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The Queen on the Application of Quintavalle v Human Fertilisation and Embryology Authority

C1/2003/0101

Court of Appeal (Civil Division)

16 May 2003

Neutral Citation Number [2002] EWCA Civ 667

2003 WL 21047341

Before: Lord Phillips of Worth Matravers, MR , Lord Justice Schiemann and Lord Justice Mance

Friday 16th May, 2003

On Appeal from Queen's Bench Division Administrative Court and Divisional Court

The Hon Mr Justice Maurice Kay

Representation

David Pannick QC and Dinah Rose (instructed by Messrs Morgan Cole) for the Appellant.

James Dingemans QC and Martin Chamberlain (instructed by Messrs Coningsbys) for the Respondent.

James Eadie (instructed by Department of Work and Pensions) for the Secretary of State for Health as Intervener.

JUDGMENT

Lord Phillips, MR:

1. Mr and Mrs Hashmi have five children. The fourth, a son Zain was born with a blood disorder known as beta thalassaemia major. By the time that he was 2½ years old this had reduced him to a parlous condition, requiring him to take a daily cocktail of drugs and to submit to regular blood transfusions in hospital in order to remain alive. His life expectancy is uncertain. Mrs Hashmi had been aware that she had a genetic predisposition to producing children with this disorder and, when pregnant with Zain had undergone prenatal testing to see whether, if she carried Zain to term, he would be born with the disorder. The test failed to disclose that this was indeed the position.

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

3. Mrs Hashmi resolved to have another child, in the hope that it would have matching tissue. She conceived, but prenatal testing showed that the child would have beta thalassaemia major, so she underwent an abortion. She conceived again, and a healthy son was born, but unfortunately his tissue did not match that of Zain.

4. At this point Mrs Hashmi met Dr Simon Fishel, the Managing and Scientific Director of Centres for

Assisted Reproduction Limited ('CARE'). CARE is the largest single provider of in vitro fertilisation ('IVF') services in the United Kingdom. It provides these services at various locations both to NHS and private patients. Dr Fishel told Mrs Hashmi of a procedure, at the cutting edge of technology, that had been developed at the Reproductive Genetics Institute ('RGI') in Chicago in the United States and which might provide the solution to her problem. In summary, that procedure would include the following stages:

i) The fertilisation 'in vitro' ('IVF') of a number of eggs taken from Mrs Hashmi with sperm taken from her husband to form embryos.

ii) The removal from the developing embryo of a single cell by a biopsy.

iii) The examination of that cell using molecular genetics to see whether the embryo carried the beta thalassaemia disease. This process is commonly described as 'Pre-implantation Genetic Diagnosis ['PGD'].

iv) Use simultaneously of the same process to identify whether the embryo had the same tissue type as Zain. Because this process involves examination of proteins known as human leukocyte antigens ('HLA'), this form of PGD is described as 'HLA typing'. I shall refer to it by the more popular phrase of 'tissue typing'.

v) Jettison of embryos found by this analysis to be either disease bearing or of a different HLA type to Zain and implantation in the womb of Mrs H of an embryo shown to be disease free and of the same HLA as Zain.

5. Mrs Hashmi asked Dr Fishel whether it would be possible for her to be impregnated in this country with an embryo created and selected in this way. IVF treatment can only be carried out in this country under licence issued by the appellant ('HFEA') pursuant to the Human Fertilisation and Embryology Act 1990 ('the Act'). For some years PGD screening against genetic disease had been carried out as part of IVF treatment licensed by the HFEA. Tissue typing had never, however, been carried out as part of such treatment and Dr Fishel considered that this procedure required express authorisation under licence from HFEA. After careful consideration of the implications, CARE applied to the HFEA for a ruling as to whether an IVF clinic could properly apply for a licence to administer treatment including tissue typing.

6. The HFEA announced their decision in a press release on 13 December 2001. They would be prepared in principle to grant a licence for treatment that included tissue typing, subject to a number of conditions. The HFEA decided that tissue typing should only be permitted where PGD was already necessary to avoid the passing on of a serious genetic disorder. They also decided that licences permitting PGD in conjunction with tissue typing should only be granted on a case by case basis. Such licences would only be granted subject to the following conditions:

a) The condition of the affected child should be severe or life threatening, of a sufficient seriousness to justify the use of PGD

b) The embryos should themselves be at risk of the condition affecting the child

c) All other possibilities of treatment and sources of tissue for the affected child should have been explored

d) The techniques should not be available where the intended recipient is a parent

e) The intention should be to take only cord blood for the purposes of the treatment

f) Appropriate counselling should be given to the parents

g) Families should be encouraged to take part in follow-up studies

h) Embryos should not be genetically modified to provide a tissue match

7. In accordance with this decision, on 22 February 2002, the HFEA granted a licence to Park Hospital operated by CARE in Nottingham to carry out IVF treatment that included PGD for 'beta thalassaemia in conjunction with HLA typing for patients known as Mr and Mrs H'.

8. Mr and Mrs Hashmi then made two attempts to produce a child by IVF treatment involving PGD and tissue typing. In the first IVF was effected at Park Hospital. 15 embryos were produced. The biopsied cells from those were then flown to RGI in Chicago for genetic analysis, while the embryos were frozen awaiting the results. Only one embryo proved to have an exact tissue match, but it carried the beta thalassaemia disease. Mr and Mrs Hashmi travelled to RGI for the second attempt. 10 embryos were produced. Two of these proved disease free and to have a tissue match with Zain. One was implanted in Mrs Hashmi, but no pregnancy resulted.

Mr and Mrs Hashmi were prevented from a further attempt by the judgment that is the subject of this appeal.

The science involved

9. Dr Fishel in his witness statement described how PGD in conjunction with tissue typing is carried out by the RGI. There is no need to attempt to describe the entire process; it suffices to identify the following two stages.

i) About 3 days after in vitro fertilisation, when the embryo has sub-divided into 8 cells, one of these cells is removed by a biopsy.

ii) The genetic material in the cell is then tested with a genetic probe, the DNA sequence of which has been so prepared as to identify whether there is a tissue match and whether the embryonic tissue contains any form of thalassaemia disease.

The Challenge

10. The Respondent, Josephine Quintavalle, acts on behalf of Comment on Reproductive Ethics ('CORE'). CORE is a group whose purpose is 'to focus and facilitate debate on ethical issues arising from human reproduction and, in particular, assisted reproduction'. Absolute respect for the human embryo is a principal tenet of CORE. The respondent sought and obtained permission to seek judicial review of the HFEA's decision announced on 13 December 2001. She challenged that decision on the ground that the HFEA had no power to issue a licence that permitted the use of HLA typing to select between healthy embryos. Her challenge succeeded. On 20 December 2002 Maurice Kay J. gave judgment in her favour, quashing the HFEA's decision.

11. Maurice Kay J. gave permission to appeal against his judgment to this Court because of the importance of the issue of whether tissue typing can lawfully be licensed by the HFEA. The Secretary of State for Health was concerned that the judgment has wider implications — in particular that it puts in doubt the legitimacy of the beneficial practice of PGD screening for genetic diseases. Accordingly the Secretary of State obtained permission to intervene to support the HFEA's appeal.

The Act

12. The 1990 Act was passed "to make provision in connection with human embryos and any

subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish a Human Fertilisation and Embryology Authority", and for other purposes.

13. The following provisions of the Act are particularly material:

2.

(1) In this Act—

…

'treatment services' means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

Activities governed by the Act

3. Prohibitions in connection with embryos

(1) No person shall

(a) bring about the creation of an embryo, or

(b) keep or use an embryo,

except in pursuance of a licence.

5. The Human Fertilisation and Embryology Authority

(1) There shall be a body corporate called the Human Fertilisation and Embryology Authority.

Scope of licences

11. Licences for treatment, storage and research

(1) The Authority may grant the following and no other licences—

(a) licences under paragraph 1 of Schedule 2 of this Act authorising activities in the course of providing treatment services,

(b) licences under that Schedule authorising the storage of gametes and embryos, and

(c) licences under paragraph 3 of that Schedule authorising activities for the purposes of a project of research."

Licence conditions

12. General conditions

The following shall be conditions of every licence granted under this Act—

(a) that the activities authorised by the licence shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible."

13. Conditions of licences for treatment

(1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.

…

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

Schedule 2 Activities for which Licences may be Granted

Licences for treatment

1.

(1) A licence under this paragraph may authorise any of the following in the course of providing treatment services—

(a) bringing about the creation of embryos *in vitro* ,

(b) keeping embryos,

(c) using gametes,

(d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,

(e) placing any embryo in a woman,

(f) mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is complete and, in any event, not later than the two cell stage, and

(g) such other practices as may be specified in, or determined in accordance with, regulations.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services”

Licences for research

3.

(1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos in vitro, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of—

(a) promoting advances in the treatment of infertility,

(b) increasing knowledge about the causes of congenital disease,

(c) increasing knowledge about the causes of miscarriages,

(d) developing more effective techniques of contraception,

or

(e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,

or for such other purposes as may be specified in regulations.

(3) Purposes may only be so specified with a view to the authorisation of projects of research

which increase knowledge about the creation and development of embryos, or about disease or enable such knowledge to be applied.

…

(6) No licence under this paragraph shall be granted unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research.

General

4.

(1) A licence under this Schedule can only authorise activities to be carried on on premises specified in the licence and under the supervision of an individual designated in the licence.

(2) A licence cannot—

(a) authorise activities falling within both paragraph 1 and paragraph 3 above,

(b) apply to more than one project of research,

(c) authorise activities to be carried on under the supervision of more than one individual, or

(d) apply to premises in different places."

14. For present purposes it is important to note the following scheme of the Act. prohibits the creation or use of an embryo except in pursuance of a licence. Section 11 restricts the power of the Authority to grant licences by reference to the provisions of Schedule 2 . Schedule 2 sets out lists of activities which may be authorised by a licence and makes provision for adding to these by regulations. So far as treatment is concerned, the Authority is, however, subject to the overriding restriction that it cannot authorise any activity unless it appears necessary or desirable for the purpose of providing 'treatment services'.

The Issues before the Judge

15. Before Maurice Kay J two issues were canvassed:

i) Does genetic analysis of a cell taken from an embryo involve the 'use of an embryo'?

ii) Is genetic analysis for the purpose of tissue typing 'necessary or desirable for the purpose of providing treatment services'?

16. The first issue arose out of the submission on behalf of HFEA that tissue typing did not require a licence because it was performed on a cell extracted from an embryo rather than the embryo itself. HFEA accepted that the removal of the cell by a biopsy constituted 'use of an embryo', but submitted that testing the cell thereafter did not constitute such use. Mrs Quintavalle contended that tissue typing did constitute 'use of an embryo' and, in consequence, could not be carried on without a licence.

17. The second issue arose only if the HFEA failed on the first issue. In that event the HFEA contended that they could lawfully licence such use in that tissue typing was 'desirable for the purpose of rendering treatment services'. The HFEA argued that the relevant test was whether the activity under consideration was 'at least desirable for the overall purpose of providing fertility treatment'.

18. Mrs Quintavalle relied upon the definition of 'treatment services' and submitted that it could not be said that tissue typing was for the purpose of those services. The purpose of tissue typing was not to 'assist women to carry children' but to ensure that a child born to a particular woman would have tissue that was compatible with the tissue of a sibling.

The Judgment of Maurice Kay J.

19. The Judge held against the HFEA on both issues. There were a number of reasons why he held that tissue typing involved the use of an embryo, including the fact that it was inconceivable that Parliament intended to leave an activity such as tissue typing, which had potential for misuse, outside the control of the Act. As to the second issue he observed that tissue typing of an embryo had no impact on the ability of a woman to carry the embryo after implantation. In those circumstances it could not be said that tissue typing was 'necessary or desirable for the purpose of assisting a woman to carry a child'.

The issues before us

20. Mr Pannick QC, who appeared for HFEA, accepted that the first issue considered by Maurice Kay J. did not go to the heart of the case. He recognised that the primary object of carrying out a biopsy of each embryo was to carry out tissue typing of the cell that was removed. It was common ground that the biopsy involved 'using' the embryo. If the tissue typing was not carried out 'for the purpose of assisting a woman to carry a child', then the biopsy could not be said to be for that purpose either. More broadly Mr and Mrs Hashmi's case demonstrated the true nature of treatment involving tissue typing. The primary object of the entire treatment, comprehending creation of the embryo, biopsy for PGD and tissue typing, the analysis of the cell removed by the biopsy and the implantation of the embryo, if it proved to be free of disease and a tissue match for Zain, was to produce a child whose umbilical cord would provide the stem cells which might save Zain's life. The vital question was whether this treatment was 'for the purpose of assisting a woman to carry a child'.

21. Mr Pannick submitted that the answer to this question was 'yes'. He submitted that the Judge had wrongly concluded that treatment services had to have as their sole object the assistance of the physical process of producing a child. IVF coupled with PGD was a practice aimed at enabling women to have children free of hereditary diseases. Analysis of the Act, and of background material to which it was legitimate to have resort, demonstrated that treatment services extended to embrace PGD designed to prevent the implantation of embryos which would result in the birth of a children carrying genetic defects. Such screening assisted a woman to carry a child because it gave her the knowledge that the child would not be born handicapped. Without such knowledge some women who carried genetic diseases would not be prepared to have children. In the same way tissue typing would assist Mrs Hashmi to carry a child, for her wish to do so was conditional upon knowing that the birth of that child would be capable of saving the life and health of Zain.

22. Mr Pannick accepted that under this reasoning PGD with the object of ensuring that a child had certain characteristics for purely social reasons might also be said to be 'for the purpose of assisting women to carry children' but submitted that it was for the Authority to control PGD to ensure that this was not used for purposes which were ethically objectionable. That accorded with the scheme of the Act. It was only practices that were unquestionably objectionable that were prohibited by the legislation. PGD for the purpose of avoiding genetic defects was not objectionable at all.

23. Mr Pannick accepted that it would not be enough for him to show that tissue typing was a practice that assisted women to carry children. He had to show that a biopsy with the object of tissue typing was one of the specific activities listed in paragraph 1 (1) of Schedule 2 . He submitted that it fell within:

> (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose

Suitability could have regard to the desired characteristics of the child that would be produced by the embryo.

24. Mr Dingemans QC, for Mrs Quintavalle, challenged these submissions. He did not abandon the primary submission that 'treatment services' only extended to services designed to assist women in overcoming problems in conceiving and carrying a child to term. Most of his energies were, however, directed to an alternative argument. Even if PGD for the purpose of screening out genetic defects fell within the definition of 'treatment services', such a practice differed in principle from PGD screening designed to reject healthy and viable embryos because they lacked some desired characteristic.

While the former might be said to assist a woman in carrying a child the latter certainly could not.

Background material

25. Maurice Kay J. did not consider it necessary to resort to background material when interpreting the Act but before us both parties devoted much time to exploring the history of the legislation. I have found this a helpful exercise because that history bears closely on the issue of construction that we have to resolve. The *House of Lords in R (Quintavalle) v Secretary of State for Health [2003] UKHL 692; [2003] 2 WLR 692* recently considered another issue of construction of the Act raised by Mrs Quintavalle and Lord Bingham of Cornhill gave the following summary of the legislative history and purpose of the Act. This is a good starting point.

> "11. The birth of the first child resulting from in vitro fertilisation in July 1978 prompted much ethical and scientific debate which in turn led to the appointment in July 1982 of a Committee of Inquiry under the chairmanship of Dame Mary Warnock DBE to
>
> 'consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.'
>
> The Committee reported in July 1984 (Cmnd 9314). A White Paper, Human Fertilisation and Embryology: A Framework for Legislation, was published in November 1987 (Cm 259) when the Department of Health and Social Security recognised, at para 6, 'the particular difficulties of framing legislation on these sensitive issues against a background of fast-moving medical and scientific development.'
>
> 12. There is no doubting the sensitivity of the issues. There were those who considered the creation of embryos, and thus of life, in vitro to be either sacrilegious or ethically repugnant and wished to ban such activities altogether. There were others who considered that these new techniques, by offering means of enabling the infertile to have children and increasing knowledge of congenital disease, had the potential to improve the human condition, and this view also did not lack religious and moral arguments to support it. Nor can one doubt the difficulty of legislating against a background of fast-moving medical and scientific development. It is not often that Parliament has to frame legislation apt to apply to developments at the advanced cutting edge of science.
>
> 13. The solution recommended and embodied in the 1990 Act was not to ban all creation and subsequent use of live human embryos produced in vitro but instead, and subject to certain express prohibitions of which some have been noted above, to permit such creation and use subject to specified conditions, restrictions and time limits and subject to the regimes of control briefly described in paragraph 4 above. The merits of this solution are not a matter for the House in its judicial capacity. It is, however, plain that while Parliament outlawed certain grotesque possibilities (such as placing a live animal embryo in a woman or a live human embryo in an animal) it otherwise opted for a strict regime of control. No activity within this field was left unregulated. There was to be no free for all."

26. Neither party now suggests that tissue typing is an activity that is left unregulated by the Act. The issue is whether it is absolutely prohibited by the Act, whether it is an activity that the Secretary of State could by regulation permit to be licensed but has not yet done so, or whether it is a practice which can be licensed because it falls within paragraph 1(1)(d) of Schedule 2 . A more detailed analysis of the background material is needed to assist in resolving this issue.

The Warnock Report

27. The first eight chapters of the Warnock Report address techniques for the alleviation of infertility. Chapter 9 is headed 'The Wider Use of these Techniques'. This addresses the problem of hereditary

diseases. It contemplates the possibility of avoiding transmission of a gender linked hereditary disease by PGD screening for gender to avoid implantation of embryos with the vulnerable gender. It states:

> We see no reason why, if a method of selecting the sex of a child before fertilisation is developed, this should not be offered to couples who have good medical reasons for choosing the sex of their child.

The Report goes on to consider the possibility of gender selection for purely social reasons and concludes that it is not possible to make positive recommendations on this issue other than that the acceptability of such a practice should be kept under review.

28. Chapter 12 of the Report is headed 'Possible Future Developments in Research'. This opens with the following comments:

> "12.1 There is a number of specific techniques and procedures involving the use of human embryos which have caused much public anxiety. Many of these have not yet reached the stage where they are practical possibilities. We believe that our recommendations for the regulation of research will allay much of that anxiety, as it will be the duty of the proposed licensing body (13.3) to keep these and other new techniques under constant review; indeed, in some instances our proposals will preclude certain developments altogether. It is important, however to consider whether further restrictions are required, although it must be borne in mind that we cannot foresee all possible developments."

29. The Chapter specifically considers the possibility of embryonic biopsy followed by PGD in order to diagnose whether an embryo is genetically abnormal and concludes that this is unlikely to become feasible for a considerable time.

30. Chapter 13 of the Report recommends the establishment of a new statutory licensing authority both to regulate those infertility services which should be subject to control and to licence research involving the use of embryos in circumstances where this is justified by the objectives of the research.

The White Paper

31. The White Paper, produced after consultation on the Warnock Report, announced the Government's intention to create a Statutory Licensing Authority. As recommended in the Warnock Report one function of this Authority would be to licence the provision of 'infertility services'. So far as research was concerned, however, the consultation process had disclosed strongly conflicting views. The Government proposed to leave it to Parliament to decide whether the Authority's role should extend to licensing embryo research, or whether such research should be absolutely prohibited.

32. The White Paper set out in an annex the arguments for and against permitting the licensing of research. Arguments in favour included:

> "49. It is argued that the greatest potential benefits of research involving human embryos lie in the prevention of congenital disorders. Studies of eggs, sperm and early embryos may lead to ways of preventing some chromosomal abnormalities developing. Also, in the future, those who support research envisage the development of techniques including embryo biopsy which might allow the very early detection of embryos which had single gene or chromosome defects which would result in seriously abnormal babies. In the UK some 7,000 babies a year (about 1 per cent of all babies) are born with an obvious single gene inherited defect. Pre-implantation 'diagnosis' could ultimately result in some fall in that number."

A footnote explained:

> "1. Male infertility is the sole cause in about 30 per cent of cases of infertility and it is a

factor in some others.

2. The technique of embryo biopsy could extend the use of IVF from treating infertile couples to those at risk of passing on an hereditary handicap. It would involve the removal and culture of one or two cells from an embryo still in vitro and need not affect the subsequent development of the embryo. It could, however, give the possibility in some instances of rejecting defective embryos in favour of healthy ones and reducing the number of requests for abortion on grounds of fetal abnormality. Attempts are also being made to develop non-invasive techniques for detecting defective embryos."

33. The White Paper commented:

"29. The key distinction in the debate surrounding embryo research appears to be between the use of an embryo with the intention of achieving (with that embryo) a successful pregnancy leading to a healthy baby; and its use for other reasons (eg improvement of knowledge about disease). Those who are opposed to all research involving human embryos argue that procedures which lead to the destruction of the embryo or which make it unsuitable for transfer to a woman should not be permitted in any circumstances. Procedures which do not damage the embryo, or which are actively beneficial to it, do not give the same cause for concern even though such procedures may form part of what some would regard as a programme of research (for example the observation of embryos developing in different nutrient fluids prior to transfer to a woman.)

30. The Government therefore proposes that the alternative draft clauses which will be made available to Parliament should be along the following lines:

It will be a criminal offence to carry out any procedures on a human embryo other than those aimed at preparing the embryo for transfer to the uterus of a woman: or those carried out to ascertain the suitability of that embryo for the intended transfer.

Except as part of a project specifically licensed by the SLA, it will be a criminal offence to carry out any procedures on a human embryo other than those aimed at preparing the embryo for transfer to the uterus of a woman or those carried out to ascertain the suitability of that embryo for the intended transfer."

34. The latter is plainly the origin of the provision that ultimately became paragraph 1(1)(d) of Schedule 2 . It is to be noted that 'suitability' is not defined, but that procedures carried out to ascertain suitability for transfer were considered to be appropriate for licensing, whether or not embryo research was prohibited.

Proceedings in Parliament

35. The Bill that became the Act was introduced in the House of Lords on 22 November 1989. As presaged in the White Paper there were alternative draft provisions, one which permitted the licensing of research and one which prohibited this. On the second reading on 7 December 1989 the clause permitting embryo research was carried by 154 votes. The second reading in the House of Commons took place on 2 April and the third reading on 29 April 1990. Proposed amendments imposing a ban on embryo research were heavily defeated. By the time of the third reading it was known that Dr Robert Winston had successfully implanted female embryos after genetically screening out male embryos which were, or might have been, affected with gender linked genetic disorders.

36. In the course of debate on the third reading, Mr Kenneth Clarke, the Secretary of State for Health, remarked:

> Not all reproductive technologies are aimed at helping infertile couples to have children. Some are designed to help people to have healthy normal children by allowing a range of congenital diseases and handicaps to be detected prenatally by pre-implantation diagnosis. The possibility of preventing genetic disease is one of the reasons most frequently cited in support of embryo research.

Mr Clarke was then addressed by Mrs Ann Winterton, who was opposed to embryo research. She was anxious to refute the suggestion that a ban on research would lead to a ban on PGD screening for hereditary defects. She asked him to confirm that ' Schedule 2 paragraph 1(d) would allow such pre-implantation screening for genetic handicaps to continue even if today we voted for a ban on destructive embryo research'. Mr Clarke confirmed that 'that treatment, now that it is being developed, could be continued if the amendments were agreed to'. Mrs Winterton later made the same point again and it was subsequently repeated by others.

Discussion

37. Maurice Kay J did not find it appropriate to consider whether the Act permits PGD screening for hereditary diseases. Mr Pannick's argument founded on this question as a stepping stone to the construction for which he contended. It seems to me not merely appropriate but necessary to consider the implications of any suggested construction on the position of screening for hereditary diseases. As I have shown, this practice was an important feature of the context in which the Act was passed.

38. Mr Pannick submitted that paragraph 3(2)(b) of Schedule 2 was significant. This permits the licensing of embryo research activities for the purpose of 'developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation'. Mr Pannick argued that it would be strange if Parliament approved research to develop a method for achieving an objective which was prohibited elsewhere in the Act. The clear inference of permitting such research was that Parliament approved of PGD to avoid implantation of embryos carrying genetic defects. The phrase 'for the purpose of assisting women to carry children' and of 'suitable for that purpose' in Schedule 2 paragraph 1(1)(d) had to be read so as to embrace that activity.

39. I found this argument persuasive. The Warnock Report recommended permitting the licensing of existing techniques of infertility treatment. It went on to consider wider uses of IVF to screen out hereditary diseases. It was in favour of gender selection to screen out gender linked diseases, which was the only form of PGD screening which seemed likely to prove feasible in the immediate future. It anticipated the remote possibility of PGD involving single cell biopsy of the type with which this appeal is concerned, and recommended permitting regulated research. The White Paper left open the question of whether research under licence should be permitted. The decision turned essentially on whether the potential benefits from research outweighed the ethical objection to creating and then destroying human embryos. Foremost in the potential benefits was the possibility of preventing the passing on of hereditary diseases to children.

40. Parliament chose to permit the licensing of research. It makes little sense for Parliament, at the same time, to prohibit reaping the benefit of that research, even under licence.

41. The matter is, in my judgment, put beyond doubt by the statement made by the Secretary of State in the course of Parliamentary debate. This is one of those rare cases where, under the application of the principle in Pepper v Hart [1993] AC593 , it is legitimate to resort to such material. The Minister made an express statement to Parliament upon the very issue of construction under consideration and it is clear that the issue in question was of particular concern to Parliament.

42. The question remains whether the two vital phrases 'for the purpose of assisting women to carry children' and 'designed to secure that the embryo is suitable for the purpose of being placed in a woman' are appropriate to describe the object of IVF treatment which is designed not to assist the processes of fertilisation and gestation, but to ensure that the child which is produced by those processes is healthy.

43. My initial reaction to the meaning of 'for the purpose of assisting women to carry children' was the same as that of Maurice Kay J. The phrase naturally suggests treatment designed to assist the physical processes from fertilisation to the birth of a child. But if the impediment to bearing a child is

concern that it may be born with a hereditary defect, treatment which enables women to become pregnant and to bear children in the confidence that they will not be suffering from such defects can properly be described as 'for the purpose of assisting women to carry children'. I believe that it is appropriate to give it this meaning in order sensibly to reconcile the provisions of the Act that deal with treatment and those that deal with research. I also think that it is legitimate when deciding to adopt this construction to have regard to the fact that the more narrow alternative construction would render unlawful a practice which has been carried on for over a decade and which is patently beneficial. It is also legitimate to have regard to Mr Clarke's statement to Parliament.

44. What of the actual process of biopsy and PGD — can that properly be said to be 'designed to secure that the embryo is suitable for the purpose of being placed in a woman'? Here I agree with Mr Pannick that, once satisfied that the treatment as a whole is for the purpose of enabling a woman to carry a child, no further problem arises. The word 'suitable' takes its meaning from its context. Where the object of the treatment is to enable a woman to bear a child confident that it will not carry a hereditary defect, an embryo will only be suitable for the purpose of being placed within her if it is free of that defect. PGD is thus designed to secure that the embryo is suitable for this purpose. The reassurance which Mr Clark gave to Parliament was not one which did violence to the language of paragraph 1(i)(d) of Schedule 2 .

45. I should add that Mr Dingemans suggested that it was possible to accommodate PGD testing within the narrow construction of the Act reached by Maurice Kay J on the basis that embryos with genetic defects are more prone to result in miscarriage. Mr Eadie, for the Secretary of State, sought permission to adduce evidence from a geneticist, Professor Alexander Raeburn, that shows that some hereditary diseases do not affect the development of the embryo within the woman. If it mattered, I would have had regard to this evidence, but there is ample other evidence which shows that the primary concern about genetic defects was and is not that they imperil the pregnancy but that they lead to the birth of children carrying the defects.

Tissue Typing

46. I said that Mr Pannick used the question of whether the Act permitted PGD screening as a stepping stone to the construction of the Act for which he contended. It remains to consider whether this stepping stone takes him safely to his destination.

'Treatment for the purpose of assisting women to bear children'

47. The discussion thus far had led me to the following conclusion. When concern as to the characteristics of any child that she may bear may inhibit a woman from bearing a child, IVF treatment coupled with PGD that will eliminate that concern can properly be said to be '… for the purpose of assisting women to carry children'. When the Act was passed women who had reason to fear that they would give birth to children with genetic defects were probably the only section of the population for whom it was envisaged that IVF treatment could be justified on this basis. No evidence suggests that the wish of a woman to bear a child in order to provide a source of stem cells for a sick or dying sibling was anticipated at that time. Such a wish is now the reality, and the case of Mr and Mrs Hashmi is not unique.

48. The activities that the HFEA has licensed in the case of Mr and Mrs Hashmi, are the same as those it has regularly licensed for the purpose of assisting women to bear children free of hereditary diseases:

i) creation of embryos

ii) biopsies of the embryos

iii) analysis of the cells removed by biopsy by the use of a DNA probe in order to identify those embryos likely to produce children with desired characteristics

iv) implantation of those embryos

The difference is as to the desired characteristics.

That difference may be critical in determining whether or not the HFEA will decide to licence the activities in question. I cannot see, however, that the difference can be critical in determining whether or not the treatment, including the PGD, is 'for the purpose of enabling women to carry children'. My conclusion is that whether the PGD has the purpose of producing a child free from genetic defects, or of producing a child with stem cells matching a sick or dying sibling, the IVF treatment that includes the PGD constitutes 'treatment for the purpose of assisting women to bear children'.

'Designed to secure that the embryo is suitable for the purpose of being placed in the woman'

49. Just as in the case of PGD screening for genetic defects, the meaning of 'suitable' falls to be determined having regard to its context. When the object of the treatment is to enable a woman to bear a child with a tissue type that will enable stem cells to be provided to a sick sibling, an embryo will only be suitable for the purpose of being placed within her if it will lead to the birth of a child with the tissue type in question. Accordingly I conclude that the HFEA was right to decide that the Act authorised it to licence IVF treatment with PGD for the purpose of tissue typing subject to such conditions as it considered appropriate.

Conclusion

50. IVF treatment can help women to bear children when they are unable to do so by the normal process of fertilisation. Screening of embryos before implantation enables a choice to be made as to the characteristics of the child to be born with the assistance of the treatment. Whether and for what purposes such a choice should be permitted raises difficult ethical questions. My conclusion is that Parliament has placed that choice in the hands of the HFEA. For the reasons that I have given I would allow this appeal.

Lord Justice Schiemann

51. The advances of science have made possible *in vitro* fertilisation and the creation of embryos outside the human body. Those embryos can be used for experimental and other purposes. They can, even after use for experimental or other purposes, be implanted inside a woman. All this, for which the Common Law made no special provision, gave rise to a considerable amount of public anxiety. Some wished to prevent the creation of such embryos *in vitro* . Others considered that the benefits to be gained by such creation outweighed the disbenefits. By the Human Fertilisation and Embryology Act 1990 Parliament decided in principle not to forbid the creation of embryos *in vitro* and their subsequent use but to regulate what could be done.

52. The Act provided for the setting up of the Human Fertilisation and Embryology Authority with a general power to keep under review information about embryos and about the provision of treatment services and activities governed by the Act. Part of the regulatory mechanism established by the Act is the issue of licences by or on behalf of the Authority.

53. The underlying task which faces the Court in the present case is one of construction of this Act. It is clear from the Act that Parliament itself has regulated some matters: other matters it has left to be regulated by the Authority. We have to decide whether the issue of a licence to permit tissue typing in order to test an embryo for tissue compatibility with a sibling affected by a particular disorder is in principle open to the Authority. The Judge held it was not. For reasons which I shall endeavour to set out I respectfully differ.

54. The structure of the Act is as follows.

Some activities are forbidden outright

55. Parliament has made the decision that the activities enumerated in section 3(2) and (3) of the Act are unacceptable in any circumstances.

56. Section 3(2) provides:

"No person shall place in a woman—

(a) a live embryo other than a human embryo, or

(b) any live gametes other than human gametes."

57. Section 3(3) provides:

"A licence cannot authorise—

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal,

(c) keeping or using an embryo in circumstances in which regulations forbid its keeping or use, or

(d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo."

58. Section 41(1) provides:

"A person who—

(a) contravenes section 3(2) … of this Act, or

(b) does anything which by virtue of section 3(3) of this Act, cannot be authorised by a licence

is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years …"

Some activities are forbidden unless done in pursuance of a licence

59. Some activities are forbidden unless done in pursuance of a licence or of a direction given by the Authority — see s.3(1) and s. 23(3) .

60. Section 3(1) provides:

"No person shall—

(a) bring about the creation of an embryo, or

(b) keep or use an embryo

except in pursuance of a licence"

61. A person who contravenes s.3(1) is guilty of an offence carrying a lesser maximum penalty of 2 years imprisonment — see s.41(2) and (4) .

The licensing regime

62. Parliament has imposed inhibitions on what a licence can authorise. The phraseology imposing those inhibitions is sometimes in positive form.

63. Thus section 11 indicates that the only activities for which licenses may be granted are — (a) activities in the course of providing treatment services, (b) storage and (c) research. From that one can deduce that Parliament has decided that licences may not be granted for other activities.

64. The phraseology is sometimes in negative form forbidding outright the licensing of some types of activity. I have drawn attention to the outright prohibitions in s. 3(3) on what can be authorised. But

there are other inhibitions.

65. Thus Paragraph 1(4) provides that a licence can not authorise altering the genetic structure of any cell while it forms part of an embryo. Schedule 2 paragraph 4(2) sets out further inhibitions on what a licence can do.

66. The phraseology is sometimes in the form of forbidding an activity unless certain preconditions are satisfied. One example of this legislative technique is provided by Schedule 2 paragraph 1(3) which in my judgment is the crucial provision in this appeal. It provides that:

> "A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services."

I shall return to this paragraph later.

67. There seems to me no practical differences between inhibitions imposed in the negative and those imposed in the positive form.

68. One should note that Parliament has not imposed any express obligation on the Authority to grant a licence in any prescribed circumstances.

What a licence can authorise

69. By contrast with the *inhibitions* as to what may be done and as to what may be authorised by a licence, subparagraphs 1(1) and (2) of the Second Schedule set out what *may* be authorised by a licence. A provision to which reference has been made in the argument is the following:

> "1
>
> (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services—
>
> …
>
> (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose"

The Decision under attack

70. The decision of the Authority which was quashed by the Judge was the decision in principle to allow tissue typing to be used in conjunction with preimplantation genetic diagnosis for serious genetic diseases. It was made clear by the press release that, before this technique could be used in treatment, approval would be required from an HFEA Licence Committee which would consider applications on a case-by-case basis and that licences would be subject to strict conditions. A licence has indeed been issued designed to assist Mr and Mrs Hashmi to have a further child which will not suffer from the genetic disease from which Zain suffers and whose tissue is compatible with his. The validity of that licence is, however, not directly in issue before us.

71. The whole process envisaged by the Authority was

> i) the removal of a cell from an embryo created by *in vitro* fertilisation,
>
> ii) the testing of that cell to see both

a) whether the embryo carries a genetic disorder and

b) whether the embryo enjoys tissue compatibility with a sibling affected with that disorder,

iii) where it was established that the embryo both did not carry the genetic disorder and enjoyed tissue compatibility, the implantation of the embryo in the mother of the affected sibling.

iv) Hereafter I shall refer to this whole process as the Process in Issue.

Analysis : Schedule 2 subparagraphs 1(3)

72. It is convenient at this point to set the relevant subparagraph again

"1

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services."

73. The crucial question for the Court is whether the Process in Issue could lawfully appear to the Authority as being necessary or desirable for providing treatment services.

74. The definition of treatment services appears in section 2(1) . This provides:

"In this Act—

'treatment services' means medical, surgical or obstetric services provided to the public or a section of the public for the purposes of assisting women to carry children."

75. Incorporating that definition into paragraph 1(3) of the second schedule leads to the following result—

"A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable *for the purpose of providing medical, surgical or obstetric services provided to the public or a section of the public* for the purpose of assisting women to carry children."

76. All parties, faced with this inelegant amalgam, have proceeded on the basis that the issues before us can be resolved more easily by simply ignoring the words which I have placed in italics. I agree that this seems the most sensible approach. The primary question can thus be phrased thus: *Can the Process in Issue lawfully appear to the Authority as necessary or desirable for the purpose of assisting a woman to carry a child?*

Some background considerations

77. It is clear that Parliament decided to permit the creation *in vitro* and subsequent use of embryos in some circumstances for some purposes. There is therefore not the absolute ban on this type of activity, which undoubtedly some would have wished. There is, however, an absolute ban on certain segments of this type of activity which are absolutely prohibited as being ethically objectionable in all

circumstances and thus within what it is convenient to call a Prohibited Area.

78. The dispute between the parties has centred on whether the Process in Issue falls within the Prohibited Area or within the area which is to be regulated by the Authority.

79. The ethical concerns which underlie this legislation are concerns about (a) the creation of embryos and (b) the use of embryos. Four separate matters fall for consideration:—

> i) the creation of the embryos,
>
> ii) their use in the course of carrying out the biopsies and also (so it is argued) the testing procedures in relation to the extracted cell,
>
> iii) the implantation of an embryo after tests have revealed that it does not suffer from a genetic defect and its tissue is compatible with that of a sibling, and
>
> iv) allowing embryos which did not suffer from a genetic defect to perish because their tissue is not so compatible.

80. It is a commonplace practice in one IVF cycle to create several embryos. One is then implanted. The others are stored ready for implantation in a later cycle if a further attempt to achieve pregnancy is needed. If however a pregnancy results and there is no wish for a further pregnancy, the other embryos are allowed to perish. This is so even though there is no reason to suspect any abnormalities in them. Paragraphs 44–48 of the White Paper make clear that the Government did not regard this as always unacceptable. Section 17 of the Act seeks to ensure that proper arrangements are made for the disposal of embryos that have been allowed to perish.

81. It seems to me that the creation of embryos with the knowledge that some perfectly healthy embryos will deliberately be allowed to perish was not regarded by Parliament as always unacceptable. The contrary has not been argued.

82. Further, it seems to me that the use of an embryo by implantation after tests have revealed that it does not suffer from a genetic defect was not regarded by Parliament as always unacceptable in itself. Again, the contrary has not been argued.

83. Allowing embryos which do not suffer from a genetic defect to perish was also not regarded by Parliament as always unacceptable. Again the contrary has not been argued.

84. The submissions have concentrated on the concern identified in paragraph 79(ii). This relates to two matters. It has not been argued before us that the use of an embryo by carrying out of a biopsy to extract one cell was itself regarded by Parliament as always unacceptable. The evidence is that this process need not harm the embryo from which the cell has been extracted.

85. There is in my judgment no indication in the Act that the carrying out of tests on cells extracted from an embryo was regarded by Parliament as unacceptable as such. Again the contrary has not been argued although I think that Mr Dingemans wished to leave the point open.

86. It is clear that amongst the purposes for which embryos are permitted to be used are projects of research specified in the licence: Schedule 2 paragraph 3(1) . Amongst those purposes can be developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, increasing knowledge about the causes of congenital disease and other serious disease and enabling such knowledge to be applied in developing treatments for serious disease: see Schedule 2 paragraph 3(2) and The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 . These are all matters which Parliament has permitted the Authority to sanction.

Conclusion

87. The analysis undertaken in the preceding paragraphs indicates that Parliament was not opposed in principle to doing to an embryo any of the things which are likely to happen to it if the decision of

the Authority is implemented. On the other hand Parliament did not sanction a free for all. No part of the Process in Issue (with the possible exception of carrying out tests on the extracted cells) can lawfully be done without a licence granted by an Authority specially set up by Parliament to supervise developments in this field. The phraseology of paragraph 1(3) immediately points to the Authority as the primary decision taker.

88. One of the tasks of that Authority was to determine whether the Process in Issue appeared to it to be necessary or desirable for the purposes of assisting a woman to carry a child. That involved the Authority in determining whether the Process in Issue would assist a woman to carry a child and, if so, whether it was necessary or desirable for that purpose.

89. In my judgment it was lawfully open to the Authority to come to the conclusion that the Process in Issue would assist some women, who would otherwise refrain from conception or abort either spontaneously or deliberately, to carry a child.

90. Further in my judgment it was lawfully open to the Authority to come to the conclusion that the Process in Issue was necessary or desirable for that purpose.

91. I therefore consider that the Authority's decision in principle does not infringe Paragraph 1(3) of the Second Schedule .

92. It remains to consider whether the sanctioning of the Process in Issue is inhibited by Paragraph 1(1)(d) of the Schedule.

93. Since the Process in Issue does not offend against subparagraph 1(3) it follows that it will be done for the purpose of assisting a woman to carry a child. If that be so, it will also be done ‘in the course of providing treatment services’ and thus fall within the opening words of paragraph 1(1).

94. It does not appear to me that the separation out of various activities in the latter part of paragraph 1(1) presents any further difficulties if I am right in my conclusions so far.

95. The creation of the embryo *in vitro* is expressly listed. So is the placing of an embryo in the woman.

96. Once one accepts, as I do, that the Process in Issue can in some circumstances lawfully be regarded by the Authority as desirable for the purpose of assisting a woman to carry a child, then this implies in my judgment that the concept of suitability in paragraph 1(1)(d) is wide enough to embrace ensuring that the embryo does not suffer from a genetic defect and tissue incompatibility. I therefore consider that the remaining proposed activities fall comfortably within the phrase “practices designed to determine whether embryos are suitable” for the purpose of implantation.

97. For these reasons I would allow this appeal.

98. I point out in conclusion that Parliament did not impose upon the Authority any express obligation to sanction the grant of licences even if what was proposed was indubitably necessary for the purpose of assisting a woman to carry a child. That seems to me to dispose of much of the force of the argument that if what has been sanctioned in principle here and licensed in one case is lawful, then licensing activities for the purpose of social selection is an unavoidable consequence. If the decision of the Authority is upheld in the present case it does not mean that parents have a right to in vitro fertilisation for social selection purposes.

Lord Justice Mance

Introduction

99. The facts of this case excite great sympathy. But the issue is one of law. It involves the construction of the Human Fertilisation and Embryology Act 1990 , in the context of scientific developments which go beyond any specifically envisaged at the time of the Act. Mr and Mrs Hashmi presently have five children, one of whom, Zain, suffers from a potentially fatal blood disorder, beta thalassaemia, so that he produces no or inadequate red blood cells. His condition fluctuates, sometime giving great cause for concern, but giving him, even at the best of times, a quality of life which is described as “extremely miserable” in relation to the other children. His future is uncertain. He may live to his 30s or even early 40s on evolving medication and frequent blood transfusions; he could become allergic to medication, which could itself be life-threatening; and he might at any time

develop fairly rapid organ failure. All this could be cured by a successful stem cell transplant from a matched donor, after which Zain could achieve a relatively normal life.

100. A matching donor may sometimes be found in the form of an existing relative willing to assist, or in a donor bank. Failing success in one of these ways, Dr Fishel, the Hashmi's clinical embryologist, explains that consultants commonly suggest the delivery of a sibling matching the sick child. Following the birth of such a sibling, stem cell blood can be recovered from the umbilical cord and donated to the sick child. This procedure does not in any way invade the new child's body. Mrs Hashmi has tried to give birth to a matching sibling on two occasions. This has led to one pregnancy being terminated because of the presence of beta thalassaemia and to the birth of the Hashmi's son, Haris, who is not however a tissue match for Zain.

101. Against that background Care at the Park Hospital, Nottingham ("the Care Clinic") applied to the Human Fertilisation and Embryo Authority ("HFEA") on 27 th September 2001 for a licence to perform a Preimplantation Genetic Diagnosis ("PGD"), including thereby screening for beta thalassaemia and tissue (or Human Leukocyte Antijen) typing for Mr and Mrs Hashmi. The term PGD is in the previous sentence used in a wide sense to include tissue typing. The documents before us show that the term is sometimes used in a narrower sense to cover simply testing for genetic defects. The proposal was for embryos created by *in vitro* fertilisation ("IVF") to be biopsied and for the biopsied material to be transported to Chicago for screening and tissue typing. In November 2001 a committee of the HFEA and (as it had become) the Human Genetics Commission had approved such screening "where there is a significant risk of a serious genetic disorder being present in the embryo", but had "agreed that there were sufficient ethical difficulties" with tissue typing "that it should be subject to further discussion before its use was considered". Despite this, the HFEA received favourable advice from its ethics committee on 22 nd November 2001 on the proposal relating to Mr and Mrs Hashmi. After discussing this, the HFEA at its meeting on 29 th November 2001 concluded that, in circumstances where there would have in any event to be a biopsy to screen for beta thalassaemia, the HFEA might in very rare circumstances and under strict controls, permit further testing of cells derived from the embryo, including in particular tissue typing. That decision was announced by press release dated 13 th December 2001. The present proceedings were brought by Josephine Quintavalle on behalf of Comment on Reproductive Ethics ("Core") on 5 th March 2003, seeking an order quashing the HFEA's decision and declaring that a licence granted by the HFEA cannot authorise practices designed to test an embryo for tissue-compatibility with an affected sibling.

102. After consideration by the HFEA the Care Clinic's application led to the grant of a licence on 22 nd February 2003 for various listed activities to be carried out under the supervision of Mr Simon Thornton, including IVF, PGD and Preimplantation Genetic Screening for Aneuploidy.

103. The licence is subject to extensive conditions, set out in Annex A , which in turn refers to Annexes B, C and D . In particular, section (5)a) of Annex A provides that, with respect to any PGD programme, it is a condition "that PGD may only be carried out for those disorders specifically listed in the PGD licences Annex C to the licence". Annex C provides for "Sexing for X-linked diagnosis" in respect of haemophilia, Duchenne muscular dystrophy and Linz syndrome, for "Specific diagnosis" in respect of cystic fibrosis, beta thalassaemia, sickle cell anaemia and chromosomal translocation and for the following "Special Category":

> "#-thalassaemia in conjunction with HLA typing for patients known as Mr and Mrs H".

104. All these tests appear in Annex C under the general heading of PGD. Screening for genetic defects and tissue typing both involve a detailed genetic analysis using the same cells taken from an embryo by biopsy. But genetic screening for abnormalities such as beta thalassaemia can be undertaken without at the same time undertaking tissue typing.

105. A note to Annex C refers back to Annex A, sections 4 and 5 for additional conditions relating to PGD. Section 4 makes it a condition with respect to any programme involving blastomere/polar body biopsy

> "b) that no embryo or material removed from it may be subjected to a test which supplies genetic information about the embryo that is not listed in an annex to this licence or specifically approved by a licence committee in any particular case.
>
> c) that no embryo may be transferred to a woman where that embryo, or any material

> removed from it or from the gametes that produced it, has been subject to a test, which supplies genetic information about the embryo, that is not specifically listed in an Annex to this licence or not specifically approved by a licence committee in any particular case.
>
> d) that centres should not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons."

106. The licence is capable on its face of covering any number of treatments, save for its (unprecedented) inclusion, in Annex C , of the "Specific Category" referring to Mr and Mrs Hashmi. Two unsuccessful IVF procedures had been undertaken by the time the present case brought by Mrs Quintavalle came before Maurice Kay J for hearing. On 20 th December 2002 he gave judgment quashing the decision in principle announced by the HFEA on 13 th December 2001. The present appeal is brought by the HFEA with the support of the Secretary of State. The arguments have developed before us along rather different lines to those raised before the Judge.

The Human Fertilisation and Embryology Act 1990

107. I need not repeat the statutory scheme, which has been set out by the Master of the Rolls. The relevant starting point consists in the prohibitions under s.3(1) on bringing about the creation of an embryo (defined in s.1(2) as meaning creation outside the human body) or use of an embryo, except in pursuance of a licence. A licence can only authorise activities "in the course of", and which appear to the HFEA to be necessary or desirable "for the purpose of", providing treatment services": see s.11 and Schedule 2 paras. 1(1) and (3) . Treatment services are defined by s.2(2) as "medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children". Treatment services extend beyond the activities for which any licence would be required. There are of course many medical, surgical and obstetric services (including advice, medicine and hospital facilities) "for the purpose of enabling women to carry children" which do not involve the creation outside the human body, or the keeping or use, of an embryo.

108. The *House of Lords in R (Quintavalle) v. Secretary of State for Health [2003] UKHL 692; 2 WLR 692* has recently considered the statutory scheme. Lord Bingham (with whose speech Lords Steyn, Hoffmann and Scott all agreed) identified the Act as imposing three levels of control:

> "The highest is that contained in the Act itself. As is apparent, for example from section 3(2) and (3), the Act prohibits certain activities absolutely, a prohibition fortified by a potential penalty of up to ten years' imprisonment (section 41(1)). The next level of control is provided by the Secretary of State, who is empowered to make regulations for certain purposes subject (so far as relevant here) to an affirmative resolution of both Houses of Parliament (section 45(1), (4)). Pursuant to section 3(3)(c) the Secretary of State may make regulations prohibiting the keeping or use of an embryo in specified circumstances. The third level of control is that exercised by the Authority. Section 3(1) prohibits the creation, keeping or use of an embryo except in pursuance of a licence, and the Act contains very detailed provisions governing the grant, revocation and suspension of licences and the conditions to which they may be subject: see, among other references, sections 11–22 of and Schedule 2 to the Act. A power is also conferred on the Authority to give binding directions: sections 23–24."

109. The House of Lords had, as we have, to grapple with at first sight contrasting rules that a statute always bears the meaning that it had when Parliament passed it and that a statute is always speaking, and with the difficulty that arises in deciding whether a modern invention or activity falls within statutory language used at a time when it did not exist. The House approved Lord Wilberforce's description (in *Royal College of Nursing of the United Kingdom v Department of Health and Social Security [1981] AC 800* , 822) of the court's role in this situation:

> "In interpreting an Act of Parliament it is proper, and indeed necessary, to have regard to the state of affairs existing, and known by Parliament to be existing, at the time. It is a fair presumption that Parliament's policy or intention is directed to that state of affairs. Leaving aside cases of omission by inadvertence, this being not such a case, when a

> new state of affairs, or a fresh set of facts bearing on policy, comes into existence, the courts have to consider whether they fall within the Parliamentary intention. They may be held to do so, if they fall within the same genus of facts as those to which the expressed policy has been formulated. They may also be held to do so if there can be detected a clear purpose in the legislation which can only be fulfilled if the extension is made. How liberally these principles may be applied must depend upon the nature of the enactment, and the strictness or otherwise of the words in which it has been expressed. The courts should be less willing to extend expressed meanings if it is clear that the Act in question was designed to be restrictive or circumscribed in its operation rather than liberal or permissive. They will be much less willing to do so where the subject matter is different in kind or dimension from that for which the legislation was passed. In any event there is one course which the courts cannot take, under the law of this country; they cannot fill gaps; they cannot by asking the question 'What would Parliament have done in this current case — not being one in contemplation — if the facts had been before it?' attempt themselves to supply the answer, if the answer is not to be found in the terms of the Act itself."

Tissue typing as use of an embryo

110. The prohibition in s.3 on creation or use without a licence relates to any "embryo". Under s.1(1) , except where otherwise stated, embryo means "a live human embryo where fertilisation is complete", but also includes "an egg in the process of fertilisation". The Judge concluded that tissue typing itself involved use of an embryo. The most substantial reasons the Judge gave were that Parliament could not have intended to leave an activity such as tissue typing outside the direct control of the Act, and that Schedule 2 para.1(1)(d) covers practices designed to secure the suitable condition, or to determine the suitability, of embryos to be placed in a woman. The Judge's view would have significant practical consequences. Under s.12(a) (though subject to the possibility of directions under s.24, subss.(3) and (4) in particular) a licence must provide that the activities which it authorises shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible, i.e. here at the Care Clinic under Mr Thornton's supervision. On the Judge's view, the transporting of embryonic cell material to a laboratory outside the Care Clinic (e.g to Chicago, as in this case) would, at least in the absence of any relevant qualifying directions, be impermissible.

111. I do not consider that the Judge's view was correct. An embryo is distinct from embryonic cell material, which is extracted from an embryo leaving the embryo free to continue to develop. S.3A(1) with its distinction between an embryo and female cells taken or derived from an embryo also confirms this. The points made by the Judge overlook the fact that the creation outside the human body, biopsying and implantation of an embryo all fall within s.3 . They can all only take place under a licence, which may impose strict conditions regarding the nature of any testing permissible in respect of any embryonic cell material removed from such an embryo. Clause (d) also controls the purpose for which any such biopsy must take place, a point to which I will return. The fact that *some* practices (e.g a biopsy) designed to secure the suitable condition, or determine the suitability, of embryos to be placed in a woman involve use of an embryo does not mean that *all* practices for such a purpose involve "use" of the embryo, or therefore require to be licensed as activities under paragraph 1(1) of Schedule 2 . The language of the HFEA's press notice and licence are open to the forensic comment that at points they equate embryonic cells with an embryo from which they have been removed, and treat PGN (including here both screening and tissue typing) as activities themselves requiring to be licensed. But these documents cannot construe for us the true scope of the legislative provisions.

Creation and biopsying of an embryo for the purpose of any form of PGD

112. The central issues are thus whether the activities of bringing about the creation by IVF of an embryo and, particularly, its biopsying are activities capable of being licensed, when the purpose is to test embryonic cells removed from the embryo by PGD, including tissue typing, and only to place the embryo in the relevant woman if the embryo is both free from genetic disorder and has tissue compatible with an existing sibling.

113. These issues turn, firstly, upon the definition of "treatment services" in s.2(1) as "medical, surgical or obstetric services provided to the public or a section of the public for the purpose of

assisting women to carry children". Licences may (as stated in paragraph 107) only be granted authorising activities which satisfy the two initial criteria, that they are "in the course of", and appear to the HFEA to be necessary or desirable "for the purpose of", providing treatment services (s.11 and Schedule 2 paras. 1(1) and (3)).

114. Treatment services are already defined by s.2(1) to include a required purpose (that "of assisting women to carry children"). Schedule 2 para. 1(3) , in providing that any activity must appear to the HFEA necessary or desirable for the purpose of services for that purpose, is to say the least inelegant. There is a duplication of "purposes" if the full definition is read into para. 1(3). It does not make sense to consider whether an activity (consisting for example of "placing an embryo in a woman") is necessary or desirable for the purpose of providing medical services for the purpose of assisting women to carry children. The intention must be that the activity should appear to the HFEA to be necessary or desirable for the simple purpose of assisting women to carry children. The true function of Schedule 2 para. 1(3) is to establish the standard by which the HFEA must form its judgment as to whether an activity should be licensed.

115. Provided an activity meets the two initial criteria, and in the absence of any regulation under Schedule 2 para.1(1)(g) , it must also fall within one of the particular heads of Schedule 2 para.1(1) . The most relevant one is (d) — "practices designed … to determine whether embryos are suitable for that purpose [viz "to be placed in a woman"]. Part of clause (d) was relied on in the Claim Form, but it was not relied on as a bar to the HFEA's objection by the Judge, or it seems raised as such in argument before him. There was no respondent's notice seeking to raise it before us. Nevertheless, it was referred to before us and is important to consider. Curiously, the only relevant argument raised in the Claim Form related to the initial words of clause (d) "in a suitable condition to be placed in a woman". The Claim Form submitted, firstly and correctly, that these words focus on condition; secondly, that they are only concerned with "those characteristics of the embryo which *in objective terms* render it unsuitable to be placed *in any woman* "; and thirdly that any contrary interpretation would permit the HFEA to license selection for characteristics such as sex, intelligence or hair colour. The first submission ignores the critical later words: "practices designed … to determine whether embryos are suitable for that purpose". These words go on any view wider than the condition of the embryo, to allow some consideration of its inherent characteristics or qualities. I return to the second submission in paragraph 127 and to the third in paragraph 145.

The permissibility of screening out genetic defects?

116. The Judge said that the case did not require him to resolve whether not only tissue typing, but also PGD, in the limited sense of screening to avoid use of any embryo showing genetic defects, was unlawful. But, in deciding in Mrs Quintavelle's favour, he interpreted "treatment services" in a way which, the HFEA submits, could present obstacles to screening of embryos for genetic defects, as well as to the taking of decisions not to implant particular embryos based on the results of such screening. The Judge associated the concept of "assisting women to carry children" with problems arising from "an impaired ability to conceive or to carry a child through pregnancy to full term and birth", and observed that the carrying of a child would be "wholly unaffected by the tissue typing". By focusing on the single question whether the woman could conceive and carry a child to full term and birth, the Judge on one view eliminated the possibility of any test the main purpose or effect of which could be said to determine whether the child would, after its birth, be healthy or suffer from, or be the carrier of, some abnormality, as well as the possibility of deciding against the implantation of a particular embryo because of any abnormality detected that would affect the viability of the embryo while being carried.

117. It is doubtful whether so limited an interpretation was advanced to the Judge. The skeleton argument lodged on Mrs Quintavelle's behalf in the Administrative Court contains these passages:

> "15. …
>
> (c) Parliament was aware of the possibility of genetic testing by embryonic biopsy and, in the light of that knowledge, provided that a licence could authorise "practices designed to … determine whether embryos are suitable" to be placed in a woman: see Sch. 2, para. 1(1)(d).

…

> (e) But there are some activities which Parliament placed beyond the reach of regulations … [Sch. 2 para. 1(3)] ensures that any such [genetic] testing must be carried out for the purpose of assisting women to carry children (e.g. by screening out embryos with a genetic defect) and *not* for any other purpose — for example, to allow parents to choose a male or female child or (to take another more extreme example) to choose a baby with a preferred eye or hair colour."

118. Those passages regarding Parliament's knowledge and intentions are amply born out by the information regarding research which took place and came to Parliament's attention during the Parliamentary process as well as by the debate recorded in Hansard, to which the Master of the Rolls has referred. Before us, Mr Dingemans QC for Mrs Quintavelle sought to reconcile the Judge's words with the general permissibility of genetic testing. He submitted that the Judge's formulation would not restrict genetic testing to screen out abnormalities, because abnormal genetic conditions involve a greater risk of problems in carriage and birth, even though this risk may not materialise in any particular case. He drew attention, as the only relevant evidence, to a passage in the witness statement of Dr Fishel, to the effect that most chromosomal abnormalities "are not compatible with normal foetal development". On that basis, he submitted (in the words of his skeleton argument) that "If it is right that most defects cause an embryo to be non-viable, the dire consequences predicted by the [HFEA] do not follow". The Secretary of State sought to put before us fresh evidence from Professor Raeburn, at which it was agreed that we could look provisionally (or *de bene esse*). It was that chromosomal abnormalities are likely significantly to impair the viability of an embryo, whereas the majority of conditions caused by single gene abnormalities (which we were told include beta thalassaemia) do not affect the viability of an embryo, but almost always have a major postnatal impact.

119. Had Professor Raeburn's evidence appeared critical to this appeal, I would have been reluctant, in view of the importance of the issue, to proceed without it and without admitting in reply any further evidence that the respondent might have been able to adduce. But we know, as Dr Fishel's statement tells us, that some abnormalities are compatible with normal foetal development. One has also to ask whether Parliament can have intended to limit the assistance given to women to carry children to treatment for infertility, including treatment to determine the viability of an embryo for implantation, carriage to and birth at term; or whether Parliament must be taken to have had a broader concern for the health of the child after birth and future generations. Children with inherited genetic problems are of course loved and receive exceptional care from their families, as in the case of Zain. That does not however bear directly on the question whether it is open to a family to choose that the potential mother in the family should not conceive a child who may suffer disability, pain and perhaps an early death or who as a carrier may expose his or her own children to the same fate.

120. The legislation contains a number of indications telling against any limitation of focus to mere viability. First, Parliament resolved the choice left to it as a result of the White Paper of November 1987 ("Human Fertilisation and Embryology: A Framework for Legislation, para. 30) in favour of permitting research under licence on embryos. It therefore included s.11(1)(c) and Schedule 2 para.3 . Under Schedule 2 para.3 such licences may authorise creation and use of embryos "for the purpose of … (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation" or for other purposes which might be specified in regulations "with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied". Regulations permitting licences for the purposes of increasing knowledge about the development of embryos and about serious disease and of enabling any such knowledge to be applied in developing treatments for serious disease have now been made (the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 , SI 188). While it is theoretically possible that Parliament intended to permit research into methods of detecting abnormalities, or into applications of knowledge acquired about disease, which it would be impermissible to licence for practical use unless the Act was amended, it seems improbable that it was contemplated that research, a particularly contentious matter, should be permissible into methods and applications the use of which in practice Parliament had decided to exclude.

121. Second, under Schedule 2 para.1(1)(f) licences may be granted authorising the mixing of sperm "for the purpose of testing the fertility or normality of the sperm".

122. Third, there is some support in s.13(5) for a conclusion that Parliament cannot have limited its sights to matters going to the viability of an embryo for the purpose of being implanted, carried to term and born as a child. It is true that s.13(5) is a condition which must be included in every licence under Schedule 2 para.1 (and is included in the licence relating to Mr and Mrs Hashmi), and that its role is to require the treating body, here the Care Clinic, to take account of the welfare of every child who may be born as a result of the treatment and of any other child who may be affected by the birth. This is a requirement that must not only apply before, but continue throughout the administration of treatment services. On the respondent's case it is not a requirement which the clinic can fulfil in one most effective way, by screening to avoid the implantation of an embryo which has or may have a genetic abnormality which would affect the child after birth (and, potentially, also affect siblings, in cases where the birth of such a child might impose heavy stress on the family generally). In short, s.13(5) points towards a wider concern for the future child and siblings, which is better served if the legislation is read as permitting such screening.

123. Fourth, I note that "treatment services" are defined as "medical, surgical and obstetric services provided to the public or a section of the public". Although their purpose must be to assist women to carry children, they are not services provided exclusively to women. The potential father is someone to whom such services may be being provided, and whose natural concerns about future health and welfare would be expected to be relevant (cf also s.28). This too tends to point against any conclusion that the legislation focuses solely on the woman's narrow physical ability to become pregnant and give birth.

124. I turn to the Warnock report, which inspired much of the subsequent Act. The Judge did not consider it appropriate to have regard to this report, but the relevance of it and the subsequent White Paper as background, and of the mischiefs intended to be addressed as indicated by these documents, is confirmed by the House of Lords' reasoning in the first Quintavalle case. The Warnock committee took a positive view towards the wider use of techniques (then in their infancy) as a facility or service available in cases other than infertility (Chap. 9). Chap. 9.2 dealt with the transmission of hereditary disease "which may be severely handicapping to the next generation, either because the individual has the condition or is a carrier". The committee also identified among these techniques sex selection for "couples who have good medical reasons for choosing the sex of their child" (Chap. 9.11), while observing that, "if an efficient and easy method of ensuring the conception of a child of a particular sex became available, it is likely that some couples would wish to make use of it for purely social reasons", which could affect not only the individual family and the children involved, but society as a whole (Chap. 9.11). While "dubious" about the use of sex selection techniques on a wide scale, the committee did not find it possible to make any positive recommendations. It considered that the whole question of the acceptability of sex selection should be kept under review, and referred in this context to Chapter 13 , where it recommended the establishing of an authority such as the HFEA.

125. The White Paper focuses on the issue of research, on which the government proposed to leave Parliament with a choice. But it contemplated expressly (in paragraphs 29–30) that embryos could under the proposed legislation be screened by PGD, so as to achieve "successful pregnancy leading to a healthy baby", that embryos would only be implanted "if suitable", and that they would be allowed "to perish where they were not to be transferred (eg because an abnormality had been detected)". As I shall demonstrate in more detail (in paragraphs 135–139 below), the White Paper does not suggest that any different approach than that adopted in the Warnock report was being taken to the particular wider techniques on which the Warnock report had commented in its Chapter 9 .

126. I am in these circumstances left in no real doubt that the concept of "medical, surgical or obstetric services … for the purpose of assisting women to carry children" was intended to embrace not merely services to assist women physically to carry to term and give birth, but also services to assist them to give birth to children who would be normal and healthy during their lives and would in turn be able to have normal and healthy children. I have equally little difficulty in concluding that the words "practices designed … to determine whether embryos are suitable for that purpose [namely to be placed in a woman]" in Schedule 2 para.1(1)(d) were intended to embrace PGD in the form of screening to avoid the use of any embryo with an abnormality which might affect the viability of the embryo if implanted or which might affect any resulting child either during that child's own life or any future generation because the child would be a carrier. "Suitable" is explained in Longman's Dictionary of the English Language as "meeting the requirements of a use, purpose, or situation". But here the statute only identifies the next step or immediate purpose, leaving it to those interpreting it to

ascertain from its background and other terms the more distant purposes and wider context that may admissibly be taken into account when judging suitability.

127. The initial words of para.1(1)(d) — “Practices designed to secure that embryos are in a suitable condition to be placed in a woman” — focus on the need to protect the embryo's condition, by for example keeping and treating it in an appropriate way. The second half of para.1(1)(d) deals in a more general way with the “suitability” of the embryo to be placed in “a woman”. The abstract and impersonal way in which this is expressed is explicable because the paragraph is dealing with practices that may and will usually be authorised by a licence granted to a clinic in general terms for classes of activity in relation to women who have not yet been ascertained. It does not follow from this formulation that the suitability of an embryo for implantation is to be assessed objectively without reference to the particular woman in whom it is to be placed. That would make no sense. The compatibility of the particular embryo with the particular mother must, at least, be a fundamental consideration.

128. I add this consideration. To see the legislation as interested only in women's ability successfully to experience the physical process of pregnancy and birth would seem to me to invert the significance of the human wish to reproduce. Just as “placing an embryo in a woman” is only a first step towards a successful pregnancy, so pregnancy and the experience of birth are steps towards an expanded family life, not an end in themselves.

The permissibility of tissue typing?

129. This brings me to the more difficult question whether the concepts of “treatment services” and “practices suitable … to determine whether embryos are suitable” to be placed in a woman cover the present case. Mr Eadie for the Secretary of State submitted that this question does not arise in circumstances like those of Mr and Mrs Hashmi, with which the HFEA's decision announced on 13 th December 2001 was also concerned. A biopsy is necessary in any event for the legitimate purpose of testing embryonic cells to screen out beta thalassaemia. Taking the opportunity to test the same cells to check for tissue compatibility with an affected sibling would not itself constitute an activity requiring a licence and would not affect the legitimacy of the licensed activity of taking a biopsy to screen out beta thalassaemia. In Mr Eadie's skeleton argument, this argument was put on the basis that the HFEA was only prepared to permit tissue typing tests “where the genetic test (the dominant and necessary purpose of the biopsy) is to take place”.

130. Mr Pannick (while not adopting Mr Eadie's present argument in other respects) did submit that there was no evidence that Mr and Mrs Hashmi would not want another child in any event (provided only that the child was free of an abnormality such as beta thalassaemia). If necessary, I would infer that Mr and Mrs Hashmi would, in their whole family's interests, decide against having another child unless they could be confident of realising their hopes to improve the whole family's life by curing Zain. But, whether this is so or not, the present proceedings relate to a decision by the HFEA announced in December 2001 which was directed to circumstances where both screening out of a genetic defect and tissue typing were (and in the case of Mr and Mrs Hashmi are) important purposes of an intended biopsy. If one looks at the actual licence granted to the Care Clinic in respect of Mr and Mrs Hashmi, this also confirms that, whatever other longer term decision might or might not be taken, the biopsy envisaged by the HFEA's decision and the Care Clinic licence had a dual purpose, which was to authorise both PGD to screen out abnormalities *and* tissue typing. Indeed, Mrs Hashmi in her powerful oral plea before us underlined her family's desire to save Zain, while stressing the protection that any new child brought into the family home would enjoy.

131. Where a biopsy has two basic purposes of this kind, I do not, as presently advised, think that a licence can be given for it, if one of those purposes falls outside those permitted under s.2(1) and Schedule 2 para.1(1)(d) . Mr Pannick was therefore right in my view to accept that in such circumstances the appellant has to establish that each of these purposes can properly be regarded as being “for the purpose of assisting women to carry children” and as falling within the concept of “practices … designed to determine whether embryos are suitable” to be placed in a woman. The former phrase is the primary control, which only Parliament can relax. The latter concept would be capable of expansion within the limits of the former phrase, by the Secretary of State making regulations under Schedule 2 para.1(1)(g) and s.45(1) of the Act.

132. It follows from paragraphs 129 to 131 that whether a biopsy for the purpose of tissue typing is *capable* of being licensed cannot depend upon whether or not a biopsy is also intended for the

purpose of PGD screening for genetic abnormalities. The HFEA by its decision announced in December 2001 and by its licence to the Care Clinic restricted tissue typing to cases where a biopsy was anyway necessary to screen out genetic abnormalities. But that was a restriction introduced not because the HFEA regarded the Act as requiring it to limit any licence in this way, but because the HFEA, exercising its judgment, considered that the invasive procedure of a biopsy should only be undertaken on an embryo if it was necessary in the first instance from the point of view of the embryo, in other words to confirm the embryo's genetic normality. If a biopsy was necessary in any event on that ground, then there was no objection to allowing it for the further purpose of tissue testing.

133. For reasons that I have already considered in relation to PGD screening to exclude abnormalities, the assistance to women to carry children which the Act contemplates is not limited to assistance in the narrow physical operation of becoming pregnant and giving birth. It extends to assistance in ensuring that any child born will so far as possible be free of genetic defects and not be a carrier of some hereditary problem which could affect a future generation. Considerations relating to the future well-being of yet-to-be-born children will weigh heavily with any prospective parents. So too will any effect that a new child would be likely to have on an existing sibling. Families which cannot, for financial reasons or because of the needs of an existing sibling, accommodate another child, may take steps to avoid having one. Families may equally have another child with the idea in mind that he or she will be company for an existing child. Such considerations may no doubt also play a significant role in the clinical judgment, about the welfare of any child who may be born and of any other child who may be affected by the birth, which is contemplated by s.13(5) of the Act. Whilst that subsection probably had primarily in mind consideration of any adverse effects on the welfare of the future or any existing child, the language does not exclude positive effects. The relevant considerations may indeed point in opposite directions. For example, it might be to the benefit of an existing child to have a companion, but there might be a countervailing risk to the welfare of the new child in the form of some hereditary disability.

134. It is, however, at the core of the respondent's case that the services which may be provided do not extend to assisting women to carry children selected for particular characteristics unrelated to any abnormality. Screening out genetic abnormalities is one thing. Screening out certain normal characteristics is another. The crucial distinction has been put as being between “screening out abnormalities” and “screening in preferences”. That distinction raises a spectre of eugenics and “designer babies”. But it is a crude over-simplification to view this case as being about “preferences”. The word suggests personal indulgence or predilection and the luxury of a real choice. But there is no element of whim in the circumstances that the HFEA had it in mind to licence in December 2001, and Mr and Mrs Hashmi are not seeking to indulge themselves. The case is about a family's reaction, understandable in the light of current scientific possibilities, to a cruel fate which one of its members is suffering and will continue to suffer, without a successful stem cell transplant. Ethical concerns that a child to be born might be used as a vehicle, or would not be valued and loved were, for good reason in the circumstances as they appear, not at the forefront of any submissions made to us in the present case. Other concerns, for example regarding any increase in the numbers of embryos that might be discarded, were raised. But I do not regard any of them as in any way decisive, or as having any relevance approaching that which attaches to the Warnock report and White Paper, which evidence the immediate background to the legislation and the aspects of IVF which were being addressed. On the HFEA's and the Secretary of State's case, such ethical concerns as may be raised by the presently proposed procedures fall appropriately to be addressed by the HFEA and the Care Clinic in the exercise of their respective functions.

135. Returning to the discussion in the Warnock report, Chap.9.11, on sex selection (see paragraph 124 above), the present circumstances lie conceptually between the two poles of “good medical reasons” for tests, by which the Warnock committee was referring simply to medical reasons affecting children yet to be born, and testing for “purely social reasons” which the Warnock committee said would “obviously affect the individual family and the children involved, and would also have implications for society as a whole”. However they lie far closer in spirit in my view to the former pole that to the latter. There are here good medical reasons for screening any embryo, although they do not relate to any future child's health. The concerns to which the HFEA's decision and the licence for Mr and Mrs Hashmi are directed are anything but “purely social”, relating as they do to the health of a sibling and the well-being of the whole family. What matters in any event is that the Warnock committee proposed in Chap.9.11 of its report to leave even the general question of the acceptability of sex selection to the authority which it recommended should be established.

136. Mr Dingemans submitted that the Warnock committee had elsewhere made clear that the legislation should prohibit absolutely any development such as the presently proposed tissue typing.

He referred to Chap.12.16. The committee in Chap.12 anticipated the future development of various techniques (among them in Chap.12.11 cloning by embryo-splitting, in Chap.12.12–13 embryonic biopsy to identify any abnormality and in Chap.12.14 nucleus substitution). In Chap.12.15, it anticipated a possible further technique to identify and replace a defective gene. Then, in Chap.12.16, the committee said this:

> "Public anxiety about these techniques centres, not so much on their possible therapeutic use, but on the idea of the deliberate creation of human beings with specific characteristics. This has overtones of selective breeding. We regard such techniques as purely speculative but believe that any developments in these fields are precluded by the controls we have already recommended …."

It added:

> "We would go further. We recommend that the proposed licensing body promulgates guidance on what types of research, apart from those prohibited by law, would be unlikely to be considered ethically acceptable in any circumstances and therefore would not be licensed. We envisage this guidance being reviewed from time to time to take account of both changes in scientific knowledge and changes in public attitudes."

137. When speaking of "such techniques" as purely speculative, it is not clear that the Warnock committee had in mind all the possible future techniques previously discussed, or whether it was referring to techniques with "overtones of selective breeding". But, assuming that it was speaking of all the possible future techniques, its reference to "the controls we have already recommended" did not contemplate that all such techniques would be absolutely prohibited under the legislation. The "controls" in question were to consist of a combination of absolute prohibitions (see e.g. Chap.12.8 and 9) and the performance by the proposed licensing body of its function. See also Chap.12.1, where the committee said that:

> "We believe that our recommendations for the regulation of research will allay much of that anxiety, as it will be the duty of the proposed licensing body (13.3) to keep these and other new techniques under constant review; indeed, in some instances our proposals will preclude certain developments altogether."

138. In these circumstances, I see no inconsistency between Chaps.9.11 and 12.16 of the Warnock report.

139. One of the potential future techniques to which the Warnock report referred without recommending any absolute prohibition was embryo-splitting (Chap.12.11). Lord Bingham noted this as a point of some relevance when he concluded in Quintavalle (at p.701F—G) that the Act permitted the licensing of cloning by cell nuclear replacement ("CNR"), involving implanting a replacement nucleus in an unfertilised egg, as distinct from replacing the nucleus of an already fertilised embryo. The White Paper did, however, go further than the Warnock report in two other areas — by recommending absolute prohibitions of nucleus substitution and of techniques aimed at modifying the genetic constitution of an embryo. Lord Bingham inferred in Quintavalle that s.3(3)(d) of the Act was enacted to give effect to this White Paper recommendation. It is in my opinion of considerable relevance to this appeal that neither Warnock nor the White Paper recommended any absolute prohibition in relation to embryonic testing or in relation to sex selection for reasons unrelated to the child-to-be-born's medical condition.

140. Mr Pannick also pointed out that the effect of s.4(1)(b) (which contains a limited extension of protection beyond embryos to sperm) is to enable use in the course of providing treatment services (as defined in s.2(1)) to prospective parents together of sperm sorted to select sex. That is not to say that the same approach governs sex selection in relation to embryos. It clearly does not. Embryos enjoy on any view a higher level of protection, and, when their use is permissible at all, it is only under the control of the HFEA. But it is at least clear that there is no absolute bar on sex selection in all circumstances.

141. The Act was framed at a time when PGD to screen out disabilities was understood as a possibility, and was (as I have concluded) contemplated in certain of its provisions. In contrast, tissue

typing and other techniques to screen out certain normal characteristics were only speculative possibilities at the time of the Act. That the distinction between these procedures may itself be debatable, as Mr Pannick exemplified by taking the instances of dyslexia and deafness, does not really help, since problems of scope on any view arise. But it can be said that the concept of “services … for the purpose of assisting women to carry children” seems on its face wide enough to embrace some forms of activity in relation to healthy embryos, e.g. testing to ensure that the right sperm and egg had been used, although the considerations here differ from those presently under consideration.

142. More importantly, once it is recognised that the concept of “services … for the purpose of assisting women to carry children” extends beyond purely physical problems affecting the viability of the embryo during pregnancy and birth, and allows the screening of embryos for genetic abnormalities, it becomes clear that such services may have regard to prospective parents' and society's concern for others and for the future. The concept is in other words to be read in a general, rather than a restrictive sense. If that is so, I see no basis for drawing a line which excludes the services envisaged by the decision announced on 13 th December 2001. The assistance to carry a child provided can be viewed either as assistance to have a child whose addition to the family could, without any invasion of tissue, bring very special benefits for a sibling and for the family as a whole and who would be expected to be valued correspondingly, or more narrowly as assistance to the parents in giving them crucial information to decide whether the potential mother should go ahead to have an embryo placed in her. In whichever way the assistance is viewed, I regard it as coming within the statutory concept of “services … for the purpose of assisting women to carry children”.

143. Where Parliament intended to put absolute limits in the fields of potential scientific development identified by the Warnock report and White Paper, it did so expressly, as in s.3(2) and (3) . Notably it did not include any absolute prohibition in the area of sex selection for “social purposes”. The inference is that even this was left to be regulated by the licensing authority with the assistance of clinics (on which licences must under the Act impose conditions extending well beyond the purely medical or surgical to matters of general welfare). The present circumstances involve a form of selection which is much less obviously problematic than, and very far removed from, selection for social purposes. But, as I have stressed, what matters is that the HFEA's judgment of the desirability of the proposed treatment services has not, as such, been challenged, if it lay within its powers to make it at all. I would therefore hold that it was, in circumstances such as those faced by the Hashmis, open to the HFEA under the Act to conclude that a biopsy for the purpose of selecting an embryo with tissue compatible with that of a very sick child was an activity necessary or desirable for the purpose of treatment services as defined.

144. Viewing the issue in terms of the guidance provided by Lord Wilberforce's formulation (paragraph 109), a biopsy for the purpose of tissue typing is, in the wider sense, a form of PGD. Its direct purpose is to establish the embryo's genetic makeup and in that light to decide whether or not it should be implanted. The differences between the testing of embryonic cells for abnormality and for tissue typing lies in the precise aspects of the genetic makeup tested and in the factors taken into account when deciding whether to implant. In the one case, it may be said, the procedures are with a view to ensuring the health of the child to be or of future generations, while in the other they are to promote the health of a sibling and the general welfare of the existing family. The taxonomy of statutory provisions may offer no easy answer (cf the difference of judicial opinion in Royal College of Nursing itself), but I would regard these as differences falling in Lord Wilberforce's terms within the same genus (even if not the same species) of facts as those to which the expressed statutory policy has been formulated. Indeed, I would go further for reasons which I have already indicated. The background (in the form of the Warnock report and White Paper) supports the view that Parliament envisaged the possibility or likelihood of future developments (even though it could not know precisely what they would be) and positively intended to bring all such procedures within the sphere of the HFEA, with the exception of those specifically prohibited.

145. It remains to consider Schedule 2 para.1(1)(d) . I have rejected the suggestion that this clause is only concerned with characteristics which in objective terms render an embryo unsuitable to be placed in *any* woman (paragraph 127 above). The compatibility of the particular embryo with the particular woman is fundamental. Clause (d) also enables a clinic and parents to consider before implantation not merely whether the embryo can viably be implanted and carried to term, but also whether the future child will himself or herself be healthy or a carrier of an hereditary disease which may affect future generations (paragraphs 126 to 128). I have further concluded that a biopsy for the purpose of tissue typing and of enabling a choice to be made regarding implantation based on the compatibility of the embryo's tissue with that of a sibling is capable of constituting a service for the

purpose of assisting woman to carry children (paragraph 142). But is suitability for placement in a woman, in contrast to treatment services, to be judged only by considering whether the embryo is viable and capable of leading to a healthy child who will not be a carrier of an hereditary disease? If it is, there is still the possibility of the Secretary of State widening the ambit of licensable activities by regulation under Schedule 2 para.1(1)(g) . Nevertheless, I consider it improbable that this was a distinction or a limitation that Parliament intended at this point to introduce by the bare requirement that a licensed practice should be designed to determine whether an embryo was suitable to be implanted. As I have observed, that requirement leaves open the more distant purposes and wider context by reference to which suitability may be judged (paragraph 126). Having concluded that the concept of treatment services embraces the situation addressed by the HFEA's decision announced on 13 th December 2001, it is natural also to regard the concept of suitability as apt to do so. Tissue typing is aimed at providing assistance matching the felt and perceived needs of the family as a whole and the parents and siblings in particular. The HFEA must already bear their interests in mind when determining whether to issue any licence. The HFEA, when granting any licence, may, in the exercise of its powers under s.11 and Schedule 2 para.1(1) and (2) , limit in such way as it considers appropriate the practices which it licenses or the purposes for which they may be undertaken — as it in fact did (see paragraph 105 above). Clinics are bound to have regard to the interests of siblings as well as those of any child-to-be-born under s.13(5) when providing any treatment services; and their performance of that role is likely to be assisted by information obtained from tissue typing. I conclude that the suitability of the embryo to be placed in a (particular) woman may be considered in the context of objectively established aims and perceived needs relating to the child-to-be-born's parents and to an affected sibling, of the kind that the HFEA had in mind in reaching its decision announced on 13 December 2001 and in later granting the Care Clinic's licence.

Conclusion

146. I would for these reasons hold that the appeal succeeds. I would accordingly set aside the order whereby the Judge quashed the HFEA's decision in principle announced on 13 December 2001 to allow tissue typing to test an embryo for tissue compatibility with an affected sibling.

Order: 1. Appeal allowed with costs. 2. Claim for judicial review refused. 3. Permission to appeal to the House of Lords refused.