



SCHEDULE TO JUDGMENT

The Statutory Scheme

1. The 1990 Act sets out the circumstances in which various forms of medically assisted procreation can lawfully take place in the UK. It establishes the HFEA as the statutory licensing authority (section 5). Sections 3 and 4 of the 1990 Act set out the activities governed by the 1990 Act, and provide that the following activities (amongst others) may only be carried out pursuant to a licence:
 - (i) bringing about the creation of an embryo (section 3(1)(a));
 - (ii) storing any gametes (section 4(1)(a));
 - (iii) in the course of providing treatment services for any woman (i.e. assisted conception services) the use of any sperm other than partner-donated fresh sperm (section 4(1)(b) read with section 2(1)).
2. Section 4(1), creates a general prohibition on the unlicensed use of gametes, and provides, so far as is relevant, that:

No person shall - store any gametes, or ... use the sperm of any man unless the services are being provided for the woman and the man together ... except in pursuance of a licence.
3. Section 11 entitles the HFEA to grant licences. Section 12 provides in mandatory terms the conditions to be included in every licence granted under the Act. Section 12(c) requires that licences only be granted in compliance with Schedule 3 to the 1990 Act.
4. Schedule 3 provides, so far as is relevant:
 1. A consent under this Schedule must be given in writing and, in this Schedule “effective consent” means a consent ... which has not been withdrawn ...
 2. (2) A consent to the storage of any gametes ... must –
 - (a) specify the maximum period of storage ... and
 - (b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it ...
 3. (1) Before a person gives consent under this Schedule -

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 below.

4. (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant.

(2) -----

5. (1) A person's gametes must not be used for the purposes of treatment services unless there is an effective consent by a person to their being so used and they are used in accordance with the terms of the consent.

(2) -----

6. -----

7. -----

8. (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent -----

(2) -----

5. "Storage" of sperm pursuant to the 1990 Act means preservation, whether by cryopreservation or otherwise: section 2(1).

6. Any storage or use of gametes otherwise than in pursuit of a valid licence constitutes an offence under s.41(2)(b) of the 1990 Act, which provides:

A person who- ... keeps or uses any gametes in contravention of section 4(1)(a) or (b) of this Act ... is guilty of an offence.

No prosecution can be brought without the consent of the DPP (s. 42) and s. 41(10) and (11) provide defences in the following terms:

"(10) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1) or 4(1) of this Act, cannot be done except in pursuance of a licence to prove -

(a) that the defendant was acting under the direction of another, and

(b) that the defendant believed on reasonable grounds -

(i) that the other person was at the material time the person responsible under the licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given by virtue of section 24(9) of this Act, and

(ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question.

(11) It is a defence for a person charged with an offence under this Act to prove -

(a) that at the material time he was a person to whom a licence [or third party agreement] applied or to whom directions had been given, and

(b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.”

7. Sections 23 and 24 of the 1990 Act enable the HFEA to give specific directions as to particular matters. Anything done by a person in pursuance of directions is to be treated for the purposes of the Act as done in pursuance of a licence (see section 23(3)).

8. Section 24(4) deals with the export of gametes and embryos, and enables the HFEA to dispense with the need for compliance with s.12(c) and thus Schedule 3 of the 1990 Act. Section 24(4) provides so far as is relevant:

Directions may authorise any person to whom a licence applies ... to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

9. The HFEA issues two types of directions: General and Special. General Directions apply generally to licensed clinics; Special Directions may be issued in cases not falling within the scope of the General Directions. (The Claimant is seeking a Special Direction for export from the HFEA, since she cannot satisfy the requirements of the General Directions issued by the HFEA regarding export).

General directions

10. The HFEA has issued the following General Directions regulating the export of embryos and gametes.

11. General Direction 1991/8 governed the export of gametes until July 2007. It provided, in particular, that the person who provided the gametes to be exported must have given, and not withdrawn, their consent in writing to their being exported, and that before giving consent the person must have been provided with a written notice saying that the law governing the use of gametes and the parentage of any resulting

child may not be the same abroad as it is the UK. (The Claimant was therefore unable to satisfy this requirement).

The 1990 Act: parentage provisions

12. Section 28 of the 1990 Act sets out provisions as to who will be the father of a child born as a result of treatment services. Following amendments to the Act in 2003, a man may be treated as the father of a child resulting from assisted conception treatment undertaken after the man's death. In relation to deaths occurring after 18 September 2003, however, the man must have consented to the use of his sperm after his death and to being treated as the father of any resulting child (see s 28(5A)). The right to be treated as the father is limited to the right to be registered as the father in the Register of Births, and does not carry with it any other legal rights, such as rights of succession or nationality (see s 28(5A) read with s28(51)).
13. (The HFEA maintain that as no such consent was provided by the Claimant's husband prior to his death, he could not be registered as the father of any resulting child in the Register of Births).
14. The amendments to the 1990 Act to enable a man to be treated, in the circumstances above, as the father of a child, resulting from assisted conception treatment undertaken after his death, were by way of insertion of new subsections (5A) and (5B) into section 28 of the 1990 Act.
15. As originally enacted, section 28(6) of the 1990 Act provided that where (a) the sperm of a sperm donor was used in treatment services, or (b) where sperm, or embryos created with that sperm, were used posthumously, in neither case would the man be treated as the father of the child.

(I agree with the HFEA that (a) this reflected the clear policy decision in the White Paper that sperm donors and those whose sperm was used posthumously (even with consent, as provided for in the 1990 Act) should not be treated as the fathers of any resulting children: see White Paper, paras. 59 and 88, (b) this section has no bearing on the issue of the consent to be given by posthumous donors and does not "acknowledge the possibility that sperm might be used after [the sperm donor's] death without consent", (c) rather, it provides that, even in circumstances where the required statutory consent has been given, a posthumous donor is not (save in the limited circumstances now set out in sections 28(5A) and (5B) of the 1990 Act, and discussed above) to be regarded as the father of the resulting child, and (d) it would apply, for example, in a case where the donor had given the required consent to his sperm being used after his death, but had not given consent to being treated for the purpose of the 1990 Act as the father of any resulting child (as required by section 28(5A)(d)(ii)); or in a case where a donor had consented to the use of his sperm after his death, but he and his partner had not commenced treatment services and were not married at the time of his death.)

EC Directives

16. Up to 7 July 2007 section 24(3) of the 1990 Act additionally gave the HFEA the power to authorise the keeping of gametes or embryos by a person to whom a licence applies in the course of their carriage to or from any premises (The HFEA maintains that the statutory scheme therefore required a clinic wishing to export sperm to be authorised both (a) to export the sperm, and (b) to keep it in the course of carriage.)

17. Pursuant to this power, General Direction 1991/8 additionally authorised the keeping of sperm in the course of their carriage between licensed premises and their foreign destination.
18. Between March 2004 and October 2006 the European Parliament and Council passed three Directives regulating various activities concerning human tissues and cells. These are jointly referred to as the “EU Tissue and Cells Directives” (‘EUTCD’). Directive 2004/23/EC of 31 March 2004 (‘the First Directive’) lays down common safety and quality standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Article 6 of the First Directive establishes a system of mandatory accreditation or licensing for establishments within Member States carrying out any of these activities on human tissue or cells intended for human application (including clinics providing assisted conception).
19. In relation to consent, Article 13(1) of the First Directive provides that “the procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met”. The Annex to the First Directive requires, in relation to deceased donors, that “all information must be given and all necessary consents and authorisations must be obtained in accordance with the legislation in force in Member States”.
20. To the extent that the requirements of the EUCTD applied to gametes and embryos they were implemented in the United Kingdom by means of amendments to the 1990 Act. The need for accreditation within the EEA was reflected in amendments to section 24 of the 1990 Act, and, in particular, by the insertion of a new section 24(3A) governing the keeping of gametes and embryos intended for human application. (The HFEA maintain that section 24(3A) now only gives it a discretion to authorise keeping of gametes in the course of carriage to another EEA state where they are being carried between licensed premises in the UK and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of that State, in accordance with the requirements of the EUTCD.) This amendment entered into force on 7 July 2007.
21. With effect from 31 March 2008 the HFEA issued revised, fuller General Directions, revoking and replacing General Direction 2007/4. General Direction 2007/6 remains in force. General Direction 2008/2 governs the export of gametes and embryos to Gibraltar and the EEA. It reiterates the requirements of accreditation set out in General Direction 2007/6, and the requirements of consent, donor information and the need for treatment to be lawful in the UK, which were set out as far back as General Direction 1991/8.
22. (The HFEA maintains that when its Regulation Committee considers the Claimant’s application for a Special Direction it will need to be satisfied that any clinic identified by her as a receiving clinic is accredited and licensed according to the requirements of the EUTCD. The Claimant may at that stage dispute this.)

Article 8 of the Convention

23. This provides that:

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

2. 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. ”

The relevant articles of the EC Treaty

24. These are Articles now 49 and 50 (and were Articles 59 and 60 when *Blood* was decided). They provide so far as is relevant;

“49. Within the framework of the provisions set out below, restrictions on freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community other than that of the person to whom the services are intended.

50 Services shall be considered to be "services" within the meaning of this Treaty where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.

Services shall in particular include: ----- (d) activities of the professions.”

25. It is accepted, as it was in *Blood*, that these articles give the Claimant a right directly enforceable by her (and therefore as part of English law) to receive medical treatment in another member state.