



CentreLGS

AHRC Research Centre for Law, Gender and Sexuality

## **RESPONSE TO THE PUBLIC CONSULTATION ON THE HUMAN FERTILISATION AND EMBRYOLOGY ACT**

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## Questions and proposals for consultation

### The model and scope of regulation

1. The Government believes that both the development and use of human reproductive technologies, and their regulation in response to public concerns, should continue to be subject to legislation. (Paragraph 2.7).

Yes, we agree that the development and use of human reproductive technologies should continue to be subject to legislation. However, the fundamental ethical principle which should underpin law and regulation in this area is *procreative autonomy* or *procreative liberty*. Ronald Dworkin defines this as a person's "right to control their own role in procreation unless the state has a compelling reason for denying them that control".<sup>1</sup>

Framed in this way, the right to procreative autonomy doesn't directly entail any practical conclusions since we still need to know whether or not the state has "a compelling reason" to restrict reproductive freedom in any given policy area. However, it does at least provide a starting presumption: that unless the state can demonstrate that there are compelling reasons for prohibiting a practice, then that practice should be allowed. It does not of course follow from this that the state is obliged to fund or otherwise actively *support* these practices; that is a separate issue and not one which we address here.

2. On balance, the Government believes that the current model of regulation,

<sup>1</sup> Ronald Dworkin, *Life's Dominion: an argument about abortion and euthanasia*, London: HarperCollins 1993, p.148.

whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has worked well and should continue. (Paragraph 2.14).

Yes, the speed at which human reproductive technologies develop and change means that an independent statutory authority is the appropriate licensor of activities since it can draw on specialist expertise and adapt to new findings more quickly than Parliament. However, given the need for democratic accountability, it is appropriate for Parliament to set the general parameters of any such regulation.

**3.** However, the Government also accepts that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law. In particular, the Government accepts the need to clarify the extent of any policy-making role of the regulator. (Paragraph 2.15).

Yes, the parameters of policy-making should be clear and subject to parliamentary debate.

**4.** The Government believes that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation. (Paragraph 2.20).

Yes, all human embryos outside the body should be within the scope of regulation. The House of Lords interpreted the existing law purposively so as to include those embryos created through nuclear transfer which were not literally covered by the 1990 Act in *R v Secretary of State for Health, ex parte Quintaville* [2003] 2 All ER 113. But the fear that the cloning of embryos was not regulated led to the hasty adoption of the *Human Reproductive Cloning Act 2001* which makes reproductive cloning a criminal offence, liable to up to 10 years in prison. Greater statutory clarity about the scope of regulation helps to minimise such fears and to prevent rushed and overly punitive legal responses.

**5.** The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research. (Paragraph 2.22).

A regulatory approach is preferable to the prohibitive approach adopted by the *Human Reproductive Cloning Act 2001*. Embryos developed for reproductive purposes should be held to a higher safety standard than those developed for research purposes.

**6.** The Government proposes that eggs undergoing processes intended to result in the creation of embryos – whether fertilisation or other non-fertilisation processes – should continue to be subject to regulation. (Paragraph 2.27).

We agree. There is little reason to distinguish between such eggs and early stage embryos for regulatory purposes.

**7.** The Government believes that the potential use of artificial gametes raises safety issues and that some uses may also raise ethical concerns. Therefore the Government proposes that the use of artificial gametes in assisted reproduction treatment should not be permitted but that the HFE Act should contain a regulation-making power giving Parliament more flexibility to allow the use of artificial gametes in future should it wish to do so. (Paragraph 2.31).

We take the view that this issue requires fuller evaluation. but that the suggested regulatory framework is preferable to an outright prohibition, as it allows for the possibility of detailed consideration of the complex issues raised at a future date.

**8.** The Government seeks views on the extent to which regulation should apply to the use of a couple's "fresh" gametes. Should this be limited to technical and safety issues only or should treatment involving a couple's fresh gametes be subject to the full requirements of the HFE Act where these are relevant? (Paragraph 2.37).

Regulation of fresh gametes should be limited to technical and safety issues. Those availing of assisted conception techniques are subjected to more invasive regulation than those using traditional conception methods. The starting point should be one of respect for the individual's reproductive autonomy, with further regulation mandated only where strictly necessary.

**9.** The Government intends to make the operation of internet services which involve the supply of gametes subject to regulation. Should the law (a) prohibit the operation of such services, (b) regulate the safety and quality aspects of such services, (c) regulate safety and quality and remove any anomalies with other methods of gamete donation? (Paragraph 2.42).

The best approach is that advocated in Option C. Users of internet services should be protected in terms of safety and quality. It is not clear that the internet raises regulatory issues that are substantially different from other modes of service delivery. As such, we would agree that it is anomalous for donor gametes supplied this way to remain outside of the regulatory framework which currently governs licensed clinics.

**10.** The Government seeks views on whether moving toward the transfer of a single embryo during a treatment cycle should (a) be a matter for legislation, (b) be a matter for the regulator, (c) be a matter for the professional bodies only. (Paragraph 2.47).

Moving to a system of single embryo transfer may seriously impede a

woman's chances of a successful pregnancy. As such, weighing the risks and benefits of a multiple transfer is a matter for the judgment of the patient concerned, in consultation with her clinician.

11. The Government invites views on what, if any, powers the regulator should have in relation to the costs of assisted reproduction treatments provided to private patients. (Paragraph 2.49).

We support the general notion that the state should have the power to control the costs of private services. Given the fact that assisted reproduction treatments are rationed with the NHS, some individuals will need to use privately provided treatments in order to fulfil their reproductive wishes. Therefore, the regulator should ensure that assisted reproduction treatments are reasonably priced so as to limit the potential for exploitation of those who use privately provided treatments. In so far as further reforms do not change the current situation whereby single women and lesbian couples will find it harder to meet NHS criteria for public treatment, a failure to regulate the costs of privately provided treatments will have a disproportionately harsh impact on them and so is arguably indirectly discriminatory.

12. The Government invites comments on the desirability of making the regulator's licensing powers more flexible, for instance (a) the ability to licence clinical trials, and (b) explicitly allow training of clinicians and researchers. (Paragraph 2.56).

### Welfare of the child

13. The Government seeks views on whether taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act *obligation* on persons providing treatment services. (Paragraph 3.19).

**The existing welfare of the child provision is objectionable on several different grounds and should be abolished.** These grounds include –

1. The present law is inconsistent in singling out IVF for restrictive regulation, because other practices with the same aim (e.g. surgical procedures aimed at restoring fertility, lifestyle advice given by GPs) are not similarly regulated.<sup>2</sup>

2. In virtually all cases, predicting a possible future child's quality of life is extremely difficult and healthcare professionals' attempts to do this are likely to be unreliable and/or excessively burdensome (both for themselves and their patients). Quality of life is affected by many different variables (e.g. health, wealth, education, emotional support), which can change significantly

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<sup>2</sup> See further: Emily Jackson, 'Conception and the Irrelevance of the Welfare Principle' (2002) 65 *Modern Law Review* 176-203.

over time, and healthcare professionals often do not have the relevant particular expertise to assess non-medical variables. In these circumstances quality of life assessment too easily becomes speculation about people's ability to parent, which is even less predictable and more likely to be discriminatory.

The main exceptions to this difficulty with predicting future child welfare are cases where possible future children are at high risk of suffering from those

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3 See: House of Commons Select Committee on Science and Technology (2005), *Human Reproductive Technologies and the Law*, #107; Human Fertilisation and Embryology Authority (2005), *Tomorrow's Children: a consultation on guidance to licensed fertility clinics on taking in [sic] account the welfare of children to be born of assisted conception treatment*; S. Sheldon & S. Wilkinson (2006) 'Tomorrow's Children: child welfare, adoption, and assisted conception', in : HOLM, S. (ed), *A Life of Value*, forthcoming.

4 The *Adoption and Children Act 2002* contains a variant of this principle in s.1(2) which provides that the paramount consideration of the court or adoption agency must be the child's welfare, throughout her life.

5 One additional complication that we leave to one side for now is that there are also issues of 'fit': i.e. what's best for one particular child may not be best for all other children.

6 See for example: David Archard, 'Wrongful Life', *Philosophy*, 79.3, July 2004; Allen Buchanan, Dan Brock, Norman Daniels, & Daniel Wikler, *From Chance to Choice*, (Cambridge: Cambridge University Press 2000); Jonathan Glover, *Fertility and the Family: the Glover Report on reproductive technologies to the European Commission*, London, Fourth Estate, 1989; John Harris, 'Wrongful Birth', M.E. Dalton and J. Jackson (eds.) *Philosophical Issues in Reproductive Medicine* (Manchester: Manchester University Press, 1990); John Harris, *On Cloning*, London: Routledge 2004, Chapter 3 ('The Welfare of the Child'); John Harris, 'The Welfare of the Child', *Health Care Analysis*, 2000, vol. 8; Derek Parfit, *Reasons and Persons* (Oxford: Clarendon, 1984); Melinda Roberts, *Child Versus Childmaker: Future Persons and Present Duties in Ethics and the Law* (Boulder: Rowman and Littlefield, 1998); John Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* (Princeton: Princeton University Press, 1994); Bonnie Steinbock, *Life Before Birth: the moral and legal status of embryos and fetuses* (Oxford University Press 1992); Stephen Wilkinson, *Bodies for Sale: ethics and exploitation in the human body trade*, London: Routledge 2003, Section 8.3 ('The Welfare of the Child').

7 It should be remembered that the consideration of child welfare is a condition of licences for treatment, and not for storage: ss. 13 and 14 of the 1990 Act. As such, there may be scope for remedying this problem without reform of the primary legislation, for example, through advice to clinics that welfare determinations should be made at the time that embryos are to be used, rather than at the time they are created. This, however, raises a number of further difficult, and we believe insurmountable, problems relating to the ethics of creating embryos for a woman, which she then may never be allowed to use.

8 See S. Sheldon (2004) 'Evans v Amicus Health Care: Revealing Cracks in the "Twin Pillars"?' *Child and Family Law Quarterly* 437-52 for a more detailed exposition of this argument in the context of *Evans*.

9 House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law*, 2005, #107.

serious genetic disorders which inevitably condemn sufferers to lives of excruciating pain. Here, quality of life may be relatively predictable based on medical evidence.

3. People sometimes try to defend the Welfare of the Child provision by claiming that IVF is like adoption. Thus, they argue that since prospective adopters are subjected to 'fitness to parent' tests, consistency demands that prospective recipients of infertility treatment services be subjected to the same tests.<sup>3</sup>

Our view is that the comparison of adoption with IVF is misleading and that the two practices are different in important ways. In the case of adoption, we are allocating existing children to new social parents. One quite plausible allocation principle that we might use for adoption is a *welfare maximisation principle* according to which children should be placed in the *best available* homes (ranked in terms of their ability to give a child a high level of welfare).<sup>4</sup> On this view, if there are 10 children and 20 homes (each able and willing to take one adoptee), the 10 children should go to the best 10 homes.<sup>5</sup>

Could the same principle be used to justify 'fitness to parent' checks on users of assisted conception services? No, because the choice that faces us when we decide whether or not to withhold infertility treatment services is not *where best to place* a future child, but rather *whether or not to allow this child to come into existence at all*. So the relevant welfare question is not "is this the best available home for this child?" but rather "ought the creation of this child to be permitted?"

4. Similarly, we must always keep in mind that when we withhold infertility treatment on Welfare of the Child grounds, this does not generally mean creating a better off rather than a worse off child. Rather, it means that the child is not created at all. Exactly how 'welfare of the child' considerations apply in these 'existence vs. non-existence' scenarios has been the subject of considerable philosophical debate and we do not attempt to summarise this here.<sup>6</sup> Nonetheless, we note that there is a large body of opinion (with which we concur) to the effect that, in such cases, we do no harm to the child by permitting or facilitating its creation, provided that its life will be 'worth living', provided that it would not, if born, be 'better off dead'. And if we do no harm to the child by creating it, it is hard to see how its welfare can serve as a reason to prevent it from coming into existence.

Of course, it does not follow from this that, once children exist, we should be content for them to have low levels of welfare, lives 'barely worth living'. Once children exist, we must do what we can to ensure that their rights are respected and that their welfare levels are as high as is practicable.

5. It is also our belief that the Welfare of the Child ground may discriminate against a small number of particularly vulnerable women. Men with testicular cancer are routinely offered the option of storing sperm for future use before undergoing treatment for their cancer. A female ovarian cancer sufferer who wishes to preserve the possibility of having her own genetic child is not able to

rely on egg storage, which is at an early and experimental stage and has resulted in very few successful pregnancies worldwide. Female, but not male, cancer sufferers thus have a medical need to store their genetic material in the form of embryos. This means that only female cancer sufferers are forced to open their relationships up to the scrutiny of clinics, in the way required by the welfare requirements of s.13(5).<sup>7</sup> This specific discrimination problem was raised on the facts of *Evans v. Amicus Healthcare Ltd* [2004] E.W.C.A. (Civ.) 727 but, unfortunately, not argued in this form before any of the courts that have heard that case.<sup>8</sup>

The root of the inequality here is clearly one imposed by biology and the state of medical science: sperm stores well, unfertilised eggs do not. But it is not only biology but also the operation of the law that imposes such stringent restrictions on the options that are open to cancer sufferers seeking gamete storage. Moreover, elsewhere, we have not been content to preserve other aspects of female disadvantage that are due to biology. Biology dictates that pregnancy and breast-feeding are uniquely female activities. But law and social policy have attempted to ensure that certain adverse social consequences do not result from these biological differences by developing a regime of protection that, however unsuccessfully, aims to allow women to combine these activities with a life outside the home.

All of the reasons cited above lead us to agree with the conclusion of the House of Commons Select Committee on Science and Technology that “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 ... It should be abolished in its current form.”<sup>9</sup>

**14.** The Government seeks views on whether, if a welfare of the child requirement remains in the HFE Act, compliance with it should be a matter for “good medical practice” and the clinician’s judgement, rather than be subject to HFEA guidance and regulation. (Paragraph 3.23).

We have advocated the complete abolition of the Welfare of the Child provision (above). However, if it were to be retained, it should be a matter for “good medical practice” only in so far as the medical welfare of the child should be considered (see 15). Clinicians do not normally have the expertise or information to apply non-medical welfare criteria and leaving non-medical welfare criteria to the clinician’s judgement facilitates speculation about parenting abilities.

**15.** If you agree with this, do you think that clinicians should only be required by the legislation to take account of the *medical* welfare of the child? (Paragraph 3.24).

We have advocated the complete abolition of the Welfare of the Child provision (above). However, *if* it were to be retained, then only the medical welfare of the child should be considered. Our reasons for this are those



given under Q13

**16.** If a legal obligation to consider the welfare of the child is retained, should it be reformulated to refer to a risk of serious harm? For example, should it specify that treatment should not be provided where the clinician believes there is risk of significant harm? (Paragraph 3.26).

We have advocated the complete abolition of the Welfare of the Child provision (above). However, *if* it were to be retained, it should be reformulated to apply only to cases in which there is a well-evidenced substantial risk of serious harm to the child created. Given the considerations cited in Q13, very few cases would be prohibited on this ground. There may however be a small number of ‘wrongful life’ cases: for example, where the possible future child is at high risk of having a genetic disorder that would inevitably condemn her to a life of unbearable suffering.

**17.** Do you think that the requirement to take account of “the need of the child for a father”, as part of considering the welfare of the child, should be removed from the Act? Alternatively, do you think that it should be replaced with “the need of the child for a father and a mother”? (Paragraph 3.32).

We have advocated the complete abolition of the Welfare of the Child provision (above). However, *if* it were retained, it should be reformulated to exclude the ‘need for a father’. This aspect of Section 13(5) has been widely criticised on the grounds that it discriminates against lesbian couples and single women<sup>10</sup> and is incompatible with more recent statutory developments such as the Adoption and Children Act 2002 which allows for same sex adoption, and the Civil Partnership Act 2004 which gives couples in same sex relationships the same rights as married heterosexual couples. Section 13(5) is also arguably an infringement of single or lesbian women’s Convention rights (Articles 8, 12 and 14 ECHR) to privacy and family life, to marry and found a family, and to non-discrimination given that it imposes an unreasonable obstacle to the execution of these rights.

We thus agree with the House of Commons Select Committee on Science and Technology that: “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”.<sup>11</sup>

Whether or not children need fathers is largely an empirical matter and, as the Government notes in the consultation document, the extant sociological evidence “cannot ... be considered as providing conclusive evidence either way about the value of the father’s role in children’s development, although

<sup>10</sup> D. Cooper and D. Herman, ‘Getting “The Family Right”: Legislating Heterosexuality in GB, 1986-

1991’ (1991) 10 *Canadian Journal of Family Law* 41 at 43; G. Douglas, ‘Assisted Reproduction and the Welfare of the Child’ (1993) 5 *Current Legal Problems* 53

<sup>11</sup> House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law*, 2005, #101

they do point to the quality of parenting, rather than the parents' gender, as being the factor of prime importance".<sup>12</sup> Given this lack of evidence, there can be no justification for the 'need for a father' clause and it would clearly be wrong to cite in legislation a 'need' which we have little or no reason to believe exists.

Any reference to "the need of the child for a father and a mother" is also objectionable for the above reasons.

### The use and storage of gametes and embryos

**18.** The Government believes that on balance, the HFE Act's existing requirements for written consent remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors. Do you agree? (Paragraph 4.10).

The consent provisions of the 1990 Act have already been subject to a thorough and searching review. We agree with the findings of that review that the consent provisions are basically sound.<sup>13</sup> However, the unfortunate recent case of *Evans*<sup>14</sup> might suggest that the way in which consent obtained in practice does not always live up to the ideals of the legislation or the HFEA's Code of Practice.<sup>15</sup> Further, *Evans* might suggest two further issues relating to the consent provisions which are worthy of further scrutiny:

- a) that **the interplay between the consent provisions and those governing the attribution of the status of legal parent might need to be revisited**. Specifically, the consent provisions allow anyone who has contributed gametes, including someone donating gametes for the use of others, to withdraw consent (effectively rendering impossible the use of stored embryos). This can have serious implications when the stored embryos now represent an individual's only chance of becoming a (genetic) parent. **One possibility which might have aided a resolution in *Evans* would be to distinguish between 1) men's consent to become legal parents and 2) men's consent for the embryos to be used by former partners**. Men could then be allowed to withdraw the consent to parent under s.28(3), while maintaining their consent for the embryos to be used by former partners. Whether this is permissible under the existing legislation is, in our view, unclear.<sup>16</sup>
- b) Whether parties are unduly constrained in their ability to decide what should happen to embryos in the future. Should the parties be allowed

<sup>12</sup> Department of Health, *Review of the Human Fertilisation and Embryology Act: a public consultation*, 2005, #3.28.

<sup>13</sup> S. McLean *Review of the Common Law Provisions Relating to the Removal of Gametes and of the Consent Provisions in the Human Fertilisation and Embryology Act 1990* (London, Department of Health 1998)

<sup>14</sup> [2003] EWHC 2161 (Fam), [2004] EWCA (Civ) 727, currently pending before the European Court of Human Rights.

<sup>15</sup> See further, S Sheldon (2004) '*Evans v Amicus Health Care: Revealing Cracks in the "Twin Pillars"?*' *Child and Family Law Quarterly* 437-52 on this issue.

<sup>16</sup> *Ibid.*

to waive their right to withdraw future consent to the use and storage of the embryos, at the time when consent is taken?<sup>17</sup>

**19.** Should the requirement for *written* consent be extended to apply to all assisted conception treatments provided in licensed clinics, including treatment using a couple's own 'fresh' gametes such as IUI and GIFT? (Paragraph 4.11).

Generally, the legal significance of consent is to provide a record of what has been agreed by the party undergoing medical treatment. We see no advantage to making written consent a formal legal requirement in the circumstances described above. However, as a matter of good medical practice, most clinics will prefer to obtain written consent also in these circumstances.

**20.** The Government proposes that the law should allow the *storage* of gametes without the consent of a person lacking capacity where the gametes were lawfully removed. Do you agree? (Paragraph 4.16).

Yes, we agree. In certain, rare circumstances this will be necessary to preserve the future procreative options of children and adults who will become temporarily incapacitated. Consent for continued storage should be obtained as soon as the individual concerned (re)gains capacity.

**21.** The Government proposes that a person's gametes stored in these circumstances may only be *used* with the consent of that person. Do you agree? (Paragraph 4.17).

Yes.

**22.** The Government invites views on whether the law should be changed to require the withdrawal of the consent of *both* parties whose gametes were used to create an embryo in order to allow a stored embryo to perish, and that such an embryo should otherwise continue in storage until the statutory maximum storage period is reached. (Paragraph 4.21).

Subject to the response to Q 18, continued storage of embryos should require ongoing consent of both parties.

**23.** Do you think that the law should continue to set statutory maximum storage periods for gametes and embryos and if so how should these be determined? (Paragraph 4.25).

Maximum storage periods should be determined in light of research into the efficacy of gametes/embryos which have been stored for long periods. If 20 years is the period of time after which embryos no longer offer a realistic chance of a successful pregnancy, then the statutory maximum storage

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<sup>17</sup> Ibid.

period should be no less than 20 years. Recent reports have referred to the case of children who were conceived using gametes (sperm) which were stored for 21 years. If such reports are true they provide a prima facie case for raising the limits in respect of gametes at least, and probably embryos. But any such change should be dependent on medical research.

**24.** If you think that the law should continue to set statutory maximum storage limits, should the storage limits for donation be brought into line with the storage periods for treatment? (Paragraph 4.26).

In a context where individuals have stored their own gametes with a view to their own future treatment, there is an argument for allowing a longer storage period, as there is a particularly pressing case for use of the particular gametes/embryos. Drawing on the general ethical principle set out in our response to Q1, we would support a more generous storage period in such cases, coupled with the ethical duty on the advising clinician to advise on the chance of a successful pregnancy given the age of the genetic material in question.

**25.** The Government invites views on whether the requirement on licensed centres to provide “such relevant information as is proper” should remain a legal requirement. (Paragraph 4.35).

Fully informed consent is vital in ensuring respect for procreative autonomy. The objective of Information disclosure should be ensuring that patients have all the information that they want, having been made aware of what information is available. The implications of the status provisions regarding parenthood should also be clearly explained. If patients seek counselling, it should be provided. However, counselling of patients should not be mandatory.

**26.** If so, should that requirement be extended to require clinics to be specific about which treatments they provide are outside the National Institute for Clinical Excellence’s clinical guideline on infertility treatment? (Paragraph 4.36).

Yes, we agree with the Science and Technology Committee’s recommendation (# 292) that patients should be informed when they are being offered services/treatments that fall outside of the National Institute for Clinical Excellence’s guideline on infertility, with explicit explanation for *why* they are being offered such treatments and whether there are any alternatives.

**27.** The Government invites views on whether the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation. (Paragraph 4.40).

Yes, such an offer should remain a legal obligation. We agree with the

observations of the Science and Technology Committee that the value of counselling may not be fully appreciated by clinicians, but that it is important that counsellors should seek to provide evidence-based analysis of their impact (#168).

**28.** Alternatively, should the legal requirement to offer a suitable opportunity to receive counselling apply only in the case of treatment involving donated gametes and embryos? (Paragraph 4.41).

Counselling *opportunities* should remain for all patients seeking or receiving treatment. 'Ordinary' IVF using a couple's own gametes can put a strain on the individuals involved, so the offer of counselling would remain appropriate. The case of *Evans*, mentioned above, also provides a very clear example of the kind of circumstances where counselling might be beneficial even when the gametes to be used are the couple's own.

**29.** The Government invites views on whether the appropriate level of compensation for donors should be set by the regulator or by Parliament by means of regulations, rather than by the HFEA as now. (Paragraph 4.45).

The regulator should set the appropriate level of compensation within Parliamentary guidelines. The regulator is better able to judge and amend appropriate levels in light of diverse circumstances or changes in cost rates.

**30.** The Government invites views on whether payments for the supply of gametes (other than compensation for expenses or inconvenience) should be prohibited in all circumstances, including research that is currently outside the scope of the HFE Act. (Paragraph 4.47).

We believe that there is nothing intrinsically wrong with paying someone for sperm or ova. In so far as the potential for exploitation does exist, we believe that this problem can be dealt with through appropriate regulation. And increased payment may prove necessary to halt the decline in the number of donors since the removal of donor anonymity. While the HFEA's SEED review, published in October 2005, seems to have considered that a £250 maximum expenses/compensation payment is adequate, it is arguable that this does not fully compensate female donors given the greater risks and inconvenience of retrieving eggs as contrasted to sperm.

#### Reproductive choices: screening and selection

**31.** The Government invites views on whether legislation should set out the general criteria under which embryo screening and selection can be undertaken. If so, what should those general criteria be? (Paragraph 5.19).

As noted in our response to Q 1 the fundamental ethical principle which should underpin law and regulation in this area is *procreative autonomy* or *procreative liberty*. With this in mind, our proposed criteria are as follows.

**Embryo selection should be permitted where the following three conditions are met.**

- (1) The resultant child must have a good chance of having a 'life worth living' (e.g. not a life of unbearable suffering) *and*
- (2) There is little or no evidence that the particular kind of screening/selection will substantially and unjustly cause harm to any existing third parties *and*
- (3) *Either*:
  - (A) the prospective parents are unable to have a child without screening/selection; *or*
  - (B) screening/selection will (probably) result in a child with a quality of life that is better than, or at least no worse than, that expected for the most likely alternative 'unscreened' child; *or*
  - (C) screening/selection will (probably) deliver substantial benefits to third parties (including but not limited to the resultant child's relatives) and will *not* result in a child with a significantly lower quality of life than that expected for the most likely alternative 'unscreened' child.<sup>18</sup>

(1) and (2) aim at harm prevention, to the child itself and to third parties. (3) is not about harm prevention but rather offers three positive justifications, at least one of which must be in play. (A) justifies selection by reference to the fact that, without it, there would be no life, rather than a life worth living. (B) justifies selection by appealing to the fact that there is an increase, or at worst no reduction, in child welfare. (C) justifies selection by weighing substantial benefits to existing people against a small (less than 'significant') reduction in child welfare.

This is a slightly less permissive view than that of some liberals for whom (1) and (2) *would* be sufficient to justify selection. Embryo selection is a cause of considerable moral concern and controversy and some people believe it to be socially dangerous. Since not all of these concerns and beliefs are unreasonable, it seems to us appropriate, at least for the time being, to insist that selection only takes place where there is some positive justification for *it*.<sup>19</sup> This is what condition (3) does. However, as will become clear in our later answers, we believe that many contested types of selection can, at least in certain circumstances, meet all three of our conditions.

As regards the implementation of these principles, the particular uses of

<sup>18</sup> The unscreened comparator could be either a child resulting from sexual intercourse (where practicable) or a child created by randomly selecting from a set of IVF embryos.

<sup>19</sup> We are not suggesting that the beliefs cited here are true, simply that they are ones that people could reasonably hold; more generally, these are difficult issues about which reasonable people can, and often do, disagree.

embryo screening and selection should remain a matter for decision and licensing by a statutory regulator. The general ethical principles listed above should guide the actions of the regulator.

**32.** Do you think that there should be a prohibition on deliberately screening *in*, or selecting *for* impairments and disabilities – as opposed to screening *out*, or selecting against? (Paragraph 5.20).

First, we note that ‘impairments and disabilities’ is a very broad expression and covers a wide range of different conditions and states of well-being. Therefore, there is no straightforward answer to this question. That said, we believe that there should *not* be a specific prohibition on this form of selection. Rather, the practice and regulation should be guided by the general principles set out in our answer to Q31.

In response to Q31, we said that the resultant child must have a good chance of having a ‘life worth living’. This would rule out some, but probably only a small minority, of cases in which parents wish to ‘select for’ disability &/or impairment.

In order for selecting impairment &/or disability to be permissible, one of sub-conditions (3A), (3B), or (3C) must also be satisfied. Our view is that there are some possible cases of selecting impairment and/or disability that do meet one of these criteria; but equally there are many that do not. So our criteria for the permissibility of selection in general, ‘cut across’ the selecting disability issue.

We do not know of any actual cases in which (3A) is engaged but the existence of a couple who can only have a child if an impaired embryo is selected and implanted is at least a theoretical possibility. As regards (3B), it has been argued that some disabilities do not, or do not necessarily, adversely affect quality of life, and indeed that there may be some social advantages to having the same disabilities as the rest of one’s family. Some cases of selecting disability may therefore be justified in this way under (3B).<sup>20</sup>

<sup>20</sup> Deafness is probably the leading example. Draper & Chadwick discuss the case of Philip and Linda, a deaf couple, who “want the [embryo] with congenital deafness to be implanted first ... [and] justify their decision by arguing that their quality of life is better than that of the hearing. As far as they are concerned, giving preference to the affected embryo is giving preference to the one which will have the best quality of life. They are very concerned that any hearing child they have will be an ‘outsider’ – part neither of the deaf nor of the hearing community at least for the first five or so years of his/her life”. Heather Draper & Ruth Chadwick, ‘Beware! Preimplantation genetic diagnosis may solve some old problems but it also raises new ones’, *Journal of Medical Ethics*, 1999, 25, p.116.



Similar considerations apply to (3C). It may in some cases be substantially advantageous for parents if their children share their disabilities; and provided that the disability does not lead to the child's having a *significantly* lower quality of life, then selecting disability may be justified under (3C). Much of this will depend on the facts of the case. We are not claiming that there are many (or any) *actual* cases of selecting disability that meet our criteria, just that there *may* be some.

Other possible arguments for a ban on selecting disability invoke the possibility of harm to third parties and/or society generally; these relate to our condition (2). Foremost among these is the 'cost of care' argument, the view that it is wrong deliberately to select a seriously disabled child because the child will need relatively large levels of public health and social care resourcing, resources which (assuming a fixed 'pot') would otherwise be available to other people. This argument is structurally similar to ones deployed against 'unhealthy lifestyles' (such as smoking and 'unsafe' sex) lifestyles which are allegedly immoral because they use up healthcare resources that are needed and deserved by others.<sup>21</sup>

We are unconvinced by the 'cost of care' argument, or at least do not believe that it applies to selecting a disabled child any more than it does to many other permitted practices (such as failing to live a maximally healthy lifestyle, or conversely causing oneself to have a lengthy life, which can be very costly for the State and for pension funds). Thus, to single out selecting disability for especially restrictive treatment on this ground seems discriminatory or 'disablist'. Furthermore, the practical difficulties of calculating who is and who is not a 'drain on public resources' should not be underestimated and we should not pass judgement on this unless full and reliable health-economic data are available.

**33.** Should the particular uses of embryo screening and selection remain a matter for decision and licensing by a statutory regulator in accordance with the general criteria set by Parliament? (Paragraph 5.21).

Yes, this is the approach that we favour. One of its main advantages is flexibility and the ability to respond rapidly to new technological developments. It would be impossible for Parliament to foresee all of these and therefore to 'future-proof' any very specific legislation. Furthermore, the application of general ethical principles (such as those proposed in Q31) to technically complicated cases and issues is best done on a case-by-case basis by a specialist body.

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21 For a critique of such arguments see WILKINSON, S. (1999) Smokers' rights to health care: why the 'restoration argument' is a moralising wolf in a liberal sheep's clothing, *Journal of Applied Philosophy*, 16, pp. 275-289.



34. Alternatively, should the particular uses of embryo screening and selection be a matter for patients and clinicians, within the legal limits set by Parliament? (Paragraph 5.22).

See Q33.

35. What are your views on the regulation of PGD with tissue typing? Should the legislation set out criteria under which this should be allowed? If so what should they be? Beyond that should particular uses need to be approved by the regulator – or should patients with their clinicians be free to make their own decisions? (Paragraph 5.23).

There is no need for specific legislation on this issue over and above our general Q31 criteria. These allow the selection of 'saviour siblings' under ground (3C), provided that the benefits are substantial and that the resultant child does not have a significantly lower quality of life overall than that of the likely alternative 'unscreened' children. It follows from our Q31 criteria that the recipient, in 'saviour siblings' cases, could be a parent and could even be an unrelated third party.

Here, we are thinking primarily of the use of cord blood etc. In the case of bodily tissue donated after birth then the same legal standards and protections must apply to all children, regardless of whether or not they have been selected to be 'saviour siblings'.

36. The Government invites views on what statutory controls, if any, should apply to the screening and selection of gametes. (Paragraph 5.27).

Generally speaking, since gametic and embryonic screening and selection would or could be used for the same sorts of end, then the same principles should apply to them. Hence, we support the application of our Q31 criteria to gamete selection.

One complication is that some of the identity issues are less clear in the case of gametic selection – see our answer to Q38 for more on this.

37. The Government seeks views on sex selection for non-medical reasons. In particular, should this be banned? Or should people be allowed to use sex selection techniques for family balancing purposes as the Science and Technology Committee suggest? If so, how many children of one gender should a couple already have before being allowed to use sex selection techniques to try for a child of the other gender? (Paragraph 5.32).

**We do not support a specific ban on non-medical sex selection since in some cases it may be justified using our Q31 criteria.**

There are apparently concerns about the safety of some sex selection techniques.<sup>22</sup> Criterion (3C) is sensitive to these (as is, *a fortiori*, (3B)) and would rule out the use of dangerous sex selection techniques, since the procedure must not result in a child with a significantly lower quality of life overall than that of the likely alternative 'unscreened' children.

Some of the most influential arguments against non-medical sex selection relate to our condition (2) and claim that the practice should be prohibited because it would substantially and unjustly harm third parties and society as a whole.

One of these arguments is that non-medical sex selection would cause sex imbalance in the population. This argument fails empirically since the evidence suggests that, in Western Europe at least, most parents prefer 'balanced' families.<sup>23</sup> Also, a relatively small number of parents will want to practice sex selection and so, even if they did all prefer the same sex, the impact on the whole population's sex balance would be small.<sup>24</sup>

A second argument is that non-medical sex selection is harmful because it encourages sexist attitudes and the increased societal acceptance of so-called 'designer babies'.<sup>25</sup> However, while in some cases the desire to sex-select is driven by sexist attitudes, permitting sex selection is unlikely to increase significantly the level of sexism in society, not least because of the facts just cited: that most parents prefer 'balanced' families and that few parents wish to sex-select. Similar considerations apply to the point about 'designer babies'. Furthermore, the idea of a 'designer baby', and the related concepts of commodification and instrumentalism, stand in need of a great deal of clarification and explication, and it is far from obvious that they are capable of underpinning sound arguments against sex selection.<sup>26</sup>

A third argument holds that harm lies in the impact of our permitting non-medical sex selection on other countries. This is a point made by the House of Commons Select Committee on Science and Technology: "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

<sup>22</sup> HFEA, *Sex Selection: options for regulation*, 2003

<sup>23</sup> HFEA, *Sex Selection: options for regulation*, 2003

<sup>24</sup> See: House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law*, 2005, #137

<sup>25</sup> See: House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law*, 2005, #41

<sup>26</sup> WILKINSON, S. (2006) 'Designer Babies', Instrumentalisation and the Child's Right to an Open Future, in: ATHANASSOULIS, N. (ed), *Philosophical Reflections on Medical Ethics* (London: Palgrave-Macmillan), pp.44-69; WILKINSON, S. (2003) *Bodies for Sale: ethics and exploitation in the human body trade* (London, Routledge), pp.27-55.

people to choose the sex of their child in this country we are legitimising the choices among cultures where boys are preferred.”<sup>27</sup>

While the impact of the UK’s behaviour on other states should be taken into account, this argument seems to us to overlook an important and fundamental point — that the UK cannot set a bad example unless it does something wrong. So, since we believe that (when practiced in accordance with our Q31 criteria) preconception and preimplantation sex selection are not wrong, there is no question of the UK’s setting a bad example by permitting these practices.

In response to this, it may be argued that some other countries will fail to distinguish between (a) preconception/preimplantation sex selection and sex selection through infanticide, and/or (b) sex selection in contexts where the population’s sex balance is adversely affected and sex selection in situations where it is not, and/or (c) sex selection freely chosen by both parents and sex selection forced on one parent by another, or on both parents by third parties.

These distinctions are crucial and, by advocating sex selection in the specific circumstances outlined above, we are in no way endorsing either infanticide, or actions which cause major population sex imbalance, or coerced sex selection. That leaves the question of whether other countries are capable of understanding these distinctions. We believe that they are and that it is extraordinarily condescending to argue otherwise. No nation capable of understanding these distinctions could, without disingenuity, cite the UK’s limited endorsement of preconception/preimplantation sex selection as a justification for infanticide or indeed any unethical form of sex selection. Of course, some states, and some individuals, will make dishonest moves, but there is very little that we can do to stop this and it is certainly not a sound basis for framing UK law. As a general rule, we should not allow x to be banned here simply because we disapprove of y and, if we allow x, someone in another country will falsely claim ‘if x is permissible then so is y’.

**Family Balancing – ‘Family balancing’ sex selection should *not* receive more favourable treatment than other forms.** It is not for the State to say that the choice to have four girls or four boys is less legitimate than the choice to have two of each. Similarly, the implication that single-sex families are somehow ‘unbalanced’ is bizarre and offensive.

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<sup>27</sup> See: House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law*, 2005, #140

<sup>28</sup> Deploying our Q31 criteria, specifically (3C), it must be the case that (a) that sex selection will *not* result in a child with a significantly lower quality of life overall than that of the likely alternative ‘unscreened’ children, and (b) that there will be substantial benefits to third parties (e.g. the parents, who end up with the desired family configuration).

<sup>29</sup> Edgar Dahl, ‘Sex Selection: laissez-faire or family balancing?’, *Health Care Analysis*, 13.1 (March 2005), 87-90, p.88.

One possible argument for privileging 'family balancing' is that 'balanced' families deliver higher levels of child welfare. We are not aware however of any evidence to back this up. In any case, rather than prohibiting specific practices such as sex selection, it would be better to enshrine in legislation only fundamental principles such as our Q31 criteria.<sup>28</sup>

A second possible argument for allowing only 'family balancing' sex selection is that this would reduce the danger of population sex imbalance, compared to the danger caused by permitting sex selection for all. However, as we have already noted, this danger does not seem all that great in this country. Furthermore, if population sex imbalance is the worry, other regulatory mechanisms (such as 'capping' the numbers of boys/girls selected) would be more effective than restricting sex selection to family balancing.<sup>29</sup>

Finally, it may be argued that would-be sex selectors are likely to be motivated by sexism, except in cases of 'family balancing', and that this motivation makes 'non-family-balancing' sex selection unacceptable. Although the sex-supremacist view that one sex is better than the other may underlie some people's desire to have all boys or all girls, it certainly does not necessarily do so, and we are not aware of any evidence that it usually does. For to prefer one sex, as a matter of personal taste, is distinct from believing that sex to be objectively superior. It would be unfair then to attribute, without specific evidence, supremacist views to 'non-family-balancing' sex-selectors. Furthermore, it is equally possible for 'family balancing' sex-selectors to have sex supremacist motives - and there may be cases in which, for example, parents have three girls 'naturally', are deeply disappointed owing to their supremacist views, and then turn to 'family balancing' sex selection

Another form of sexism, sex-stereotyping, occurs where parents only want to sex-select because they erroneously associate certain characteristics with a particular sex: to cite some hackneyed examples, strength and sporting prowess with men, caring and musicality with women. It seems to us however that such stereotyping is just as likely in the case of 'family balancing' sex selection as it is in other types of case. Consider these two examples. Family A want all of their children to have strength and sporting prowess and so select all boys; Family B want half their children to have strength and sporting prowess, and the other half to be caring and musical, and so use ('family balancing') selection to have half boys and half girls. Whatever the general merits of these choices, it seems clear that, as far as sex-stereotyping is concerned, the families are in the very same position; both are guilty of sex-stereotyping. Thus, it seems to us that sex-stereotyping is just as likely to underpin 'family balancing' sex selection as it is any other (non-medical) type.

**38.** The Government proposes that the prohibition in the HFE Act on genetic modification of embryos for reproductive purposes should continue and be extended to gametes used in treatment. We invite views as to whether the legislation should include a power for Parliament to relax this ban through regulations (rather than primary legislation) if assured of safety and efficacy.

(Paragraph 5.38).

Since safety and efficacy are the main sound objections to genetically modifying embryos for reproductive purposes, we would welcome the inclusion of this power for Parliament.

More generally, it is important to distinguish between identity-affecting and other choices. Identity-affecting decisions are those which affect not what life will be like for a fixed future population or person, but instead affect who will exist in the future.<sup>30</sup> So where we have a choice between implanting Embryo A and thereby creating Person A and implanting Embryo B and thereby creating Person B, this choice is an identity-affecting one, a decision to create one rather than another possible future person. These choices are to be contrasted with non-identity-affecting decisions such as whether or not to subject a foetus or child to surgery. Embryo modification (and possibly also gamete modification, though that is less clear) would normally fall into the latter category.

Our Q31 principles are designed to apply to selection scenarios, not modification scenarios. Rather different principles may apply to the latter because the choices made are not, or at least may not be, identity-affecting. More specifically, in non-identity-affecting cases it will be much easier to cause harm to the child created, because one can do this merely by lowering her level of welfare – whereas in identity-affecting scenarios harm is only caused (to the child) when a child is created without a ‘life worth living’.

### Information and the HFEA Register

**39.** The Government believes that it is essential to maintain a central register of donor treatment to which donor-conceived people can have access for information about their donor, and to find out if they are related to someone they intend to marry. Do you agree? (Paragraph 6.14).

Yes, information about donors should be centrally organised and accessible to donor-conceived people. Respondents to the Government Consultation on donor identification cited two main reasons for wanting access to such

<sup>30</sup> ‘Identity’ here refers specifically to *numerical* identity. To claim that an action or decision is identity-affecting (in this sense) is not to say that a *different kind of* person or a *person with different characteristics* will result. Rather, the claim is that a numerically distinct person will result, one which may or may not closely resemble alternative possible persons. By way of an illustration, in *this* sense of ‘identity’ (numerical identity) ‘identical twins’ are not identical (because they are distinct persons) but they nonetheless closely resemble one another.

information: responding to 'an emotional need' and helping secure 'personal confidence and a sense of well-being'.<sup>31</sup> The High Court has ruled that a genetic connection does engage the right to privacy and family life as protected by Article 8 of the European Convention on Human Rights, and that the state is under a positive obligation in this regard.<sup>32</sup>

Recognition of the significance of genetic connection/parenthood for individuals should not be taken as undermining the significance of other kinds of connection and of social parenthood.

Individuals are entitled to information about their genetic origins irrespective of their relationship intentions.

**40.** The Government invites views on whether people should be able to obtain information about whether they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18. (Paragraph 6.18).

There has been a general trend in terms of both domestic and international law to recognise the rights of minors to information regarding their origin and heritage. The United Nations Convention on the Rights of the Child stresses the participation of minors in decision-making regarding their care and treatment. By analogy it could be argued that the information referred to here should be made available to individuals below the age of 18. Changing the law to allow identifying information from the age of 16 would, of course, have to be prospective in order to respect the rights of donors.

**41.** The Government proposes to enable donor-conceived people to access information to discover whether they are related to someone with whom they intend to form a civil partnership, and would welcome comments. (Paragraph 6.20).

As in our response to Q39, we consider that individuals have a right to information about their genetic heritage irrespective of their relationship intentions. Making such information generally available to donor conceived people would remove the need to distinguish between different relationships in determining whether access should be permitted.

**42.** The Government invites views on whether the law should specify what non-identifying information about offspring can be released to gamete and embryo donors. (Paragraph 6.23).

The law should permit the release of non-identifying information about

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<sup>31</sup> DoH, 'Donor Information Consultation: Providing Information About Gamete or Embryo Donors (2001)

<sup>32</sup> *Rose v Sec of State for Health (HFEA)* [2002] EWHC 1593; (2003) 69 BMLR 83

offspring to gamete and embryo donors and should specify the nature of such information in order to protect the privacy of donor-conceived people. Permitting the release of specified information in such circumstances responds to donors' desires to know the outcome of their donation, recognises their contribution and could potentially encourage more donors in a climate of donor scarcity.

**43.** The Government seeks views on whether donor-conceived people should be able to access information about their donor-conceived siblings (where applicable). If so should this be limited to non-identifying information? (Paragraph 6.25).

Yes, donor conceived people should be able to access non-identifying information about donor-conceived siblings. Research repeatedly reveals a wish by donor conceived individuals to know of any donor conceived siblings they may have. Whilst this desire is understandable this type of information is less about fundamental questions of origin than about connected place in the world. This does not diminish the desire to know of possible siblings. It does, however, mean that the possible adverse consequences of allowing access to such information has a particular weight. Allowing access to non-identifying information should not cause any significant problems. However, without universal openness, identifying information may have consequences for other families where the donor conceived status of offspring has not been divulged. The nature of the competing interests is likely to weigh in favour of non-disclosure of identifying information.

**44.** Should the natural children of donors be able to access information about their donor-conceived siblings (where applicable) and vice-versa? If so should this be limited to non-identifying information? (Paragraph 6.26).

Yes. A greater general openness about donor conception and related relationships would constitute a general benefit in reducing stigmatisation of donor conception and afford a particular benefit to those individuals who wish to find out more about their genetic siblings. This should be limited to non-identifying information to protect privacy interests.

**45.** The Government seeks views on what measures would be appropriate, if any, to ensure that parents tell children conceived through gamete or embryo donation that they are donor-conceived? (Paragraph 6.31).

**46.** The Government invites views on whether, in future, the HFEA's data register should continue to record and publish information on all licensed treatments including outcome data (where it is satisfied that they are not misleading). (Paragraph 6.39).

Yes, the HFEA should continue to record and publish such data since it

promotes informed choice for the client and higher standards for the clinics.

**47.** If the HFEA's data register is to continue to collect information on all licensed treatments, should the dataset be expanded to facilitate more effective follow-up research? (Paragraph 6.40).

**48.** Alternatively, if the HFEA's data register is to be restricted to information on licensed treatments involving donated gametes or embryos, should licensed clinics be required to maintain local databases of additional information for research? (Paragraph 6.41).

**49.** The Government proposes that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. Do you agree? (Paragraph 6.44).

Yes, there is no good reason to treat these two kinds of information differently.

### Surrogacy

**50.** The Government invites views on what, if any, changes are needed to the law and regulation as it relates to surrogacy. (Paragraph 7.17).

The law relating to surrogacy is particularly outdated having been subject only to minimal legislative reform since 1985. Moreover, unlike the 1990 legislation, the 1985 legislation was largely a knee jerk response to public pressure and therefore was not well thought out. The unsatisfactory nature of the Surrogacy Arrangements Act, 1985, changing medical attitudes to the procedure as enshrined in professional guidance,<sup>33</sup> and evidence that voluntary organisations lack the necessary resources and expertise to regulate effectively the practice of surrogacy, all suggest the need for legislative reform.

Particular issues which need to be addressed, therefore, are whether regulation by a statutory body is necessary, whether any justification exists for regulating surrogacy separately from other forms of reproductive technology, what the appropriate role of the medical profession should be, and what, if any, payment for reproductive services is considered appropriate.

**51.** If changes to the law and regulation on surrogacy are necessary, do the recommendations of the 'Brazier Report' represent the best way forward? (Paragraph 7.18).

<sup>33</sup> See, for instance, BMA, *Changing Concepts of Motherhood: The Practice of Surrogacy in Britain*, 1996.



No. Once again the Brazier Report was commissioned in response to a controversial high profile case and the terms of reference were extremely limited. Moreover, given changing attitudes to payment of expenses for reproductive services and materials, the issue of payment to the surrogate mother needs to be considered in the context of the more general commodification of reproduction (as noted in our response to Q30 above). As numerous commentators have pointed out, given the investment that the surrogate mother makes in the surrogacy contract it is rather anomalous that her contribution should be rewarded only by the payment of documented actual expenses.<sup>34</sup> Other issues which may need to be considered include revisiting the issue of whether, perhaps subject to appropriate vetting, counselling or information provision, surrogacy contracts should be made enforceable at law, and whether the woman who carries the child should always be deemed the (sole) mother in law.

**52.** If changes to the law and regulation on surrogacy are necessary, should they be taken forward as part of the review of the HFE Act, or in separate legislation? (Paragraph 7.19).

Given the overlap between questions raised by surrogacy and definitions of motherhood, and the fact that IVF and related technologies are often utilised by those who enter into surrogacy agreements, it would seem anomalous to continue to regulate surrogacy separately. Moreover, to continue to do so may serve to reinforce the stigma evidenced in the Warnock report, which has long attached to surrogacy,<sup>35</sup> but which seems out of line with more recent judicial and legislative developments.<sup>36</sup>

Although it may be difficult to construct coherent regulatory principles which encompass the broad range of issues raised by reproductive technologies as well as research on embryos, gametes and other human tissue and materials, under the proposed new regulatory body, such an approach seems to us preferable to ad hoc legislation on disparate issues.

### Status and legal parenthood

**53.** The Government invites views as to whether the HFE Act should treat an unmarried man as the father of a child resulting from treatment in the same way it treats a married man. If so, how would this be achieved given that there is no legal definition of an unmarried couple? (Paragraph 8.16).

We welcome the move to equality of treatment between married and unmarried fathers. Currently the legal status of the unmarried father is not

<sup>34</sup> See, for instance, M. Freeman, "Does surrogacy have a future after Brazier?" (1999) *Medical Law Review* 1-20.

<sup>35</sup> See D. Morgan, "Surrogacy: An Introductory Essay in R. Lee and D. Morgan (eds) *Birth Rights: Law and Ethics at the Beginnings of Life*, Routledge, 1989.

<sup>36</sup> See J. McHale and M. Fox, *Health Care Law: text and materials*, 1997, pp. 638-51.

always as clear as it should be prior to a court decision, which contributes to uncertainty and potential for conflict. We recommend the adoption of the **'treatment together' test under s 28(3)** for both married and unmarried men as fathers of a child resulting from treatment. This would provide greater clarity and certainty, and remove the current differentiation between married and unmarried men.

**54.** Should a court be able to make a parental order in favour of unmarried as well as married couples in surrogacy cases? (Paragraph 8.18).

We welcome the commitment to equality between married and unmarried couples. Given that unmarried couples (both heterosexual and homosexual) are now to be allowed to adopt children under the *Adoption and Children Act 2002*, it is anomalous to restrict the application of s.30 orders to married couples.

**55.** The Government seeks views on whether:

- a court should be able to make a parental order (following surrogacy) in favour of civil partners, subject to the same rules and requirements that apply to married couples
- where one of the civil partners carries a child as the result of assisted reproduction treatment, the other civil partner should be treated in law as the parent of the child in line with married couples. (Paragraph 8.22).

The legal status of the civil partner (or same sex partner who is not in a civil partnership) in relation to children born into a civil partnership or same sex relationship is one of the main areas where discrimination and inequality subsists after the introduction of civil partnership for same sex couples. We welcome the move to eliminate or prevent discrimination between those who are married and those who are civil partners. Following the introduction of joint adoption by same sex couples through the *Adoption and Children Act 2002* and the stated aim of parity between married couples and civil partners, there is no reason to treat civil partners differently from married couples in regard to the status of legal parent.

**56.** The Government seeks views on whether the status and legal parenthood provisions in the HFE Act should apply to same-sex couples who *do not* form a civil partnership. If so, how would any automatic recognition of parenthood be achieved given the lack of legal ties between the couple? (Paragraph 8.24).

We welcome the move to eliminate or prevent discrimination between those who are in marriage or civil partnerships on the one hand and those who have not entered into these kinds of legal relationship on the other. Couples have all sorts of reasons for choosing not to enter such relationships that have nothing to do with their commitment to each other. Thus, it follows that, in our view, same sex couples who do not form a civil partnership should fall within the status and legal parenthood provisions in the HFE Act. This could be achieved in principle by extending the operation of

s.28(3) to recognise same sex partners for whom treatment services are provided together.

Although this issue is not raised explicitly by the questions in this consultation, we would also suggest that the Government should explore whether, in some circumstances, it may be in the best interests of a child to have more than two individuals recognised as her/his legal parents (see also our response to Q 51).

### Research

**57.** In common with the Science and Technology Committee, the Government believes that there is no case at present for either an extension or a reduction to the 14 day time limit for keeping an embryo. Any change would remain a matter for Parliament. (Paragraph 9.15).

While we agree that there is little pressure for a change in this time limit, it is difficult to defend the present position as anything other than an arbitrary cut off point, chosen for pragmatic reasons. In principle we are not opposed to research on embryos which could be used after 14 days but we do think this would require Parliamentary debate and scrutiny.

**58.** The Government believes that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, subject to licensing. (Paragraph 9.22).

We agree that there seems little difference between this and other forms of embryo research which are deemed legitimate, especially given that the procedure is currently permitted on human eggs.

**59.** Further, the Government invites views on removing the current prohibition on “replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo” for research purposes, subject to licensing. (Paragraph 9.23).

Yes, there is no moral difference in the status of the embryo which results from these various techniques used for embryo creation.

**60.** The Government invites views on whether the law should permit altering the genetic structure of an embryo for research purposes, subject to licensing. (Paragraph 9.28).

Yes, the law should so permit, given the putative benefits which may be obtained through such research and the fact that no ‘damaged’ persons will be created.

**61.** The Government invites views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to the limit of 14 days culture in vitro, after which the embryos would have to be

destroyed). (Paragraph 9.35).

Given the 'special significance' with which law invests the human embryo, it seems somewhat anomalous that, at present, research is permitted on human embryos but not on chimeras or hybrids. The current position therefore betrays some confusion, which seems to be grounded in public aversion to the creation of creatures which transgress the animal/human boundary.<sup>37</sup> We would suggest that carrying out research on early non-sentient embryos (regardless of whether they are human, animal or hybrids) is more defensible ethically than permitting such research to be carried out after this date on sentient animals capable of experiencing pain.

**62.** The Government invites views on whether the current list of legitimate purposes for licensed research involving embryos remains appropriate. (Paragraph 9.38).

We do not object to content of the existing list, but believe that it, and additions to it, should be subjected to full parliamentary scrutiny and debate

**63.** The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight. (Paragraph 9.41).

Yes. The speed of technological change which leads to new methods of creating embryos and new uses for them means that this is an important function of a regulatory body and require that the law is regularly reviewed and these issues fully debated in Parliament. In general concerns remain about the consistency of LRECs and MRECs so on these issues a national body, possessing the requisite expertise, seems appropriate.

**64.** The Government invites views on what, if any, additional regulatory requirements should apply to the procurement and use of gametes for purposes of research. (Paragraph 9.45).

The provisions in place should be consistent with those involving other forms of human tissue and organs. However, as noted above in relation to surrogacy (Q51), there has been a tendency for the reproductive services of women to be under remunerated and this may mean that payment in the form of preferential access to treatment or some monetary recompense is appropriate in recognition of the labour involved in 'donating' eggs as opposed to sperm. Similar considerations may apply regarding the greater labour and risks involved in bone marrow than in blood donations.

**65.** The Government invites comments on the desirability of allowing the creation of embryos for the *treatment* of serious diseases (as distinct from

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<sup>37</sup> See M. Fox, 'Re-thinking kinship: Law's Construction of the Animal Body' (2004) 57 *Current Legal Problems* 469-93.

*research* into developing treatments for serious diseases which is already allowed). (Paragraph 9.47).

The argument for using embryos in treatment is at least as strong, and stronger in the case of treatments that are known to be effective and safe, than the argument for using them in biomedical research.

### The Regulatory Authority for Tissues and Embryos

**66.** The Government proposes that RATE, in common with the HFEA and HTA, will be headed by a lay chairperson, and have substantial lay representation among its membership. The membership will also need to have, or have access to, sufficient medical and scientific expertise in relation to the activities that come within its remit. (Paragraph 10.4).

We agree that it is important to have a balance between lay and expert representation, and so support this proposal.

**67.** The Government proposes that:

- RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders
  - RATE will be responsible for regular inspections of premises where licensable activities are carried on.
  - RATE will issue codes of practice giving guidance to persons undertaking those activities within its remit
  - RATE will maintain a central database of, at least, information relating to the use of donated gametes and embryos, and children born as a result.
- (Paragraph 10.5).

**68.** Both the HFEA and the HTA currently have statutory functions including to monitor or review developments relating to the activities within their remits, and to provide advice to the Secretary of State where appropriate or where asked to do so. The Government believes that a similar 'advisory' function would be appropriate for RATE as this body will be well placed to observe and monitor developments through its licensing and inspection procedures and its information gathering function. (Paragraph 10.6).

**69.** The Government proposes that:

- the chairperson and members of RATE will be appointed by the NHS Appointments Commission
- RATE will publish an annual report, which must be laid before Parliament

- legislation will set out requirements for consultation and approval of codes of practice
- RATE will publish summaries of embryo research licence applications received. (Paragraph 10.7).

**70.** The Government invites views on whether legislation should define a formal role for the professional bodies in advising RATE on the content of technical standards for assisted reproduction and embryo research. (Paragraph 10.10).

**71.** The Government invites views on what sanctions should be available to the regulator to ensure compliance whilst promoting service improvement. (Paragraph 10.13).

**72.** The Government invites views on whether the maximum penalty of ten years imprisonment under the HFE Act should be altered, and if so, what should the maximum penalty be? (Paragraph 10.16).

We agree with the Select Committee on Science and Technology that a 10 year sentence is unduly harsh for these offences (#185), even if maximum sentences are extremely unlikely to be imposed.

Miscellaneous

**73.** The Government invites views on the extent to which the principles of good regulation are upheld in the Government's proposals, and any other comments or information about the regulatory impact of the measures described in this consultation document. (Paragraph R1.16).

**74.** Finally, we would welcome your views on any other issues that you feel should be considered or changes that you would like to see made to the HFE Act 1990.

**THANK YOU**

