on any embryo containing human chromosomal material is permissible up until the specified stage of development if it has received approval from a local research ethics committee and—where appropriate—peer review from a public research funding agency. (Paragraph 393)
100. Legislation will create the Regulatory Agency for Fertility and Tissues funded by fees from accredited facilities. It would have an advisory body drawn from the relevant professional bodies. The Agency will:
  - a) Ensure that clinics using procedures covered by the Act are appropriately accredited, through the use of an in-house inspectorate or recognised external accreditation bodies;
  - b) Regulate gamete and embryo donation and donation services, including the maintenance of a national database;
  - c) Set maximum limits for multiple pregnancies for treatment centres using procedures falling within the legislation; (Paragraph 395.c)
  - d) Collect and analyse outcome data;
  - e) Validate new materials or processes for the handling or embryos of gametes;
  - f) Provide information to patients, including the cost of treatment. It could intervene to ensure that patients were not charged excessive costs by private clinics;



- g) Ensure that research proposals have received adequate ethical and scientific review and publish a lay summary of all approved research projects covered by the legislation;
- h) Be supported by an advisory body for technical standards under the auspices of the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists.
- i) Undertake the role currently envisaged for the Human Tissue Authority. There should be provision for secondary legislation to bring regulation of non-reproductive tissues into line with that for assisted reproduction and embryo research in consultation with relevant professional bodies and accreditation services. (Paragraph 395.)

- 101.** Professional bodies under the auspices of the Royal College of Obstetricians and Gynaecologists would draw up technical standards for clinics offering assisted reproduction and undertaking embryo research as a basis for accreditation. The guidelines should set out how assisted reproduction techniques should be undertaken but would not specify what those techniques would be used for. These standards should be consistent with the EU Tissue and Cells Directive (Paragraph 396)
- 102.** We have argued for greater Parliamentary oversight over issues relating to assisted reproduction and embryo research. To achieve this we propose a new Parliamentary Standing Committee on Bioethics. This would undertake annual scrutiny of the Regulatory Agency for Fertility and Tissues, make recommendations on the need to amend or introduce legislation and scrutinise draft legislation brought before Parliament within its remit. (Paragraph 399)
- 103.** We propose the creation of a new Human Genetics, Fertility and Tissue Commission would expand the remit of the Human Genetics Commission to include the issues currently the domain of the HFEA and the relevant areas from the Human Tissue Authority. The bodies would provide advice and recommendations on issues which it considered that there were societal implications, such as selection for social reasons and preimplantation tissue typing, but would not provide clinical guidance. It would be informed by public consultations and could commission social science research. (Paragraph 400)
- 104.** Embryo research would need to be undertaken in an accredited facility, have been scrutinised by a local or regional research ethics committee, which would ensure that adequate consent had been sought from donors, and have been scientifically peer reviewed. (Paragraph 401)

## Formal minutes

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**Monday 14 March 2005**

Members present:

Dr Ian Gibson, in the Chair

Paul Farrelly  
Dr Evan Harris  
Dr Brian Iddon

Mr Robert Key  
Dr Desmond Turner

The Committee deliberated.

Draft Report (Human Reproductive Technologies and the Law), proposed by the Chairman, brought up and read.

*Ordered*, That the Chairman's draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 31 read and agreed to.

Paragraph 32 read as follows:

This approach emphasises the importance of the individual, specifically the autonomy of the individual and the right to make private choices. This has been challenged by Professor Robin Gill from the University of Kent, who argues that "We live in the "time of the triumph of autonomy in bioethics" in which "the law and ethics of medicine are dominated by one paradigm – the autonomy of the patient". He argues that "conceptions of individual autonomy cannot provide a sufficient and convincing starting point for ethics within medical practice". However, it is worth bearing in mind that legal tradition is that decisions which fall into the private domain are generally regarded as not of interest to the state. Certain exceptions to this maxim do, of course, exist, but these generally arise in the sphere of criminal law. Thus, when the service to be provided is the implantation of an embryo with the intention of establishing a pregnancy, and in line with Article 8 of the European Convention on Human Rights (incorporated into UK law by the Human Rights Act 1998) reproduction itself would seem to be firmly situated within the private domain. The primary consequence of this is that the right to private and family life espoused in Article 8 can be said to apply to reproductive decisions. Only if one of the possible derogations from that Article

can be established (for example where there is a threat to public health or morals) would the terms of this Article be inapplicable.

Amendment proposed, in line 12, leave out the words “in line with” and insert the words “according to a libertarian interpretation of”.—(*Paul Farrelly.*)

Question put, That the amendment be made.

The Committee divided.

Ayes, 1

Noes, 4

Paul Farrelly

Dr Evan Harris

Dr Brian Iddon

Mr Robert Key

Dr Desmond Turner

Amendment disagreed to.

Another Amendment proposed, in line 14, before the word “reproduction” insert the words “some would argue that”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 15, after the word “this” insert the words “interpretation and approach”.— (*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 15, leave out the word “can”, and insert the word “could”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 18, after the word “morals”, insert the words “or for the protections of the rights and freedoms of others”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another amendment proposed, in line 19, after the word “inapplicable” to add the words “Clearly, however, these derogations are very broad and capable of much interpretation and legal debate. Some of this debate overlaps with arguments in paragraphs 32-44 below, which examine arguments to limit and regulate reproductive freedom.”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 19, after the word “inapplicable” to add the words “In the absence of a body of court decisions, and therefore precedents, it would be possible for all sides of the debate about reproductive freedom to cite Article 8 to bolster their argument.”. —(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Question, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris

Paul Farrelly

Dr Brian Iddon

Mr Robert Key

Dr Desmond Turner

Paragraph agreed to.

Paragraph 33 read and agreed to.

Paragraph 34 read as follows:

The Chair of the HFEA, Suzi Leather, stated to us that she thought it was the special status of the embryo justified regulation, although it could be argued that the special status of the embryo is currently achieved by provisions in the HFE Act and that it is possible to achieve this without further legislation. It is interesting to note that in the Warnock report, the idea of protecting the embryo in law arose from the discussion of embryo research rather than assisted reproduction. Professor Peter Braude from Guy’s Hospital and a former member of the HFEA felt that it was the creation of a new life the justified intervention. He told us that “I do not think there is another area of medical practice that is like assisted conception. There is no other area I know other than drugs in pregnancy where, in satisfying the client [...] who come along to you and say, ‘We desperately want some children’, to solve that problem is a child”.

Amendment proposed, in line 2, leave out from the word “regulation” to the word “It” in line 4 and insert the words “It is important to draw a distinction between legislation and regulation and it is not clear that protection of the embryo requires oversight beyond that set out in legislation.”.—(*Dr Evan Harris.*)

Question put, That the amendment be made.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
 Dr Brian Iddon  
 Mr Robert Key  
 Dr Desmond Turner

Paul Farrelly

Amendment agreed to.

Paragraph, as amended, agreed to.

Paragraphs 35 to 43 read and agreed to.

Paragraph 44 read as follows:

An alternative perspective to the balance between reproductive freedom and state intervention is provided by utilitarian ethics. Here the emphasis is on measuring the benefits over burdens of particular activities. This approach was rejected by the Warnock Committee. It said “Moral questions, such as those with which we have been concerned, are, by definition, questions that involve not only a calculation of consequences, but also strong sentiments with regard to the nature of the proposed activities themselves.” Thus, for the Warnock Committee, even if evidence were available which could establish that the benefits (for example to the infertile) of unregulated access to assisted reproduction, there were underpinning moral or ethical considerations which also had to be considered, at least in some circumstances. However, the Warnock Committee did not view assisted reproduction in itself as a threshold that should not be crossed over. Thus, it would appear that both libertarian and utilitarian ethics would support the view that, in terms of the embryo intended for implantation, since the creation of a pregnancy is inherently to be regarded as a good thing, the state has no right to intervene in the choices of people to procreate unless evidence of harm can be shown.

Amendment proposed, in line 13, leave out from the word “would” to the word “in” in line 13, and insert the words “could support the view that”.—(*Paul Farrelly.*)

Question put, That the amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
 Dr Brian Iddon  
 Mr Robert Key  
 Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris

Paul Farrelly

Dr Brian Iddon

Mr Robert Key

Dr Desmond Turner

Paragraph agreed to.

Paragraphs 45 to 46 read and agreed to.

A paragraph—(*Dr Evan Harris*)—brought up, read and inserted (now paragraph 47).

Paragraphs 47 to 49 (now paragraphs 48 to 50) read and agreed to.

Paragraph 50 (now paragraph 51) read as follows:

As we have seen, IVF procedures often produce spare embryos. These may either be surplus or of insufficient quality. While the Warnock committee was unanimous about the use of these embryos for research, four of the 16 members felt that there was a “clear moral distinction” between the use of spare embryos and the creation of embryos specifically for research. These views were based on the following arguments:

- a) That the creation of an embryo for research was inconsistent with the idea that it should be afforded special status.
- b) That, unless prohibited, it would lead to the use of embryos for routine and less valid research.

The majority of the Warnock Committee felt that the medical benefits from the creation of embryos were such that it was justified in certain circumstances. We also subscribe to this view. **We believe that the research on human embryos can be undertaken without compromising its special status but that this research should have proper ethical oversight as set out in Chapters 8 and 9. We further conclude that, where necessary, embryos can be created specifically for research purposes.**

Amendment proposed, in line 15, after the word “oversight” insert the words “and regulation”.—(*Paul Farrelly*.)

Question put, that the Amendments be made.

The Committee divided.

Ayes, 1

Noes, 4

Paul Farrelly

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Another Amendment proposed, in line 15, before the word “**We**” insert the words “Presently embryonic stem cell research, for instance, is thought to offer promising avenues for the alleviation of illness or disease and”.— (*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 16, leave out the words “**where necessary**” and insert the words “**but subject to the same close ethical oversight and regulation and only where considered necessary**”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Question put, that the paragraph stand part of the Report.  
The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 50 to 53 (now paragraphs 51 to 54) read and agreed to.

Paragraph 54 (now paragraph 55) read, amended, and agreed to.

Paragraphs 55 to 59 (now paragraphs 56 to 60) read and agreed to.

Paragraph 60 (now paragraph 61) read as follows:

The placing of a human embryo in an animal raises clear issues of animal welfare but the ethical problems relating to the special status of the embryo are less clear. We are aware of no possible treatment applications that should lead us to question the current prohibition. However, if a spare embryo has been made available for research, then it could be argued that respect for the embryo should prompt us to

ensure that it is used for the best possible ends. It has been commented that very little is known about the development of the human embryo in vivo. There have been calls for the application of animal research work to human assisted reproduction. While we are aware of no interest from scientists in extending this work by placing human embryos in animals, it is conceivable that such research could yield valuable insights into the causes of infertility and miscarriage. Such a proposition would make many uncomfortable. Nonetheless, we have set ourselves the task of recommending new legislation that can cope with new technical advances and difficult issues must be taken into account.

Amendment proposed, in line 12, leave out the word “recommending” and insert the words “considering all difficult issues relating to”.—(*Paul Farrelly.*)

Question proposed, That the Amendment be made:—Amendment, by leave, withdrawn.

Paragraph agreed to.

Paragraphs 61 to 65 (now paragraphs 62 to 66) read and agreed to.

Paragraph 66 (now paragraph 67) read as follows:

While a chimera is unlikely to be able to develop very far, it may have value as a research tool, possibly as a means of testing the ability of stem cell cultures to form all forms of tissue. Similarly, hybrids formed by cell nuclear replacement might have value in deriving embryonic stem cells for research purposes. There have been reports that Chinese scientists have harvested stem cells from embryos created by introducing human cell nuclei into enucleated rabbit eggs. Professor Robin Lovell Badge from the MRC’s National Institute for Medical research told us that this technique might overcome the shortage of human cell lines, although he told us that some of this work was “to be taken with a pinch of salt”. The 2000 Donaldson Report on stem cell research stated that the 1990 Act does not control the mixing of animal eggs with other human cells but that this should be prohibited. The Lords Stem Cell Research Committee expressed some surprise at the conclusion since it could raise fewer ethical questions than for the use of a human embryo created using CNR. It should be remembered that the HFE Act aimed to give protection to the human embryo and not gametes or other forms of embryo. Provisions to protect hybrids would require a different ethical basis. **The ethical status of hybrids and chimeras is complex. While there is revulsion in some quarters that such creations blur the distinction between animals and humans, it could be argued that they are less human than, and therefore pose fewer ethical problems for, research, than fully human embryos. We recognise concerns that hybrids and chimeras could be used for reproductive purposes and recommend that new legislation defines the nature of these creations and makes their creation legal for research purposes only if they are destroyed in line with the current 14-day rule for human embryo cultures.**

Amendment proposed, in line 14, to leave out from the word “embryo” to the end of the paragraph, and to add the words “The ethical status of hybrids and chimeras may be a complex issue for some and clearly there is also revulsion that such creations blur the distinction between animals and humans. New legislation, however, should not shy from



addressing such advances in scientific technology and the issues involved should be properly debated. We have received no evidence, however, which suggests that – as with insertion of human embryos in animal wombs or vice-versa – that there are any benefits in new legislation permitting the creation of hybrids or chimeras for either reproductive or research purposes. Again, should the government receive expert advice to the contrary, given the ethical issues involved, any such change should be a matter for Parliament and primary legislation.”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Noes, 1

Paul Farrelly

Paragraph agreed to.

Paragraphs 67 to 79 (now paragraphs 68 to 80) read and agreed to.

Paragraph 80 (now paragraph 81) read, amended and agreed to.

Paragraphs 81 to 92 (now paragraphs 83 to 93) read and agreed to.

Paragraph 93 (now paragraph 94) read, amended and agreed to.

Paragraphs 94 to 95 (now paragraphs 95 to 96) read and agreed to.

Paragraph 96 (now paragraph 97) read as follows:

The HFEA reported other concerns that the time and cost of carrying out the welfare of the child assessment is disproportionate to the benefit gained. Professor Allan Templeton of the Royal College of Obstetricians and Gynaecologists told us that “It has been a distortion of clinical practice; it has been absolutely beyond any effect at all in terms of trying to enhance the welfare of the child”. He argues that there is no need for specific welfare of the child issues within any act as “it is good medical practice”. Witnesses from the British Fertility Society and the Association of Clinical Embryologists told us that they had compared notes in advance of the session. Of the four clinics they represented, they said that their “hit rate” for stopping treatment based on welfare of the child was between 0% and 0.3%. This suggests that if the welfare of the child provision were abolished, we would, in theory, be exposing around 10 children a year to potential harm. It is possible, however, that the provision has had a deterrent effect or that patients have withdrawn from treatment when it became clear that inquiries were being made about their background. The HFEA reports that while clinics sometimes make further enquiries to other agencies, they very rarely turn patients down for treatment. When they do, the most common reasons are medical (because the patient has an infectious disease or they are being treated for cancer), psychiatric (because the patient has a mental illness or a drug or alcohol problem) or, occasionally, social (because the couple lives apart). The consultation document sets out a range of approaches for the implementation of the HFE Act’s provision:

- a) The maximum welfare principle, which considers a child’s welfare to be of paramount importance and places the burden of proof upon the prospective parents to demonstrate their competence;
- b) The minimum threshold principle, which places great importance upon the autonomy of the prospective parents and seeks to override their wishes only when their child would be at high risk of serious harm; and
- c) The reasonable welfare principle, which reflects a compromise position.

Amendment proposed, in line 12, after the word “harm” to insert the words “For many this in itself would be a persuasive reason to keep the welfare of the child provision.”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 97 to 106 (now paragraphs 98 to 107) read and agreed to.

Paragraph 107 (now paragraph 108) read as follows:

**The welfare of the child provision discriminates against the infertile and some sections of society, is impossible to implement and is of dubious value in protecting the interests of children born as a result of assisted reproduction. We recognise that there will be difficult cases but these should be resolved by recourse to local clinical ethics committees. The welfare of the child provision has enabled the HFEA to make judgements that are more properly made by patients in consultation with their doctor. It should be abolished. Doctors should minimise the risks to any child conceived from treatment within the constraints of available knowledge but this should be encouraged through the promotion of good medical practice not legislation.**

Amendment proposed, in line 1, to leave out the word “discriminate” and insert the words “may be considered to discriminate”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Noes, 4

Paul Farrelly

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Another Amendment proposed, in line 2, to leave out the word “impossible” and insert the words “is difficult”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 2, to leave out the word “dubious” and insert the words “questionable practical”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment proposed, in line 7, to leave out the words “it should be abolished” and insert the words “The government should, therefore, consider carefully the case for its abolition rather than retention in any new Act. It should also carefully consider the case that”.—(*Paul Farrelly.*)

Question, That the amendment be made, put and negatived.

Another Amendment made.

Paragraph, as amended, agreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 108 to 123 (now paragraphs 109 to 124) read and agreed to.

Paragraph 124 (now paragraph 125) read as follows:

The application of selection becomes more problematic when the expression of the gene is not 100% and when there are available cures. The use of PGD for cancer predispositions and to eliminate carriers of genetic conditions is likely to remain controversial. We took evidence from Dr Maureen McHugh, a contributor to our online consultation who has Parkinson’s disease. She stated that “If it were possible to deselect an embryo at the very early pre-implantation stage to exclude the possibility of Parkinson’s disease, then I think it would be morally wrong to allow that embryo to develop further. [...] This is not discriminating against disabled people and it is not murder. It is simply trying to prevent disability, pain and misery”. **We have concerns about the criteria imposed by the HFEA. PGD is limited in that it can only be used to screen out disorders and thus it can never be**

**used to create the “designer babies” We see no reason why a regulator should seek to determine which disorders can be screened out using PGD. Nevertheless, clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements.**

Amendment proposed, in line 10, to leave out from the word “misery” to the end of the paragraph, and to add the words “As the technology currently stands, PGD is limited in that it can only screen our disorders and cannot be used to create so-called ‘designer babies’ in the popular understanding of the term. Scientific advance, however, is rapid and the state, either through primary legislation or regulation, does have an interest in influencing those disorders which can be screened out or in using PGD. Clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements and oversight.”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Noes, 1

Paul Farrelly

Paragraph agreed to.

Paragraphs 125 to 128 (now paragraphs 126 to 129) read and agreed to.

Paragraph 129 (now paragraph 130) read as follows:

The term “saviour sibling” has been coined, yet little attention has been given to the prospect of saviour sons or daughters, or even nephews and nieces. The HFEA ethics

committee, while supporting the use of PTT for siblings, drew the line at the use of the technology to benefit other members of the family. To make this distinction implies that there is evidence to suggest the psychological impact on the child, and the nature of the family's relationship, would be different if the recipient of the stem cells were not a sibling. The HFEA's review of its policy acknowledged this issue but stated merely that it raised "distinct and significant issues" and should be the subject of further consideration. **We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.**

Amendment proposed, in line 9, to leave out from the word "We" to the end of the paragraph and to add the words "**We recommend that Parliament does indeed consider the approach to such wider issues as part of any new Act.**".—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Noes, 4

Paul Farrelly

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 130 to 141 (now paragraphs 131 to 142) read and agreed to.

Paragraph 142 (now paragraph 142) read as follows:

Doubts have been cast over the validity of the data gathered by the HFEA in support of its conclusions on sex selection. However, even if the HFEA exaggerates the public's hostility to sex selection for social reasons, we have little reason to doubt that

a majority of the British public oppose it. Professor Tom Shakespeare from Newcastle University has provided confirmation of this from his own research. Nevertheless, we do not see this as adequate grounds for prohibition. In paragraph 46, we stated that while reproductive freedom needed to be balanced against harms to individuals and society, these claims of harm needed to be based on evidence. In 2001, the Ethics Committee of the American Society of Reproductive Medicine concluded that:

“Until a more clearly persuasive ethical argument emerges, or there is stronger empirical evidence that most choices to select the gender of offspring would be harmful, policies to prohibit or condemn as unethical all uses of non-medically indicated preconception gender selection are not justified.”

Four years on there is still no compelling evidence of harms to individuals and society from social sex selection. **The issue of sex selection requires greater analysis than has been afforded it by the HFEA. The onus should be on those who oppose its use for social reasons using PGD to show harm from its use. However, the use and destruction of embryos does raise ethical issues and there are grounds for caution. We urge greater efforts to establish the demographic impacts across all sectors of society and the implications for the creation and destruction of embryos in vitro.**

Amendment proposed, in line 6, to leave out from the word “Nevertheless” to the word “In” in line 6, and insert the words “Clearly, public opinion needs to be taken into account by Parliament, but any prohibition should also be based on good ethical grounds and evidence of harm.”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Another Amendment proposed, in line 22, after the words “**in vitro.**” add the words “**On balance we find no adequate justification for prohibiting the use of sex selection for family balancing.**”.—(*Dr Evan Harris.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 3

Noes, 2

Dr Evan Harris  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly  
Dr Brian Iddon

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 3

Noes, 1

Dr Evan Harris  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 143 to 153 (now paragraphs 144 to 154) read and agreed to.

Paragraph 154 (now paragraph 155) read as follows:

During our visit to Stockholm we were told that, in the 1980s, 250 children were born by donor insemination each year. We heard that, after the law ending anonymity was passed in 1985, the number of inseminations declined but that the practice did not end. Currently, around 60 children are born each year by donor insemination and it was estimated that another 200 are conceived abroad. We understand that the waiting list for donors is several years' long. The Department of Health said that the Minister's statement about the Swedish case was based largely on a report commissioned from Professor Eric Blyth at the University of Huddersfield. He reported that the change in legislation in Sweden resulted in a decline in donor recruitment, but that it was not possible to ascertain the scale of the reduction. He provided anecdotal data that recruitment had recovered following the change in legislation. It is difficult to reconcile the Department's statements with the comments we heard first hand in Stockholm. A possible solution is that the Department's evidence related to the number of donors rather than the number of children born through donation. A flaw in their approach is that it relied on input from existing clinics that offer donor insemination. We have heard that in the UK some clinics have ceased operating the service. In Sweden the same effect was observed, with five of the 10 clinics closing. Those that continued the service may have managed to maintain their own supplies despite an overall drop in the number of donors. This may seem a minor point but this has been used to provide a misleading picture of donation post-anonymity. We regret the Department's poor use of evidence in policy-making.

Amendment proposed, in line 21, to leave out from the word "We" to the end of the paragraph.—(Paul Farrelly.)



Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Another Amendment made.

Paragraph, as amended, agreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Noes, 1

Paul Farrelly

Paragraph agreed to.

Paragraphs 155 to 156 (now paragraphs 156 to 157) read and agreed to.

A paragraph—(*Dr Evan Harris*)—brought up, read and inserted (now paragraph 158).

Paragraphs 157 to 181 (now paragraphs 158 to 182) read and agreed to.

Paragraph 182 (now paragraph 184) read as follows:

Section 41 sets out the offences for breaching the provisions of the HFE Act or contravening licence conditions. In the cases of placing in a woman a live embryo other than a human embryo or any live gametes other than human gametes, mixing animal and human gametes, placing a human embryo in an animal or keeping or using an embryo after 14 days, the penalty is up to 10 years in prison. We have commented on the various prohibitions in the HFE Act and concluded that legislation should be more flexible, particularly with regard to research (see

paragraphs 331–342). We are also concerned by the size of the maximum sentence. **That the embryo only gradually acquires human rights is a widely accepted view. In this light, the maximum sentence of 10 years for breaching some of the prohibitions in the HFE Act seem unduly harsh.**

Amendment proposed, in line 8, to leave out from the word “We” to the end of the paragraph and add the words “Once those boundaries have been set, however, it is right that breaches of the law or regulations should attract harsh sentences to act as an effective deterrent in this age of rapid scientific advance and competition.”.—(*Paul Farrelly.*)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Noes, 4

Paul Farrelly

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Noes, 1

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Paul Farrelly

Paragraph agreed to.

Paragraphs 183 to 359 (now paragraphs 185 to 361) read and agreed to.

Paragraph 360 (now paragraph 362) read as follows:

The HFEA’s consultation on sex selection makes a good case history. As well as disappointing groups such as CORE for having ignored the opinion it elicited, it has been criticised for giving it too much weight. We were aware of these pitfalls in planning our own online consultation and hope we have been able to show how we have used the views put to us to reach our conclusions. At the same time, we made no efforts to quantify the views submitted. We commented above that when the

Department sought the HFEA's view on sex selection, it was not necessarily asking for the public's view. We believe that the HFEA would have been well-advised to adopt our approach, for having found that a large majority did not wish to see sex selection for social reasons it would have been very brave to conclude otherwise, unless serious ethical debate was engaged in and principles could be identified which justified proceeding on the basis of these rather than the numbers opposed. The Medical Research Council has suggested that the HFEA should consider setting up a citizens council to help guide it through ethical decision-making. This has the attraction of providing ongoing public input. Surveys and opinion polls provide useful input to policy development, but are essentially anecdotal and represent the views of a self-selecting group of individuals; often activists. Additionally, we would caution about using the weight of response to determine the outcome of any policy review.

Amendment proposed, in line 5, to leave out from the word "conclusions." to the end of the paragraph and to add the words "At the same time we made no efforts to quantify the views submitted, which may be seen by some as a serious drawback to our approach."—(*Paul Farrelly*.)

Question put, that the Amendment be made.

The Committee divided.

Ayes, 1

Paul Farrelly

Noes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Amendment disagreed to.

Question put, that the paragraph stand part of the Report.

The Committee divided.

Ayes, 4

Dr Evan Harris  
Dr Brian Iddon  
Mr Robert Key  
Dr Desmond Turner

Noes, 1

Paul Farrelly

Paragraph agreed to.

Paragraphs 361 to 399 (now paragraphs 363 to 401) read and agreed to.

Motion made, and Question put, That the Report, as amended, be the Sixth Report of the Committee to the House.

The Committee divided:

Ayes, 4

Noes, 1

Dr Evan Harris

Paul Farrelly

Dr Brian Iddon

Mr Robert Key

Dr Desmond Turner

*Resolved*, That the Report be the Sixth Report of the Committee to the House.

*Ordered*, That the Chairman do make the Report to the House.

*Ordered*, That the provisions of Standing Order No. 134 (Select Committee (reports)) be applied to the Report.

[Adjourned till Wednesday 16 March at 9 o'clock .

# Witnesses

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## Monday 14 June 2004

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**Mr Richard Kennedy**, Centre for Reproductive Medicine, Walsgrave Hospital, **Professor Neil McClure**, Department of Obstetrics and Gynaecology, Queen's University Belfast, **Dr Simon Thornton**, The Park Hospital, Nottingham, **Mrs Liz Corrigan**, Centre for Reproductive Medicine, University of Bristol, British Fertility Society and **Dr Sue Avery**, Assisted Conception Unit, Birmingham Women's Hospital, Association of Clinical Embryologists Ev 1

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**Ms Philippa Taylor**, **Reverend Christopher Johnson**, and **Mr John Ford** Ev 16

**Mr Tony Gilland**, **Dr David King**, and **Dr Calum McKellar** Ev 19

**Ms Alison Davis**, **Mr Patrick Mahon**, and **Dr Maureen McHugh** Ev 23

**Dr Neville Cobbe**, **Dr Richard Fleming** and **Dr Veronica van Heyningen** Ev 26

## Wednesday 30 June 2004

**Mr Walter Merricks**, **Mr David Gollancz**, **Ms Becky Gardiner** and **Ms Michelle Snead**, Donor Conception Network Ev 30

**Mr Alan Masterton** and **Mrs Louise Masterton** Ev 35

**Ms Sheena Young**, **Ms Sharon Griffiths** and **Ms Tracey Sainsbury** Ev 38

**Ms Lisa Saffron**, **Ms Maria Hurley**, and **Ms Barbara Salter**, Pink Parents Ev 42

## Wednesday 21 July 2004

**Professor Brian Toft**, Research Director, Marsh Risk Consulting Practice, London Ev 47

**Ms Angela McNab**, Chief Executive, **Ms Trish Davies**, Director of Regulation, **Mr Charles Lister**, Head of Policy, and **Dr Chris O'Toole**, Head of Research Regulation, Human Fertilisation and Embryology Authority Ev 52

## Wednesday 8 September 2004

**Ms Linda Ball**, nominated by Muscular Dystrophy Association, **Mr Jayson Whitaker**, father of child with Diamond Blackfan anaemia, **Mr Peter Hingston** and **Mrs Fiona Hingston**, nominated by Cystic Fibrosis Trust Ev 67

**Dr Simon Fishel**, Director, Centres for Assisted Reproduction, **Professor Peter Braude**, Head, Department of Women's Health, Guys, Kings and St Thomas' School of Medicine, and **Professor Tom Baldwin**, Deputy Chair and Chair, Ethics & Law Committee, Human Fertilisation and Embryology Authority, and Professor of Philosophy at the University of York Ev 72

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**Rev Dr John I Fleming**, Director, Southern Cross Bioethics Institute and Consultant to the Society for the Protection of the Unborn Child, **Rt Rev Dr Michael Nazir-Ali**, Bishop of Rochester, Church of England, **Ms Josephine Quintavalle**, Comment on Reproductive Ethics, and **Dr Helen Watt**, Director, Linacre Centre for Healthcare Ethics Ev 83

**Wednesday 13 October 2004**

**Professor Robin Gill**, Ramsey Professor of Modern Theology, University of Kent, **Professor Julian Savulescu**, Uehiro Professor of Practical Ethics, University of Ethics, and **Professor Alastair Campbell**, Professor of Ethics in Medicine, University of Bristol Ev 94

**Wednesday 27 October 2004**

**Dr Michael Wilks**, Chairman, Medical Ethics Committee, **Dr Vivienne Nathanson**, Director of Professional Activities, British Medical Association Ev 106

**Professor Kenyon Mason**, Professor (Emeritus) of Forensic Medicine, University of Edinburgh, **Professor Margaret Brazier**, School of Law, University of Manchester, **Ms Sarah Ellison**, Lecturer in Medical Law, University of Glasgow, and **Mr James Lawford Davies**, Solicitor, Bevan Ashford Ev 113

**Wednesday 10 November 2004**

**Ms Marilyn Crawshaw**, Lecturer in Social Work and Research Fellow, University of York, **Ms Deborah Cullen**, Legal Group Co-ordinator, British Association for Adoption and Fostering, **Professor Eric Blyth**, Professor of Social Work, University of Huddersfield, **Dr Jim Monach**, Acting Chair of BICA and Honorary Research Fellow, University of Sheffield, and **Ms Sheila Pike**, Past Chair of BICA and Counsellor, Centre for Reproductive Medicine and Fertility, Sheffield Teaching Hospitals NHS Trust Ev 124

**Professor Susan Golombok**, Family and Child Psychology Research Centre, City University, **Dr Sarah Parry**, Centre for Social and Economics Research on Innovation on Genomics, University of Edinburgh, **Dr Tom Shakespeare**, Policy, Ethics and Life Sciences Research Institute, Newcastle University, and **Professor Martin Richards**, Centre for Family Research, Cambridge University Ev 133

**Wednesday 24 November 2004**

**Professor Robert Edwards**, IVF pioneer, Chief Editor of Reproductive BioMedicine Online, **Professor Catherine Peckham**, Chair of MRC/HFEA Working Group on Assisted Reproduction, Institute of Child Health, London, **Professor Henry Leese**, Department of Biology, University of York, Editor-in-chief of Human Fertility journal Ev 145

**Professor Roger Pedersen**, Director, Cambridge Stem Cell Institute, **Professor Alison Murdoch**, Consultant Gynaecologist, Head of Department, Newcastle Fertility Centre, **Dr Robin Lovell-Badge**, Head of Division of Developmental Genetics at the MRC's National Institute for Medical Research Ev 154

**Wednesday 8 December 2004**

**Dr Richard Kennedy**, Secretary, British Fertility Society, **Professor Allan Templeton**, President, and **Professor Lesley Regan**, former Member of Royal College of Obstetricians and Gynaecologists Ev 164

**Wednesday 19 January 2005**

**Suzi Leather**, Chair, **Professor Neva Haites**, Member and Professor of Medical Genetics, University of Aberdeen, **Professor Emily Jackson**, Member and Professor of Law, Queen Mary University of London, Human Fertilisation and Embryology Authority Ev 174

**Miss Melanie Jackson MP**, Parliamentary Under-Secretary of State for Public Health, **Ms Liz Woodeson**, Divisional Head, Scientific Development and Bioethics Division, and **Mr Ted Webb**, Section Head, Assisted Reproduction: Services, Policy and Regulation, Department of Health Ev 183

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