COMMENTS AND NOTES

THE COURT OF APPEAL DEFINES EMBRYO 'SUITABILITY'.

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INTRODUCTION

The Court of Appeal's decision, *R (on the application of Quintavalle)* v *Human Fertilisation and Embryology Authority*,[1] allowed the appeal by the Human Fertilisation and Embryology Authority (HFEA) and declared lawful the licence, issued in February 2002, for the selective implantation of an embryo following *in-vitro* fertilisation (IVF) for Mr & Mrs Hashmi. The licence allowed an embryo to be selected for implantation that was free from the genetic disease *beta-thalassaemia,* as well as being a tissue-match for an existing sibling. Mr & Mrs Hashmi sought the licence, which would permit the IVF treatment, because their son, Zain, was born with a blood disorder known as *beta-thalassaemia* major. This is a serious and life-threatening, genetic disorder. Zain had been the recipient of all available treatment for the disease, except a bone marrow transplant. A bone marrow transplant is possible only when a donor with matching tissue is found, and none existed. If a child were born whose tissue type was the exact match for Zain it would be possible to transplant stem cells from the child's umbilical cord, or extract and transplant bone marrow, thus offering a cure for Zain. Clearly, it was the intention also to ensure that the IVF child was free from the debilitating genetic disorder. On its own this genetic testing requirement would have been non-contentious. It was the addition of the further test, the selection of an embryo to assist in the treatment of an existing sibling that was novel, and, the subject matter of the legal challenge. The selection of embryos to avoid the risk of inheriting a serious genetic disease had been licensed previously by the HFEA.

The case is interesting in two respects. First, the court declared that the HFEA had power to grant the licence sought. Secondly, the purposive interpretation given to the applicable legislation may have considerable importance in view of recent (and continuing) scientific developments and future licensing requests.

Lord Phillips MR gave the leading judgment. He noted that Maurice Kay J in the High Court, "did not consider it necessary to resort to background material when interpreting"[2] the relevant legislation, the Human Fertilisation and Embryology Act 1990 (Act). Furthermore, the decision in the High

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[1] [2002] EWCA Civ 667.
[2] *Ibid*, at [25].

Court[3] implied that the licensing of preimplantation genetic diagnosis (PGD), when there was a known hereditary risk, might fall outside the licensing authority of the HFEA as well. The examination of a single cell removed by biopsy from the developing embryo is the process used to detect both a genetic disease and to establish the tissue type of the embryo. Consequently, the granting of all licences for preimplantation embryo selection might be unlawful. In contrast, Lord Phillips considered an analysis of the background material was "a helpful exercise because that history bears closely on the issue of construction that we have to resolve."[4] As a result, the judgment relied heavily on references to the Committee of Inquiry report,[5] the subsequent White Paper,[6] and discussions arising during the Act's passage through Parliament.[7] Using this written public/parliamentary debate as a basis, the Court of Appeal invoked the tools of statutory interpretation legitimised in *Pepper* v *Hart*[8] and *Royal College of Nursing of the United Kingdom* v *Department of Health and Social Security*,[9] to define the relevant sections of the 1990 Act in a 2003 setting.

The judgment confirmed that Parliament had delegated to the HFEA the task of issuing licences of the type under review. Furthermore, in their legal analysis it was concluded that the power of the HFEA could extend further, to embryo selection on the basis of tissue matching when there was no risk to the embryo of inheriting a genetic disorder, and, in certain circumstances, selection on the basis of sex.[10] The Court of Appeal were clear that this did not imply that embryo selection would be permitted for purely social reasons, confirming that the PGD requested was related to "the health of a sibling and the well-being of the whole family."[11] This inclusive interpretation proffered by the Court of Appeal avoided a distinction between the screening *out* of an undesirable characteristic (a hereditary genetic disease), and the screening *in* of desirable ones (for example, tissue typing or gender). It is schedule 2 of the Act which details activities for which licences may be granted, and included within this list at paragraph 1(1)(d) are "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." As will be discussed, the Court's definition of 'suitable' is broad enough in law to include the selection of embryos on the basis of desirable characteristics, hitherto considered by some to be outside the scope of the licensing authority. It is suggested that by reaffirming legal confidence in the licensing role of the HFEA and emphasising the welfare context of the individual woman seeking assistance, the Court of Appeal's decision marks a

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[3] *R (on the application of Quintavalle)* v *Human Fertilisation and Embryology Authority* [2002] EWHC 2785 (Admin).

[4] See n 1 *supra* at [25].

[5] *Committee of Inquiry into Human Fertilisation and Embryology (The Warnock Report)*, Cm 9314 (1984).

[6] Cm 259 (1987).

[7] See n 1 *supra*, at [25 - 36].

[8] *Pepper* v *Hart* [1993] AC 593. In the course of Parliamentary Debate the Secretary of State made "an express statement to Parliament upon the very issue of construction under consideration." (Lord Phillips MR, at [41]).

[9] [1981] AC 800, 822. (Mance LJ, at [109]).

[10] See n 1 *supra*, at [135] and [140].

[11] *Ibid*, at [135].

shift from the public to the private sphere in matters of reproductive choice and assisted reproductive technology.

Background To Court Of Appeal Decision

On 22 February 2002 the HFEA granted the licence to Mr and Mrs Hashmi. This followed a statement of principle released on 13 December 2001 indicating that in certain circumstances the HFEA would consider the selection of embryos on the basis of tissue typing. The licence permitted PGD of embryos created subsequent to IVF for "*beta thalassaemia* in conjunction with HLA typing for patients known as Mr and Mrs H." HLA typing involves the examination of proteins known as human leukocyte antigens, and is known more commonly as 'tissue typing'. In order to offer the Hashmis' son Zain the best chance of a cure a tissue-matched individual was needed. Mr & Mrs Hashmi sought the licence to undergo IVF treatment and embryo selection with the hope that it would lead to the birth of a child free from the genetic disease and also produce a tissue match for Zain. On initial granting of the desired licence by the HFEA Mrs Hashmi underwent two attempts at IVF. At the first attempt only one embryo proved to be a tissue match for Zain, but it carried the *beta thalassaemia* disorder and consequently no implantation followed. At the second attempt an embryo meeting these dual requirements was implanted but did not result in a successful pregnancy.[12]

Any further IVF attempts were prevented by the action for judicial review brought by Josephine Quintavalle, (acting on behalf of CORE[13]), who claimed that the HFEA had acted *ultra vires* the Act with reference to the issuing of this particular licence. An absolute respect for the human embryo is a principal tenet of CORE. As a member of a pressure group Mrs Quintavalle had a 'sufficient interest' in the matter to be granted standing to bring the judicial review action.[14] When an issue is of considerable public interest, as is the case with PGD testing during IVF treatment, the necessary standing to bring the challenge is likely to be afforded.[15] The challenge was focussed on this particular licence "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."[16] The argument presented was that the testing of embryos in the very early stage of development carries an unknown, but presumed, risk. In the case of testing for a genetic disease any such risk could be weighed against the benefits of giving birth to a child without the disease. However, once the embryos are tested, and known to be free of the

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[12] The scientific technology necessary to carry out the PGD to exclude the genetic disorder and to determine tissue typing by HLA testing on the embryo biopsy is available at the Reproductive Genetics Institute in Chicago, USA. Approximately 3 days after *in vitro* fertilisation, when the embryo has sub-divided into 8 cells, one of these cells is removed by a biopsy. The cell biopsy was transported from Nottingham to Chicago for the PGD testing, including HLA typing, and the embryos were frozen pending the results of the tests.

[13] Committee on Reproductive Ethics.

[14] See for example *R* v *Secretary of State, ex parte Greenpeace* (1998) Envir LR 415.

[15] J Alder, *Constitutional and Administrative Law*, (4th ed, 2002, Palgrave Law Masters), p. 409.

[16] See n 1 *supra*, at [10].

disease, the further selection for tissue typing was a selection between equally healthy embryos. The HFEA concurred that embryo testing carried an unknown risk to the embryo because of the need to remove a single cell from the developing embryo. However, in this particular case, PGD was being carried out in order to avoid *beta thalassaemia* and, because HLA testing would be carried out on the same single cell biopsy, there was no additional risk associated with the HLA testing.

In more general terms, and with a view to future licensing applications, the judicial review challenge by CORE invited an analysis of the lawful scope of the power of the HFEA. Quintavalle was successful in December 2002 when the High Court declared the HFEA licence for Mr & Mrs Hashmi unlawful. Leave to appeal was granted by the High Court and the Secretary of State obtained permission to intervene in support of the HFEA because of the wider implications of the High Court decision. Of particular concern was the doubt cast upon the legitimacy of PGD screening of embryos *per se*, a practice that had been licensed for serious genetic diseases previously.

The Relevant Law

The provisions and purposes of the 1990 Act were discussed at length in the judgment, together with the activities it governs, the establishment of the HFEA, and the scope and conditions pertaining to licences granted by it.[17] Lord Phillips provided a helpful précis of the relevant provisions of the Act applicable to the case:

> "For the present purposes it is important to note the following scheme of the Act. Section 3 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 that 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'."[18]

In the course of supplying 'treatment services', the HFEA are permitted to issue licences for, *inter alia*, "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*."[19]

In the High Court, Maurice Kay J was of the opinion that the purpose of IVF, as regulated by the Act, was to enable a woman, who might otherwise be denied the opportunity, to become pregnant and carry a child to term. On this analysis, he concluded, it was necessary to use medical intervention *only* to create an embryo, implant it, and await natural developments:

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[17] *Ibid*, at [12 - 13] and [59 - 76].
[18] *Ibid*, at [14].
[19] HFEA 1990, sch 2, para 1(1)(d). Emphasis added.

> "To take the example of the unfortunate family whose problems have given rise to this case – it is not suggested that those problems arise from an impaired ability to conceive or to carry a child through pregnancy to full term and birth."[20]

Having concluded that tissue typing an embryo was unrelated to the legislative objective of assisting the woman to have a child his Lordship declared that it could not come within the definition of 'treatment services' provided in section 2(1) of the Act. Maurice Kay J did not "find it appropriate" to address the issue of PGD screening of embryos for hereditary diseases.[21] Hence, his narrow interpretation of 'treatment services' gave rise to the implication that all preimplantation genetic diagnosis might be unlawful.

The Court of Appeal proceeded on a different analytical basis. It considered that if it was established that the screening of embryos for a serious genetic disease came within the ambit of the Act, because this screening was "designed to secure that the embryo is suitable for the purpose of being placed in a woman", then the further question of whether tissue typing came within the definition of 'suitable', would be answered inevitably in the affirmative.

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

After a detailed analysis of the relevant background material leading to the passing of the Act, Lord Phillips concluded that schedule 2 paragraph 3(2)(b) specifically permitted the licensing of research aimed at increasing our understanding of genetic and chromosomal abnormalities in embryos prior to their implantation. It would be illogical to suggest that, having obtained this knowledge, the Act prohibited its beneficial use:

> "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."[22]

Whilst acknowledging the 'ordinary meaning' approach of Maurice Kay J to the phrase "assisting women to carry children", Lord Phillips noted that issues other than infertility might act as a barrier to a woman's ability to bear children. Such a barrier, he stated, might be the knowledge that there was a high risk (one in four), that the child would carry a hereditary disease. In this case 'assistance' embraced also clinical efforts to eliminate this risk. He concluded that in order to offer 'treatment services' to a woman, as envisaged by the Act, "PGD is thus designed to secure that the embryo is suitable for this purpose."[23] The embryo selected, the 'suitable' embryo, is the embryo with these desired characteristics. PGD selects an embryo free from the genetic defect. The characteristic of the 'suitable' embryo to assist Mrs Hashmi to carry a child is one free from the genetic defect and a tissue match for Zain. Lord Phillips concluded that the dual nature of the desired

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[20] See n 4 *supra*, at [17].
[21] See n 1 *supra*, at [37].
[22] *Ibid*, at [40].
[23] *Ibid*, at [44].

characteristics did not distinguish this type of preimplantation selection from PGD alone and therefore it too came within the meaning of "treatment for the purpose of assisting women to bear children."[24]

A 'suitable' embryo and a particular woman

Treatment services within the Act went further than offering assistance to enable the physical processes of pregnancy and birth, and embraced the option of ensuring that the embryo selected had characteristics that the individual woman, and the HFEA, considered both 'necessary and desirable'. Thus defined, treatment services could overcome specific, contextual, barriers to natural conception and birth, not just infertility. If specific genetic characteristics were within the definition of 'suitable' so, too, were other embryo characteristics, such as HLA typing, and, sex selection. In all cases the embryo was selected because it possessed desirable characteristics, whether that was being free from a defective gene, being a specific tissue match, or, a particular gender.

In adopting this broad definition the Court of Appeal shifted the emphasis away from a notion of objective legal parameters, or an HFEA checklist, applicable in every licensing request and focussed on the particular licence-seeking woman. They concluded that whether or not an embryo was 'suitable' for the purpose of being placed in a woman "falls to be determined having regard to its context."[25]

Mance LJ expressed unequivocally the need to consider the individual case, rather than seek a taxonomy of 'suitable' embryo characteristics, resulting in a one-size fits all legal interpretation. The text of the Act pertaining to embryo suitability, he concluded, was linked inextricably with a particular woman. The wording of the Act was, he opined, drafted as both "abstract and impersonal" because it applied to licences that would be granted to clinics "for classes of activity in relation to women who have not yet been ascertained." When an individual presented herself the meaning of 'suitable' would be refined from the general to the specific:

> "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."[26]

There is the suggestion here that this desired compatibility might be of overriding significance. If another statutory regime regulating reproductive choice, that of abortion, were compared, it would be strange indeed if the law required a woman to carry to term a foetus, which, for lawful health or welfare reasons, she considered unsuitable.[27] The Court of Appeal agreed that licences granted or refused by the HFEA could impact directly on a woman's decision to have a child at all. The granting of a licence was linked

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[24] *Ibid*, at [48].
[25] *Ibid*, at [49].
[26] *Ibid*, at [127].
[27] Abortion Act 1967.

to the reproductive process because it "would assist some women, who would otherwise refrain from conception or abort either spontaneously or deliberately, to carry a child."[28] Mrs Hashmi, subsequent to Zain's birth, became pregnant naturally twice. The first foetus was aborted because it tested positive for the genetic defect and the second resulted in a live birth but no tissue match for Zain. If a reliable, safe and effective early foetal HLA typing test was available would it be acceptable for a woman to continue to conceive naturally, undergo testing, and request a series of lawful abortions until a foetus, both free from the hereditary disease and a required tissue match was conceived? It seems unlikely.[29]

Mance LJ pointed out 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."[30] However, he confirmed that, bearing in mind the special protection offered by the Act to the embryo, if embryo testing was extended, it was the HFEA, through the granting of licences, that would control its scope. The Warnock report, he noted, considered that the question of sex selection should be "kept under review", and that the proper forum for review should be the body established by the Act, the HFEA.[31]

Lord Phillips stated that preimplantation embryo screening offered novel choices to parents considering reproduction. Discussions between the HFEA, the clinic requesting the licence, and the individuals involved, should in each case determine whether a licence should be granted:

> "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."[32]

The issuing of the challenged licence in February 2002 was followed in August 2002 by the HFEA decision to refuse a licence to the Whitaker family for HLA typing when the sibling's needs, although similar medically, did not arise because of a hereditary genetic disease. These two licensing decisions were distinguished on the basis that the HFEA guidelines for the granting of the licence to the Hashmis were subject to eight conditions, the second of which was that the embryos should themselves be at risk of the condition affecting the child. As stated by the HFEA the removal of a single cell from the developing embryo for the purpose of PGD carries an unknown risk to the unborn child. In the case of the Whitakers they were not seeking a licence for PGD to determine whether an embryo carried a genetic disorder as well as to carry out an HLA test. The HFEA concluded that the risk of

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[28] *Ibid*, at [89].
[29] See further Stephen R. Munzer, "Conditional Intention and Abortion" (2002) 41 *The Pelican Record* 58.
[30] See n 1 *supra*, at [139]
[31] *Ibid*, at [124].
[32] *Ibid*, at [50].

PGD for HLA testing alone outweighed any benefits accruing to the embryo by the mere fact of assisting a sibling, and consequently the licence for the Whitakers was refused. In view of the Court of Appeal's broad definition of 'suitable' the refusal to issue a licence for HLA typing alone may be challenged through the courts at a later date. A general requirement by the HFEA that there needs to be a risk of passing to the embryo a serious genetic disorder in order to issue a licence for *any* PGD testing was questioned by the Court of Appeal. Mance LJ stated that when a licence was sought for a combination of preimplantation testing, each test must be considered separately by the HFEA and each must be separately lawful under the Act.[33] A test, which is to be used as a basis for embryo selection, is not lawful merely because it is to be carried out together with another test for which licences are granted routinely, such as in the case under review PGD with HLA typing. The HLA typing, or any other available tests, must be lawful in its own right. The removal of the cell for biopsy, and the concomitant risks attaching to the unborn child, must be linked to activities permitted by the Act.

Responding to Public Concerns

Josephine Quintavalle, on behalf of CORE, was granted standing to bring this action for judicial review and the issues attracted considerable media interest and public discussion. Prior to the granting of the licence to Mr and Mrs Hashmi there had been significant public consultation by the HFEA and others, resulting in recommendations and guidelines for licensing. In response to perceived public concern about PGD, the HFEA, together with the Human Genetic Commission[34] launched a joint public consultation document in November 1999.[35] These two commissioning bodies formed a Joint Working Party (JWP), and the results of their discussions, taking into account responses from the public consultation, were published in November 2001.[36] The outcome of the public consultation suggested that there was support in the community for the controlled use of PGD.

It is of particular interest to note that the JWP recommended "that PGD should only be available where there is a significant risk of a serious genetic condition being present in the embryo."[37] The JWP concluded that 'ethical difficulties' meant that this recommendation ruled out, by implication, the selection of embryos subsequent to HLA typing. A later report of the House of Commons Select Committee on Science and Technology was critical of the HFEA's approach to HLA typing, and the granting of the licence in the

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[33] S 2(1) and schedule 2 para 1(1)(d).

[34] The Human Genetic Commission was formed in December 1999 and replaced the Advisory Committee on Genetic Testing in the UK.

[35] Organisations that responded to the consultation on PGD are listed under the headings: Clinical/Scientific (9); Bioethical/Social Science (6); Consumer Groups (8); Disability (10); Religious or Pro-Life (13).

[36] *Outcome of the Public Consultation on Preimplantation Genetic Diagnosis*. Copies of the documents are available on the HFEA and Human Genetics Commission websites <www.hfea.gov.uk and www.hgc.gov.uk/business_ publications.htm> respectively).

[37] Report Recommendation 11.

Hashmi case, saying that it "went beyond the scope of its own public consultation."[38]

That may be so. However, this decision of the Court of Appeal confirmed that the HFEA has the statutory authority to issue licences without the need to consult widely. Licences could be granted lawfully for PGD, HLA typing, and even sex selection, in certain circumstances. According to the Court of Appeal this interpretation of the relevant provisions of the 1990 Act springs from the wording of the Act itself. The granting of licences for PGD is lawful because, by applying Lord Wilberforce's dictum in *Royal College of Nursing of the United Kingdom* v *Department of Health and Social Security*, "they fall within the same genus of facts as those to which the expressed policy has been formulated."[39] Parliament, stated the Court of Appeal, supplied the answer to the questions raised in this action in its initial, and substantial, deliberations when the Act was being passed.

CONCLUSIONS

Artificial reproductive technologies, including IVF treatments, aim to overcome barriers to reproduction. The Court of Appeal has confirmed that, although the main barriers to conception and reproduction are associated with the physical condition of the persons seeking assistance, there are other obstacles to achieving the desired outcome. One such barrier is the fear of passing on a serious genetic disorder. These barriers are linked to the individuals seeking assistance and must be considered in the context of those individuals within the ambit of the 1990 Act. The selection of an embryo suitable for implantation in an individual case, and the technologies employed to test embryo suitability, must be considered on a case-by-case basis. The Authority created by the Act, the HFEA, was given the task of deliberating on the social, ethical and practical consequences of issuing or refusing licences after considering the welfare of the prospective child and the welfare of the family unit into which it will be born. The consultative processes carried out by the HFEA have the effect of maintaining its legitimacy within the wider community. The Court of Appeal has reiterated that the HFEA is the appropriate body, with the appropriate expertise, to issue clinical licences in this environment of rapidly developing scientific knowledge. This decision has interpreted the Act in the context of its purpose, to protect and facilitate, in matters associated with IVF. Legal capacity in respect of the issuing of licences for PGD during IVF treatment is placed firmly in the hands of the HFEA.

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[38] 18 July 2002.
[39] *Supra*, n 9.