HOUSE OF LORDS SESSION 2004–05
[2005] UKHL 28

on appeal from: [2003] EWCA Civ 667

OPINIONS

OF THE LORDS OF APPEAL

FOR JUDGMENT IN THE CAUSE

Quintavalle (on behalf of Comment on Reproductive Ethics) (Appellant)
v.
Human Fertilisation and Embryology Authority (Respondents)

ON
THURSDAY 28 APRIL 2005

The Appellate Committee comprised:

Lord Steyn
Lord Hoffmann
Lord Scott of Foscote
Lord Walker of Gestingthorpe
Lord Brown of Eaton-under-Heywood

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LORD STEYN

My Lords,

1. I have had the advantage of reading the opinions of my noble and learned friends Lord Hoffmann and Lord Brown of Eaton-under-Heywood. For the reasons they have given I would dismiss the appeal.

LORD HOFFMANN

My Lords,

2. Zain Hashmi is a little boy, now aged 6, who suffers from a serious genetic disorder called beta thalassaemia major. His bone marrow does not produce enough red blood cells and in consequence he is often very poorly and needs daily drugs and regular blood transfusions to keep him alive. But he could be restored to normal life by a transplant of stem cells from a tissue compatible donor.

3. The problem is to find compatible tissue which Zain's immune system will not reject. The chances of finding a compatible donor who is not a sibling are extremely low. Even in the case of siblings, the chances are only one in four. None of Zain's three elder siblings is compatible. In addition, the donor must be free of the same disorder. That lengthens the odds even more. Zain's mother, Mrs Hashmi, has twice conceived in the hope of giving birth to a child whose umbilical blood could provide

stem cells for Zain. Once the foetus was found to have beta thalassaemia major and she had an abortion. On the second occasion she gave birth to a child whose tissue turned out not to be compatible.

4. There is a way to save the Hashmi family from having to play dice with conception. For 30 years it has been possible to produce a human embryo by fertilisation of egg and sperm outside the body and then to implant that embryo in the womb. In vitro fertilisation (IVF) has enabled many couples who could not achieve natural fertilisation to have children. More recently, it has become possible to perform a biopsy upon the newly fertilised IVF embryo and remove a single cell to test it for genetic disorders. This is called pre-implantation genetic diagnosis (PGD). It provides a woman with information about the embryo proposed to be implanted in her body so that she may decide whether or not to proceed. Mrs Hashmi, for example, would have been spared having to have her foetus carrying beta thalassaemia major aborted if the embryo had been created by IVF and the disorder diagnosed by PGD.

5. Still more recently, and so far only in the United States, it has become possible to use the same single cell biopsy technique to test for tissue compatibility. This involves examination of the human leukocyte antigens (HLA) and is known as HLA typing. That means that if Mr and Mrs Hashmi's sperm and eggs are used to create IVF embryos which are then tested for beta thalassaemia major by PGD and for tissue compatibility with Zain by HLA typing, they can know that the child Mrs Hashmi conceives will have stem cells which could cure Zain. The question in this appeal is whether this can lawfully be done in the United Kingdom.

6. After the birth of the first IVF child or "test tube baby" in 1978, it became clear that the new technique, together with other potential developments in embryology and genetics, could raise serious medical and ethical issues. The government appointed a committee under the chairmanship of Dame Mary Warnock DBE to advise. It reported in 1984 (Report of the Committee of Inquiry into Human Fertilisation and Embryology (Cmnd 9314)). The centrepiece of the committee's recommendations was the creation of a statutory licensing authority to regulate all research and treatment which involved the use of IVF embryos.

7. This recommendation was given effect by the Human Fertilisation and Embryology Act 1990, which set up the Human Fertilisation and Embryology Authority ("the authority"). Members are appointed by the Secretary of State and it has to have a lay (ie not medically qualified or engaged in IVF treatment or research) chairman and deputy chairman and a majority of lay members: para 4 of Schedule 1. Members provide a broad range of experience: social, legal, managerial, religious and philosophical, as well as medical and scientific.

8. The source of the authority's power is section 3(1), which makes it a criminal offence to bring about the creation of an embryo or keep or use an embryo except pursuant to a licence from the authority. The proposed treatment of Mrs Hashmi to assist her in bearing a tissue-compatible child involves the creation and use of embryos and therefore requires a licence. In this case, the authority has granted a licence which permits both PGD and HLA typing. But Ms Quintavalle, the claimant in these proceedings, who is director and founder of a group which believes in absolute respect for the human embryo, says that the authority has no power to authorise HLA typing. She brought judicial review proceedings for a declaration to that effect. It was granted by Maurice Kay J but an appeal was allowed and the application dismissed by the Court of Appeal (Lord Phillips of Worth Matravers MR and Schiemann and Mance LJJ) [2004] QB 168.

9. Whether the authority can grant such a licence depends on the extent of its powers under the 1990 Act. Section 11 provides that the authority may grant three kinds of licences and no others. Licences must be (a) "authorising activities in the course of providing treatment services" or (b) "authorising the storage of gametes and embryos" or (c) "authorising activities for the purposes of a project of research". The specific activities which may be authorised in the course of providing treatment services or for the purposes of research are then set out in Schedule 2.

10. In this case we are particularly concerned with the activities which may be authorised to be done in the course of providing treatment services. "Treatment services" are defined by section 2(1) to mean, among other things, medical services provided to the public for the purpose of assisting women to carry children. IVF is of course such a service; the proposal is to assist Mrs Hashmi to carry a child conceived by the implantation of an IVF embryo. So the question is whether PGD

and HLA typing are activities which the authority can authorise to be done "in the course" of providing her with IVF treatment.

11. To find the answer, one must look at the list of activities in para 1 of Schedule 2. Para 1(3) provides that the authority may licence an activity on the list only if it appears to the authority to be "necessary or desirable for the purpose of providing treatment services". The activities include:

> "(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".

12. The authority's case is that both PGD and HLA typing are to determine whether an embryo would be suitable for the purpose of being placed in Mrs Hashmi. The definition of treatment services focuses upon the woman as the person to whom the services are provided. The authority says that Mrs Hashmi is entitled to regard an embryo as unsuitable unless it is both free of abnormality and tissue compatible with Zain. Without such testing, she cannot make an informed choice as to whether she wants the embryo placed in her body or not. The authority considers it desirable for the purpose of providing her with treatment services, ie IVF treatment, that she should be able to make such a choice. Mr Pannick QC, who appeared for the authority, pointed out that the Act does not require that PGD or HLA typing should *constitute* treatment services. They must be activities *in the course* of such services, ie in the course of providing IVF treatment.

13. The claimant, on the other hand, says that this gives far too wide a meaning to the notion of being suitable. It would enable the authority to authorise a single cell biopsy to test the embryo for whatever characteristics the mother might wish to know: whether the child would be male or female, dark or blonde, perhaps even, in time to come, intelligent or stupid. Suitable must therefore have a narrower meaning than suitable for that particular mother. Maurice Kay J thought that suitable meant only that the embryo would be viable. That would rule out a good deal of PGD, because many genetic abnormalities do not affect the viability of the foetus. The abnormality manifests itself after birth. Before your Lordships Lord Brennan QC, for the claimant, disavowed so narrow a construction. I think that he was right to do so. The narrower meaning is particularly difficult to support when paragraph 3(2)(e) lists, among the research projects which may be

licensed, "developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation." It would be very odd if Parliament contemplated research to develop techniques which could not lawfully be used. So Lord Brennan accepts that suitable means more than viable. Building on paragraph 3(2)(e), he says that an embryo is suitable if it is capable of becoming a healthy child, free of abnormalities. PGD to establish that the embryo is free from genetic abnormalities is therefore acceptable. But not HLA typing. A baby which is not tissue compatible with Zain would not be in any way abnormal. It just would not answer the particular needs of the Hashmi family.

14. "Suitable" is one of those adjectives which leaves its content to be determined entirely by context. As my noble and learned friend Lord Scott of Foscote put it in argument, a suitable hat for Royal Ascot is very different from a suitable hat for the Banbury cattle market. The context must be found in the scheme of the 1990 Act and the background against which it was enacted. In particular, one is concerned to discover whether the scheme and background throw light on the question of whether the concept of suitability includes taking into account the particular wishes and needs of the mother. If so, the authority may authorise tests to determine whether the embryo is in that sense suitable for implantation in her womb. It may, but of course it is not obliged to do so. It may consider that allowing the mother to select an embryo on such grounds is undesirable on ethical or other grounds. But the breadth of the concept of suitability is what determines the breadth of the authority's discretion.

15. The Warnock Report discussed possible future developments in embryology. Some of these, such as creating children in vitro or the gestation of human embryos in other species, it recommended should be unequivocally banned. On others, it made no such recommendations. One of these was embryonic biopsy, such as can now be used for PGD and HLA typing. It described (in para 12.13) the advantages of PGD in detecting abnormalities before implantation ("avoiding the difficult decision for the parents of whether to seek a termination where abnormality is detected") and its disadvantages, namely the need to use IVF. It concluded that it was unlikely that embryonic biopsy would become a feasible method of detecting abnormal embryos for some considerable time.

16. For present purposes, the most relevant discussion in the Warnock Report concerned gender identification. The report considered

(in para 9.8) the possibility of gender identification of an IVF embryo by single cell biopsy. Such information could be used to select embryos to "prevent the birth of a child with a sex-linked hereditary disease". The committee saw no reason why this should not be done: para 9.11. It then went on to consider the use of gender identification to select the sex of a child "for purely social reasons". After some discussion of the social issues (population distribution, the role of women in society), the committee said that it was unable to make any positive recommendations. Nevertheless:

> "the whole question of the acceptability of sex selection should be kept under review (See chapter13)."

17. Chapter 13 was devoted to recommending the establishment of what became the authority. The committee said in para 13.3 that:

> "The authority should be specifically charged with the responsibility to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions."

18. Because the authority would be concerned not merely with medical or scientific matters but with "broader matters and with the protection of the public interest" the committee recommended (in para 13.4) substantial lay representation:

> "If the public is to have confidence that this is an independent body, which is not to be unduly influenced by sectional interests, its membership must be wide-ranging and in particular the lay interests should be well represented."

19. The conclusion which I draw is that the committee contemplated that the authority would decide the circumstances, if any, in which sex selection on social grounds should be authorised. As sex selection on social grounds is the most obvious case of selecting an embryo on grounds other than its health, I would infer that the Warnock Committee did not intend that selection of IVF embryos on grounds which went beyond genetic abnormality should be altogether banned.

20. It does not of course follow that Parliament gave effect to this recommendation in the 1990 Act. But the Act was preceded by a White Paper, Human Fertilisation and Embryology: A Framework for Legislation, published in November 1987 (Cm 259), which suggests acceptance of the views of the Warnock Committee on this point. In this paper, the Government set out the general principles upon which it proposed to legislate. In para 13 it accepted the "basic principle underlying the Warnock Report recommendations – namely the need 'to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions.' " The authority would therefore exercise its functions in areas which included "any [research or] treatment involving human embryos created in vitro." (The square brackets were to leave Parliament to decide, as it subsequently did, whether to allow research at all). The intention was therefore to define the functions of the authority in very broad terms. To ensure that the legislation was flexible enough to deal with "as yet unforeseen treatment developments which may raise new ethical issues", the Bill would:

> "contain powers to make regulations (subject to the affirmative resolution procedure) to add to or subtract from the range of matters coming within the regulatory scope of the [authority]." (Para 14).

21. On prohibited areas of research (assuming that any research was to be allowed) the government did not think that the Warnock Committee had gone far enough. It had proposed (in para 12.16) that the authority should promulgate guidance on research which was "unlikely to be considered ethically acceptable in any circumstances". The government thought (in para 36) that the legislation should "clearly prohibit" some such activities, but with a power for Parliament itself, by affirmative resolution, to make exceptions if new developments made them appropriate.

22. Included in the matters which were to be prohibited were what journalists commonly call "designer babies" or, as the White Paper put it, in para 37:

> "the artificial creation of human beings with certain pre-determined characteristics through modification of an early embryo's genetic structure."

Another was the cloning of individuals by nuclear substitution. But, relevantly for present purposes, there was no proposal to include in the "clearly prohibited" list the testing of embryos to enable the mother to choose to carry a child with characteristics of her choice. One infers that the White Paper intended the fundamental ethical issues which such activities might raise to be determined by the statutory authority, subject to the regulation-making power by which Parliament could impose its own decision.

23. The structure of the 1990 Act reflects the scheme foreshadowed in the White Paper. Section 3(3)(a) prevents, as the Warnock Committee recommended, the development of the foetus in vitro by providing that a licence may not authorise the keeping or use of an embryo after the appearance of the primitive streak. Nor may the authority authorise the placing of an embryo in an animal (subsection (3)(b)) or the cloning of an embryo (subsection (3)(d)). By para 1(4) of Schedule 2, a licence may not authorise altering the genetic structure of any cell while it forms part of an embryo. These activities are all clearly prohibited. In addition, section 3(3)(c) enables the Secretary of State and Parliament by affirmative resolution to add other activities involving the keeping or using of embryos to the prohibited list.

24. Subject to these prohibitions, the licensing power of the authority is defined in broad terms. Paragraph 1(1) of Schedule 2 enables it to authorise a variety of activities (with the possibility of others being added by regulation) provided only that they are done "in the course of" providing IVF services to the public and appear to the authority "necessary or desirable" for the purpose of providing those services. Thus, if the concept of suitability in sub-paragraph (d) of 1(1) is broad enough to include suitability for the purposes of the particular mother, it seems to me clear enough that the activity of determining the genetic characteristics of the embryo by way of PGD or HLA typing would be "in the course of" providing the mother with IVF services and that the authority would be entitled to take the view that it was necessary or desirable for the purpose of providing such services.

25. The chief argument of Lord Brennan against interpreting suitability in this sense was that, once one allowed the mother's choice to be a legitimate ground for selection, one could not stop short of allowing it to be based upon such frivolous reasons as eye or hair colour as well as more sinister eugenic practices. It was, he said, inconceivable that Parliament could have contemplated the possibility of this happening.

26. Let it be accepted that a broad interpretation of the concept of suitability would include activities highly unlikely to be acceptable to majority public opinion. It could nevertheless be more sensible for Parliament to confine itself to a few prohibitions which could be clearly defined but otherwise to leave the authority to decide what should be acceptable. The fact that these decisions might raise difficult ethical questions is no objection. The membership of the authority and the proposals of the Warnock Committee and the White Paper make it clear that it was intended to grapple with such issues.

27. In this case, as I have said, Maurice Kay J thought that suitable meant no more than suitable to produce a viable foetus but Lord Brennan, understandably unwilling to argue that Parliament might have outlawed PGD, said that it meant suitable to produce a healthy foetus, free of genetic defects. But this definition is itself not free from difficulty. What amounts to a genetic defect? Marie Stopes, an enthusiastic believer in eugenics, cut off relations with her son because she considered that the woman he chose to marry suffered from a genetic defect: she was short-sighted and had to wear spectacles. Surely it would be more sensible to concentrate on whether choice on such grounds was ethically acceptable rather than to argue over whether it counted as a genetic defect. The great advantage which Parliament would have seen in using broad concepts to define the remit of the authority is that it would avoid sterile arguments over questions of definition and focus attention upon the ethical issues.

28. Even in cases in which one could clearly say that the ground for selection was not a genetic defect, a total prohibition might exclude cases which many people would think ethically acceptable. Mr Pannick drew attention to the facts of *Leeds Teaching Hospitals NHS Trust v A* [2003] 1 FLR 1091. In the course of providing IVF treatment to a husband and wife, the hospital mixed up the sperm provided by the husband with that of another man. As a result, a woman gave birth to twins, the father of whom was a stranger. But they suffered from no genetic defects and Mr Pannick points out that if the muddle had been suspected before implantation of the embryo, Lord Brennan's construction of suitability would have prevented any tests to check the embryo's DNA. Likewise, many people might agree with the authority that the tests proposed to be conducted in the present case would be ethically acceptable. It often seemed that an unstated assumption in Lord Brennan's argument was that the authority was likely to authorise anything that it was not positively prohibited from authorising or that it could not be trusted to make proper ethical distinctions. But these assumptions are in my opinion illegitimate. The authority was

specifically created to make ethical distinctions and, if Parliament should consider it to be failing in that task, it has in reserve its regulatory powers under section 3(3)(c).

29. Perhaps the most telling indication that Parliament did not intend to confine the authority's powers to unsuitability on grounds of genetic defects is, as Mance LJ pointed out [2004] QB 168, 209, para 143, the absence of any reference in the Act to selection on grounds of sex. It could be said that the Act made no reference to HLA typing because neither the Warnock Committee nor Parliament in 1990 foresaw it as a possibility. But there was intense discussion, both in the report and in Parliament, about selection for sex on social grounds. If ever there was a dog which did not bark in the night, this was it. It is hard to imagine that the reason why the Act said nothing on the subject was because Parliament thought it was clearly prohibited by the use of the word "suitable" or because it wanted to leave the question over for later primary legislation. In my opinion the only reasonable inference is that Parliament intended to leave the matter to the authority to decide. And once one says that the concept of suitability can include gender selection on social grounds, it is impossible to say that selection on the grounds of any other characteristics which the mother might desire was positively excluded from the discretion of the authority, however unlikely it might be that the authority would actually allow selection on that ground.

30. Lord Brennan referred to the well known remarks of Lord Wilberforce in *Royal College of Nursing of the United Kingdom v Department of Health and Social Security* [1981] AC 800. The question in that case was whether section 1(1) of the Abortion Act 1967, which in certain circumstances legitimated abortion "when a pregnancy is terminated by a registered medical practitioner" could include the case in which it was terminated by a nurse under the general supervision of a medical practitioner who was not actually present. The question arose because of the development since the passing of the Act of a new method for terminating pregnancy. Lord Wilberforce said (at p 822):

> "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."

31. Lord Brennan commended in particular Lord Wilberforce's opinion that the Abortion Act should be construed with caution because it was dealing with "a controversial subject involving moral and social judgments on which opinions strongly differ." That, he said, was equally true of the 1990 Act.

32. Lord Wilberforce's remarks provided valuable assistance to the House in *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. The question there was whether the definition of an embryo in the 1990 Act, which contemplated that it would be created by fertilisation, extended to embryos created by cell nuclear replacement in an unfertilised egg. This was a method of creating embryos which was not contemplated at the time of the Act and the language of the definition was to some extent inappropriate to describe it, but the House nevertheless held that the policy of the Act was to regulate the use of embryos however created. The House followed Lord Wilberforce's guidance in holding that there was a "clear purpose in the legislation" which could "only be fulfilled if the extension [was] made".

33. But, like all guidance on construction, Lord Wilberforce's remarks are more appropriate to some cases than others. This is not a case in which one starts with the presumption that Parliament's intention was directed to the state of affairs existing at the time of the Act. It obviously intended to regulate research and treatment which were not possible at the time. Nor is it a case, like the first *Quintavalle* case, in which the statutory language needs to be extended beyond the

"expressed meaning". The word "suitable" is an empty vessel which is filled with meaning by context and background. Nor is it helpful in this case to ask whether some new state of affairs falls within "the same genus" as those to which the expressed policy has been formulated. That would beg the question because the dispute is precisely over what the genus is. If "suitability" has the meaning for which the authority contends, then plainly PGD and HLA typing fall within it. If not, then not. Finally, Lord Wilberforce's recommendation of caution in the construction of statutes concerning controversial subjects "involving moral and social judgments on which opinions strongly differ" would be very much to the point if everything which the Act did not forbid was permitted. It has much less force when the question is whether or not the authority has power to authorise it.

34. Lord Brennan and Mr Pannick each relied upon different statements made by ministers in Parliament during the debates on the Bill which became the 1990 Act. As is almost invariably the case when such statements are tendered under the rule in *Pepper v Hart* [1993] AC 593, I found neither of any assistance.

35. I would therefore accept Mr Pannick's argument and hold that both PGD and HLA typing could lawfully be authorised by the authority as activities to determine the suitability of the embryo for implantation within the meaning of paragraph 1(1)(d).

36. Lord Brennan made some criticism of the way in which the authority had from time to time stated its policy and relaxed some of the conditions upon which licences were granted. For example, the authority originally gave a licence for HLA typing only if the cell biopsy was also required for PGD, because it considered that the risk to the embryo from removal of a cell did not warrant it being done for HLA typing alone. More recently, after further study of the effects of a cell biopsy, it has decided that the risk is low enough to justify a licence for HLA typing alone. That seems to me exactly in accordance with the duty of the authority to keep the state of the art under constant review.

37. Another point on which the authority has shifted its position is the use of bone marrow rather than umbilical cord blood as a source of stem cells. Bone marrow may in some cases be more suitable but involves a far more intrusive operation upon the donor child than taking cord blood. The policy formulated by the authority in 2001 (under which the licence which authorised the treatment of Mrs Hashmi was

granted) required a condition that "the intention" should be only to take cord blood. After a review in 2004, the authority decided to delete this condition. It was in practice unenforceable because once the embryo had been implanted and the child conceived, the case passed out of the jurisdiction of the authority. On 21 July 2004 the authority endorsed with amendment the following recommendation of its Ethics and Legal Committee:

> "It was acknowledged that the HFEA did not have any power to impose a condition that would prohibit any future attempt to obtain bone marrow. However the committee noted that obtaining bone marrow for the treatment of siblings from children from the age of one year was a relatively routine treatment strategy where no other matched donor was available. The committee also noted that under common law the test for the type of medical procedures that may be performed on a child is very much higher when such treatment is non-therapeutic. Although parents usually give consent to a child's medical treatment, the courts always have the power to overrule their consent where the procedure would not be in the child's best interests."

38. These reasons appear to be valid. I have no doubt that medical practitioners take very seriously the law that any operation upon a child for which there is no clinical reason relating to the child itself must be justified as being for other reasons in the child's best interests. If the question appears to be doubtful, a ruling from the court may be obtained. The authority is in my opinion entitled to assume that a child conceived pursuant to its licence will, after birth, receive the full protection of the law.

39. In my opinion, however, it is unnecessary to express any view about Lord Brennan's criticisms of the way the authority has exercised its jurisdiction. There has never been any suggestion that the authority acted unreasonably in granting a licence. The case has always been that it had no power to do so. In my opinion it did, and I would therefore dismiss the appeal.

LORD SCOTT OF FOSCOTE

My Lords,

40. I have had the advantage of reading in draft the opinions of my noble and learned friends Lord Hoffmann and Lord Brown of Eaton-under-Heywood. For the reasons they have given I, too, would dismiss the appeal.

LORD WALKER OF GESTINGTHORPE

My Lords,

41. I have had the privilege of reading in draft the opinions of my noble and learned friends Lord Hoffmann and Lord Brown of Eaton-under-Heywood. I am in full agreement with them and for the reasons given by Lord Hoffmann and Lord Brown I too would dismiss this appeal.

LORD BROWN OF EATON-UNDER-HEYWOOD

My Lords,

42. This case is all about the scope of a power, not about its exercise. The important, but limited, question it raises is whether the Human Fertilisation and Embryology Authority ("the authority"), created by the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"), is empowered by the 1990 Act to license tissue typing, a process by which embryonic cells are tested for their compatibility with the tissue of a sick sibling with a view to planting a compatible embryo into the mother's womb and the eventual treatment of the sibling with blood from the baby's umbilical cord (or, failing that, with bone marrow to be taken when the newborn child is older).

43. The ethical questions raised by such a process are, it need hardly be stated, profound. Should genetic testing be used to enable a choice to be made between a number of healthy embryos, a choice based on the selection of certain preferred genetic characteristics? Is it acceptable to follow a procedure resulting in the birth of a child designed to secure the health of a sibling and necessarily therefore intended to donate tissue (including perhaps bone marrow) to that sibling? Is this straying into the field of "designer babies" or, as the celebrated geneticist, Lord Winston, has put it, "treating the offspring to be born as a commodity?" These are just some of the questions prompted by this litigation. But troubling though such questions are, the arguments are certainly not all one way, as may be demonstrated by the facts of this very case.

44. Mr and Mrs Hashmi's fourth child, Zain, has a serious blood disorder, beta thalassaemia major. His condition is wretched, his prospects uncertain. His best chance of a cure is by a transplant of stem cells from someone with matching tissue. Since none of the three elder siblings have matching tissue, Mrs Hashmi decided to have a fifth child in the hope that its tissue would match Zain's. Having conceived, she discovered from pre-natal testing that that child too would have beta thalassaemia major and so she underwent an abortion. She conceived again and a healthy son was born, but unfortunately his tissue did not match Zain's. It was at this point that Mrs Hashmi, contemplating a sixth child, began investigating the possibilities of IVF treatment and eventually, with medical advice, sought to benefit from a licence under the 1990 Act.

45. The licence was granted by the authority on 22 February 2002. It was made subject to conditions which the authority had laid down on 13 December 2001 when announcing a policy decision to permit tissue typing in cases where pre-implantation genetic diagnosis ("PGD") was already necessary to avoid passing on a serious genetic disorder. Included amongst the conditions were that the sick sibling's condition should be severe or life threatening, of a sufficient seriousness to justify the use of PGD; that the embryos should themselves be at risk of that condition; that all other possibilities of treatment and sources of tissue for the sick sibling should have been explored; that the technique should not be available where the intended recipient is a parent; and that the intention should be to take only cord blood for the purposes of the treatment.

46. True it is that since that December 2001 policy decision the authority has contemplated licensing tissue typing on a less restricted

basis: first, in cases where there is no need for PGD; secondly, where the intention is if necessary to use bone marrow and not just blood from the abdominal cord; and thirdly, where a parent rather than a sibling is to be benefited. All this, however, goes only to emphasise the comparative narrowness of the issue presently before the House. Your Lordships are simply not concerned with the conditions under which tissue testing should be licensed, assuming it is licensable at all—nor even, indeed, with *whether* it should be licensed. Your Lordships' sole concern is whether the Act *allows* the authority to license tissue typing were it in its discretion to think it right to do so.

47. IVF treatment is a fast moving medical science. It is clear that when the 1990 Act was passed PGD was expressly foreseen but tissue typing was not. It is your Lordships' task to decide whether by the 1990 Act, Parliament was conferring power upon the newly created authority to take whatever decisions arose from such unforeseen possibilities as tissue typing, or whether Parliament must rather have been contemplating the need for further primary legislation to deal with whatever ethical questions arose out of such future discoveries.

48. Whether or not the authority is empowered to license tissue typing ultimately depends on the true construction of two particular provisions in the 1990 Act, section 2(1) and paragraph 1(1)(d) of Schedule 2. It is convenient at once to set these out (italicising the most important words) and also section 11(1), their immediate statutory context:

> Section 11(1) provides:
>
> "The authority may grant the following and no other licences—(a) licences under paragraph 1 of Schedule 2 to this Act authorising activities in the course of providing treatment services . . .".
>
> Section 2(1) provides:
>
> "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*."
>
> Paragraph 1 of Schedule 2 provides:
>
> "(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*
>
> . . .
>
> (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."

49. The critical question, therefore, put compendiously, is whether tissue testing is a practice designed to determine whether an embryo is suitable for placing in a woman (para 1(1)(d)) and necessary or desirable for the purpose of providing a medical service which itself is to assist a woman to carry the child (section 2(1)). Putting the matter quite simply at this stage, there are essentially three possible answers to this question. First, 'no' because the only embryo testing permitted by these provisions is PGD insofar as that is necessary to ensure that the woman can carry the child successfully to full term—in other words embryonic screening to eliminate just such genetic defects as may affect the viability of the foetus and no other. Second, 'no' because, whilst the 1990 Act allows PGD screening to eliminate gene and chromosome defects such as may affect that child (or be carried by that child to future generations), it does not permit tissue typing. Third, 'yes' because tissue typing also can be licensed: like PGD screening, it provides information about the characteristics of the embryo which is relevant to the woman's decision whether or not to carry the child.

50. No one now is contending for the first of those three possible meanings (although it was the meaning adopted by Maurice Kay J at first instance). The appellants contend for the second; the respondent authority and the Secretary of State for Health as intervener contend for the third (the meaning preferred by the Court of Appeal).

51. Initially, I confess to having found some considerable force in the appellant's argument that PGD screening is one thing, and properly licensable under the 1990 Act, tissue typing a completely different concept and impermissible. It is one thing to enable a woman to conceive and bear a child which will itself be free of genetic abnormality; quite another to bear a child specifically selected for the purpose of treating someone else. One can read into the statutory purpose specified by section 2(1), that of "assisting women to carry children", the notion of healthy children—only a genetically healthy

embryo being "suitable" for placing in the woman within the meaning of paragraph 1(1)(d). To read into section 2(1), however, the notion that the child will be a suitable future donor for the health of another would be to stretch the statutory language too far. And it may be said to raise ethical questions of a quite different order from those arising out of straightforward PGD screening.

52. By the end of the argument, however, I had come to the conclusion that Mr Pannick QC's contended for construction of the 1990 Act is to be preferred. My reasons for this conclusion can be grouped under three headings and, since I have now had the advantage of reading in draft the speech of my noble and learned friend, Lord Hoffmann, can be comparatively shortly stated.

The background to the 1990 Act

53. I pass over the Warnock Report, pausing only to note that in Chapter 9, headed "The wider use of these techniques" ("Techniques for the alleviation of infertility"), the committee, at paragraph 9.11, expressly envisaged the future possibility of sex selection "for purely social reasons" and concluded that "the whole question of the acceptability of sex selection should be kept under review"—review which inferentially was to be undertaken by a proposed new statutory licensing authority established "to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions." (paragraph 13.3). The White Paper which followed the Warnock Report, Human Fertilisation and Embryology: A Framework for Legislation (1987) (Cm 259), proposed at paragraph 14:

> "To ensure that the legislation is flexible enough to deal with as yet unforeseen treatment developments which may raise new ethical issues, the Bill will contain powers to make regulations (subject to the affirmative resolution procedure) to add to or subtract from the range of matters coming within the regulatory scope of [the authority]."

The scheme and structure of the 1990 Act

54. Certain activities in connection with embryos are expressly prohibited—see sections 3, 3A (a prohibition in connection with germ

cells introduced by section 156 of the Criminal Justice and Public Order Act 1994), section 4, and paragraph 1(4) of Schedule 2.

55. Consistently with paragraph 14 of the White Paper, there is power to make regulations (subject to affirmative resolution) both to add to the range of matters coming within the authority's regulatory scope—see paragraph 1(1)(g) of Schedule 2 enabling regulations to be made for the licensing of other practices in the course of providing treatment services—and to subtract from the licensing powers already conferred on the authority—see section 3(3)(c) which enables regulations to be made prohibiting the keeping or use of an embryo in such circumstances as may be specified.

56. This legislative scheme necessarily contemplates that the only fresh practices arising out of unforeseen treatment developments capable of becoming licensable by regulation under paragraph 1(1)(g) will themselves have to be characterisable as being "in the course of," and "necessary or desirable for the purpose of," providing treatment services, which itself argues for a wide construction to be given to the definition of "treatment services" in section 2(1). The scheme also, of course, enables section 3(3)(c) regulations to be made restricting the authority's powers if ever it were thought to be dealing inappropriately with the "new ethical issues" arising out of the "as yet unforeseen treatment developments" contemplated by the White Paper.

57. Lord Brennan QC sought to rely on the interpretative guidance provided by Lord Wilberforce in *Royal College of Nursing of the United Kingdom v Department of Health and Social Security* [1981] AC 800, 822, particularly with regard to legislation "dealing with a controversial subject involving moral and social judgments on which opinions strongly differ", as applied by Lord Bingham of Cornhill in *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. There Lord Bingham observed (p 697) that the 1990 Act, besides

> "outlaw[ing] certain grotesque possibilities (such as placing a live animal embryo in a woman or a live human embryo in an animal), . . . otherwise opted for a strict regime of control. No activity within this field was left unregulated. There was to be no free for all."

58. There is no inconsistency however, between that approach and the authority's stance in the present case. There it led to a newly discovered method of creating embryos being held to fall within the scope of regulatory control under the 1990 Act. So too here, the respondent's case is that tissue testing is controlled by the 1990 Act. It is not "left unregulated." There will be "no free for all." Rather the licensing of this new technique is for the discretion of the authority.

The true construction of section 2(1) and paragraph 1(1)(d)

59. I have already described (in para 49) the three possible meanings to be ascribed to section 2(1) and paragraph 1(1)(d) and the rival positions now taken by the respective parties.

60. The strength of Lord Brennan's case lies in the lengths to which Mr Pannick's argument necessarily takes him. Mr Pannick argues that PGD screening assists a woman to carry a child because it gives her the knowledge that the child will not be born handicapped. Without such knowledge some women who carry genetic diseases would not be prepared to have children. In the same way, he argues, tissue typing would assist Mrs Hashmi to carry a child because her wish to do so is conditional upon knowing that the birth of that child would be capable of curing Zain. As, however, Mr Pannick was bound to accept, under this reasoning PGD to ensure that a child had certain characteristics for purely social reasons could also be said to be "for the purpose of assisting women to carry children." (It is of course his case, supported by Mr Eadie for the Secretary of State, that it is for the authority to control PGD so as to ensure that it is not used for such ethically objectionable purposes.)

61. That consequence of the respondent's argument, I repeat, may be seen as the strength of the appellant's case. Its weakness, however, lies in the difficulty Lord Brennan himself has in establishing a satisfactory and coherent dividing line between embryo selection which is permissible and that which is not—let alone finding support for any such dividing line in the 1990 Act. As already stated, I was at one time attracted to Lord Brennan's dividing line between selection aimed purely at eliminating serious genetic or chromosome defects (permissible) and other selective criteria (impermissible). As, however, Lord Hoffmann points out at para 27 of his speech, what amounts to a serious genetic defect will itself often be contentious. Still less can one find in the statutory language any basis for saying that the elimination of

serious genetic or chromosome defects contributes to the process of "assisting women to carry children" whereas other embryo selection does not.

62. The fact is that once the concession is made (as necessarily it had to be) that PGD itself is licensable to produce not just a viable foetus but a genetically healthy child, there can be no logical basis for construing the authority's power to end at that point. PGD with a view to producing a healthy child assists a woman to carry a child only in the sense that it helps her decide whether the embryo is "suitable" and whether she will bear the child. Whereas, however, suitability is for the woman, the limits of permissible embryo selection are for the authority. In the unlikely event that the authority were to propose licensing genetic selection for purely social reasons, Parliament would surely act at once to remove that possibility, doubtless using for the purpose the regulation making power under section 3(3)(c). Failing that, in an extreme case the court's supervisory jurisdiction could be invoked.

63. For these reasons, most of which are more fully explained in Lord Hoffmann's speech with which I entirely agree, I too would dismiss this appeal.