Case No: C1/2015/2189

Neutral Citation Number: [2016] EWCA Civ 611

IN THE COURT OF APPEAL
(CIVIL DIVISION)
ON APPEAL FROM
THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
Mr Justice Ouseley
CO30772014

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 30/06/2016

Before:

THE PRESIDENT OF THE FAMILY DIVISION
LADY JUSTICE ARDEN
and
LORD JUSTICE BURNETT

- -

Between:

THE QUEEN **On the application of** **MR AND MRS M** **- and -** **HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**	**Appellants** **Respondent**

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- -

Jenni Richards QC and Rose Grogan (instructed by **Natalie Gamble Associates**) for the **Appellants**
Catherine Callaghan (instructed by **Blake Morgan**) for the **Respondent**

Hearing date: 25 May 2016

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Judgment

LADY JUSTICE ARDEN:

Issue: was the HFEA's decision to refuse to approve the proposed export and use of the appellants' deceased daughter's frozen eggs a breach of public law?

1. The appellants, Mr and Mrs M, appeal from the refusal on 15 June 2015 of Ouseley J to set aside the decision dated 3 September 2014 ("the Decision") of the Statutory Approvals Committee ("the Committee") of the respondent ("HFEA") to refuse the appellants' application to export to the United States the eggs of their late daughter, A, now in storage at a hospital in London. The appellants had made their application because they wish a centre in the United States to use A's eggs to create an embryo with anonymous donor sperm, and to implant the embryo in the second appellant, A's mother, with a view to any child who may be born being brought up as the appellants' grandchild. Their case is that this is in accordance with their late daughter's wishes. The principal ground on which the appellants seek judicial review may broadly be described as irrationality: they say that the Decision was irrational and that the Committee took into account matters which they should not have taken into account.

2. The use of gametes for fertility treatment and research is regulated by the Human Fertilisation and Embryology Act 1990 ("HFE Act"). This established the HFEA as the UK's independent regulator in this field. One of the HFEA's responsibilities is to issue licences to centres to provide fertility treatment. They can provide services using a person's gametes only where that person consents. Consent means "effective consent" and so the HFE Act provides that, before treatment, a person must be given "such relevant information as is proper", and offered counselling. Effective consent to treatment and the disclosure of relevant information are cornerstones of this carefully calibrated legislation.

3. The difficulty in this case is that, while A consented to treatment for egg removal and storage (including storage after her death) and also to the use (other than for research purposes) of her eggs after her death, she never completed any form giving details of the precise use that is now proposed.

4. The HFE Act provides a route out of the difficulty. The HFEA can waive requirements of the HFE Act when it gives approval for export of the gametes, for example, it could waive the requirement for consent to be in writing and signed by the person giving it. So the appellants applied to export A's gametes. Under well-established principles of public law, however, the HFEA cannot exercise this discretion (that is, exercise a delegated power) so as to allow circumvention of the HFE Act. Indeed, in *R v HFEA ex parte Blood* [1999] Fam 151 at 185G, Lord Woolf MR, with whom Waite and Henry LJJ agreed, held that:

> in giving a particular direction, the authority is using delegated powers, which should be used to serve and promote the objects of the legislation, which clearly attach great importance to consent, the quality of that consent, and the certainty of it.

5. The HFEA, through the Committee, considered that there was insufficient evidence that A had given consent to the proposed use of her gametes after her death, and refused approval. In reaching this conclusion, it partly relied on A's lack of information about what was now proposed after her death. The judge carefully examined each of the reasons which the Committee gave in turn. He concluded that the Committee was entitled to reach the conclusion that it did.

6. The essence of the appellants' challenge is that the Committee required A's consent to consequential decisions that would have to be taken to fulfil her wishes, such as the selection of a sperm donor and the export of her eggs.

7. In my judgment, for the reasons given below, the challenge succeeds at three levels. First, there was on the face of it the misstatement of certain of the evidence about A's consent by the Committee. Second, even if what the Committee meant was that there was a lack of effective consent because the appellants could not show that A received information on certain matters, the Decision was flawed because the Committee pointed to the lack of certain evidence without explaining why A needed to receive that information and give that consent. The third level is that the Committee did not ask the prior question of what information the HFE Act required to be given to A in the circumstances of her case. If my Lords agree, the Decision must be set aside and remitted to the Committee for further consideration of the appellants' export application.

8. I turn now to set out the background, the statutory scheme, the Decision and the judge's judgment before explaining and ruling on the submissions under the heading "Discussion".

A's egg removal and evidence of her wishes about posthumous use

9. The appellants' daughter, A, was only 21 years old when she was diagnosed with cancer. She had been to University and had a good job. She came from a loving family and was "beautiful, strong, intelligent and funny". She died six years later on 12 June 2011. She spent most of her last 5 years in hospital. She wanted to have IVF treatment in 2005 but was too ill for this purpose. Then she asked for her ovaries to be transplanted in her mother and then in 2008, during a period of remission, she was well enough to undertake treatment (in considerable pain) for the removal and storage of 3 eggs. She was very determined to have this treatment: there is no suggestion in the papers that she was under any pressure from anyone else to do this. She had had a boyfriend but she had no partner at any relevant time. Her mother suggested that she would if necessary carry children for her and A accepted this with gratitude. A's mother's evidence to the Committee was that she was certain that this was her expectation of how her eggs could be used after her death.

10. Before A received this treatment, she signed a form produced by the centre ("the Centre") providing the treatment. This form contemplated that she would be executing the form with a partner, so it was not appropriate in all respects. She consented to the mixing of her eggs by ticking the box marked "my eggs" but did not tick the box "Partner's sperm" or "Donor sperm". The form stated that she understood that she would be the mother (which under our law would be the birth mother) of any child. It went on to deal with what she wanted to happen if she died:

Posthumous storage of your eggs

The law requires that if your eggs are stored, you have to decide in advance what should happen to your eggs should you lose the ability to decide for yourself (this is called mental incapacity) or in the event of your death.

Please write **Yes** or **No** for each of the following options.

If I lose the ability to decide for myself or in the event of my death, I give my consent for:

	Mental Incapacity	Death
(i) my eggs be allowed to perish	No	No
(ii) my eggs continue in storage for later use	Yes	Yes

There is a separate form on which you can say how you want your eggs to be used. Your eggs can only be used if you have also completed the other form.

11. The HFEA issues a standard form (a "WD form") which a centre can provide to a person who wants to donate eggs either before or after death or loss of capacity. A was not given this form. This enables the donor to specify the type of use (eg treatment of others or creation of embryos), and if desired to attach conditions, and to stipulate the period of storage. The form provides for the donor to sign it but there is no other formality. There is nothing in this form suggesting that the donor of eggs must also give consent to the use of donor sperm.

12. A's mother's evidence is that she was certain that A believed that she had signed all the necessary forms to authorise her mother to carry her child after her death and that A was not given any other form to sign apart from a form authorising use for research, which A declined to sign. She also said that a child was the one thing that A wanted more than anything else in the world. She recounted a conversation involving a newly-pregnant cousin, visiting A in hospital, when A said that she already had her babies: "They are just on ice, aren't they, Mum?"

13. In January 2010, A was found not to be fit enough to fly to the US for further treatment. It then became clear to her that she was terminally ill. She told her mother:

> They are never going to let me leave this hospital, Mum; the only way I will get out of here will be in a body bag. I want you to carry my babies. I didn't go through the IVF to save my

> eggs for nothing. I want you and Dad to bring them up. They will be safe with you. I couldn't have wanted for better parents, I couldn't have done without you.

14. A also talked to one of her friends about her mother being her surrogate if she could not carry a child. In A's very final illness, according to her mother, she kept saying that she wanted her babies. She died very shortly after this from an infection. There were no further conversations involving A and her mother on the subject of A's mother bearing A's child between January 2010 and the date of A's death. In her evidence, A's mother said:

> I have absolutely no doubt in my mind that, as far as A was concerned, her eggs held a life force and were living entities in limbo waiting to be born. She was clear that she wanted her genes to be carried forward after her death. She had suffered terribly and this was the one constant in her remaining years from which she never wavered.

15. Since the Decision, one of A's aunts, D, has also given evidence of discussions with A about her mother carrying her babies after her death and her desire to thank her mother in this way, but this evidence was not before the Committee. D is unspecific on dates but some of the conversations she records occurred after A realised her condition was terminal.

16. On advice, the appellants wish to choose a sperm donor who is not known to them. This is proposed to be a sperm donor in a New York sperm bank who would be able to remain anonymous.

Material provisions of the HFE Act

17. I gratefully adopt the helpful description of the statutory framework and guidance given under it which the judge gave in his judgment. I set this out in the Appendix to this judgment.

18. Importantly, section 12 of the HFE Act obliges the holder of a licence to provide fertility treatment issued by the HFEA to obtain consent in accordance with schedule 3, which then sets out the detailed requirements for that consent.

19. The key points in schedule 3 for the purposes of this appeal are:

    1. "Effective" consent (ie written and signed consent given under schedule 3) is required for:

        a. the storage of a person's gametes;

        b. the creation in vitro of an embryo using a person's gametes;

        c. generally the use of a person's gametes. As I understand it, that would include removing gametes.

2. In addition, before giving consent under schedule 3, a person must be offered proper counselling about the implications of the proposed steps and provided with "such relevant information as is proper".

20. In paragraph 2 above, I called the HFE Act's requirement for consent one of the cornerstones of the Act. The Committee indeed directed itself that the HFE Act attached importance to the quality and certainty of consent. The requirement in the HFE Act is that the consent be "effective". In some situations it must be given again (see, for example, *Evans v Amicus Healthcare Ltd* [2005] Fam 1), but in general it does not have to be renewed, and it is not automatically revoked on death or loss of capacity.

21. The HFE Act does not set out what information has to be given before a person's consent is effective. That indicates, first, that the content of an effective consent will vary from case to case and also over time as medical science and ethics and the legal duties of treatment providers develop, and, second, that in the event of dispute the content of such information may be a matter for the courts to refine in accordance with their conventional role of interpreting statutes to give effect to Parliament's intention, and with assistance from any expert evidence as to best practice where relevant.

The Decision

22. The decision is recorded in the minutes of a meeting on 28 August 2014. The areas where potentially both consent and the offer of information was absent were identified as: export of the gametes, their admixture with donor sperm, the use of a surrogate and the use of the gametes in treating A's mother, rather than A.

23. The Committee had rejected the application on a previous occasion but no-one has suggested that we need to consider that decision. The Committee also stated that it did not need to consider any issue as to the age of A's mother or as to the family connection between her and any child, and no one has challenged that.

24. The Committee directed itself as follows in paragraph 19 of its Decision that:

> Great emphasis on consent is imposed by the Act and recognised in [*Centre for Reproductive Medicine v U* [2002] EWCA Civ 565]. "Effective" consent usually needs to be signed and set out in writing, and should be informed consent which implicitly requires the patient to be properly informed.

25. At a later stage, the Committee reminded itself of the important observations of Hale LJ (as she then was) in *Centre for Reproductive Medicine v U* [2002] EWCA Civ 565 at [24], which holds that the scheme of the HFE Act is aimed at striking a balance between the various interests involved:

> [24] The whole scheme of the 1990 Act lays great emphasis upon consent. The new scientific techniques which have developed since the birth of the first IVF baby in 1978 open up the possibility of creating human life in ways and circumstances quite different from anything experienced before

> then. These possibilities bring with them huge practical and ethical difficulties. These have to be balanced against the strength and depth of the feelings of people who desperately long for the children which only these techniques can give them, as well as the natural desire of clinicians and scientists to use their skills to fulfil those wishes. Parliament has devised a legislative scheme and a statutory authority for regulating assisted reproduction in a way which tries to strike a fair balance between the various interests and concerns. Centres, the HFEA and the courts have to respect that scheme, however great their sympathy for the plight of particular individuals caught up in it.

26. At paragraph 23, the Committee accepted that the absence of effective consents was not "decisive of the issue", adding however that:

> when [modifying the requirements of ss 12-14 of HFE Act] the Committee should only use the power to modify in ways that serve and promote the objects of the [HFE Act] which clearly attaches great important to consent, the quality of it and the certainty of it.

27. Thus, the Committee saw its task as being to consider whether there was sufficient evidence of consent, and in particular whether the evidence cumulatively showed that A gave her consent to the exact use of her eggs that her parents proposed: see paragraph 29 of the Decision, where the Committee states that the first issue to be discussed was:

> Whether in their previous discussion of the case the Committee's interpretation of the term 'sufficient evidence' was too restrictive and whether in fact the evidence points cumulatively to the posthumous use of A's eggs in the way being sought being exactly what she wished for…

28. The Committee reached its conclusion on whether there was enough evidence as to A's wishes and consent at paragraph 30 of the Decision. It noted that that:

> … the strongest and only statement of A's wishes apparently applying to the posthumous use now being sought, was her statement to her mother [in January 2010] about her mother carrying her babies and her parents bringing them up, in the context of her not expecting to leave hospital alive.

29. In paragraph 34 of the Decision, which was in the part headed "Decision", the Committee concluded that:

> it did not have evidence to support the view that:
>
> (i) A had tried to seek out more information about this treatment for herself before her death;

(ii) A had explicitly expressed a wish for her mother to carry her child as a surrogate in the event of her death, with the possible exception of the comments made in about January 2010;

(iii) A had or would have consented to the use of an anonymous sperm donor;

(iv) A consented to the use of her eggs after her death.

30. As to the conversation ("comments") in January 2010, the Committee's view was that:

> this expression of wishes was made without sufficient information for A to fully understand the implications of such a statement and the issues involved, particularly the risks for [her mother] in relation to surrogacy and the legal implications of such arrangements.

31. The Committee considered the evidence in the round ("cumulatively") but was concerned that:

> A had had ample time, for example between the conversation in about January 2010 and June 2011 to put in place clear instructions, or discuss with others, any wishes for her mother to carry her embryos (fertilised by donor sperm). None of the conversations contemplated or considered the use of donor sperm outside the UK and the particular implications of such arrangements.

32. At paragraph 37 of the Decision, the Committee then listed some of the steps that A might have taken:

i) Signing the necessary consent forms;

ii) Undergoing counselling in relation to any of these treatments;

iii) Seeking more information from others about what might be involved in such arrangements;

iv) Speaking to others about her wishes and intentions;

v) Having others witness her wishes and intentions;

vi) Leaving something as a token to the anticipated "baby";

vii) A having formal discussion with the doctors involved in her treatment;

viii) A requesting information about what might be involved in donor insemination, surrogacy, the implications for parental status;

ix) A formally noting her wishes.

33. The Committee then reached its conclusion to refuse approval:

> 38. The Committee concluded that, contrary to the submissions, it did not accept the proposed posthumous use of her eggs was exactly what A had wished for. It considered that a number of the statements contemplated [A's mother] potentially acting as a surrogate in the event A was unable to carry a child, but that the context was whilst A was still alive. In the Committee's assessment nearly all of the evidence supported an understanding of A's wishes during her life but it did not make clear her intentions in the event of her death.

34. The Decision also addressed Article 8 (right to respect for private and family life) of the European Convention on Human Rights ("the Convention"), but I do not need to set out that part of the Decision in the light of the conclusions I have reached on this appeal.

THE JUDGE'S ANALYSIS

35. The judge held that the Decision was lawful and rational. The judge was prepared to read it generously. In particular he read the findings about lack of consent as meaning lack of fully informed consent. The judge thus held that the Committee was entitled to conclude that there was no sufficiently clear evidence that she had intended her mother to act as her surrogate after her death "in the particular circumstances which prevailed" (Judgment, paragraph 46). He considered that the Committee had formed too narrow an appraisal of the evidence about the January 2010 conversation but that this was again explained by the Committee's conclusion about the lack of an informed expression of wishes (Judgment, paragraph 48). On the Committee's holding at the fourth bullet point in paragraph 34 of the Decision that there was insufficient "evidence to support the view that ...A consented to the use of her eggs after her death", the judge held that this meant that the Committee did not consider that A had addressed the circumstances which had to be faced with sufficient clarity. He accepted the Committee's views on the lack of consent to donor sperm and to export (paragraph 51). He accepted that it was significant that there had been no discussion between January 2010 and A's death (although I note that this was not entirely correct on A's mother's evidence). In conclusion the Committee was entitled to find that there was no sufficient informed consent by A to the proposed use of her eggs.

36. The judge also held that the HFEA had not adopted an unlawful approach to the scope of its statutory power to issue a Special Direction. There were material respects in which it was not clear that A had given consent. The case was distinguishable from that of *Blood* where the applicant was able to say that her husband would have consented to all the outstanding matters if he had still been alive. Here the Committee took the view that there were a number of steps A could have taken. It was not simply a problem of there being no signed form.

37. The judge also dealt with other matters, which I do not need to set out.

SUBMISSIONS

38. I am going to distil each party's case on the appellants' rationality challenge, which I see as the decisive issue, and then summarise the parties' more detailed submissions on that issue.

The appellants' case distilled

39. The essential points that Mr and Mrs M make are (1) that the Committee, in requiring there to be consent to detailed steps and the provision to A of all information relevant to those steps, failed to stand back and ask whether it could properly infer from the available evidence of the conversations and inherent probabilities of the situation that A consented to her mother bearing her child and that she would have made that decision whatever detailed steps were involved, and (2) that, in the light of the close relationship between A and her mother, the information that was relevant to her did not include all the details which the Committee said she should have considered.

The appellants' more detailed submissions on effective consent

40. To expand, the primary argument of Ms Jenni Richards QC, for the appellants, is that paragraph 34 discloses irrationality in the public law sense, that is unreasonableness to a high degree. The Committee concluded, first, that it did not have evidence on whether she tried to seek out more information about "this treatment" before her death. But she was not well enough to have any further treatment herself and she had no means of knowing what other information was available. She had not been given a form about posthumous use of her frozen eggs. The Committee concluded, second, that there was no evidence that she consented to her mother acting as a surrogate for her "with the possible exception of the comments made in about January 2010". The Committee went on to deal with that conversation in paragraph 35 of the Decision, asserting that A had insufficient information to understand the implications of the statement she made and the issues involved.

41. On Ms Richards' submissions, it was unclear why the Committee thought A needed to know about the risks to her mother as that would be a matter for her mother after A's death. Nor was it clear why A could not have simply trusted her mother to make the best decision for her on legal matters.

42. Ms Richards also submits that A's consent to posthumous use is clear from the form of consent that she signed. It was unreasonable to expect her to do more when she was battling for 5 years with what was to be a terminal illness. Ms Richards submits that it would be wrong to use the consent form that she was not given to defeat A's wishes as expressed on the form she did sign and subsequently in conversation with her mother and friends.

43. Moreover, on her submission, the Committee did not refer to other material parts of the appellants' evidence. The consent given in the consent form was only one part. A's eggs could only be used posthumously. A told her cousin in 2009 that she had already got her babies: "They are just on ice". She wanted her mother to be the mother and she confided this to a close friend. There was no basis for the Committee to doubt the conversation in January 2010. Ms Richards submits that the evidence shows that, contrary to paragraph 38 of the Decision, A's wish was that her eggs

should be used posthumously and that her mother should be the surrogate mother. Indeed the only surrogate mother she contemplated was her own mother. Having realised she would not survive, she wanted her mother to carry the child. It was very important to her that her eggs should not perish.

44. Ms Richards submits that it is improbable that A did not consent to the use of the donor sperm. A was single, she could only have been thinking of fertilisation by a sperm donor. The Committee had failed to consider whether it was more realistic to suppose that she would want her mother to choose the method of donor selection.

45. Moreover submits Ms Richards, the judge read matters into the Decision. For example, the Committee was plainly wrong to say that there was no evidence that A consented to the use of her eggs after her death.

46. As to paragraph 36 of the Decision, on Ms Richards' submission, the Committee was wrong to attach any importance to the fact that she had not consented to the export of her eggs. Ms Richards submits that treatment outside the UK could not have been in her contemplation and was not material to her. In any event the export was desired so that her mother could have treatment in the US.

47. Ms Richards submits that the Committee were influenced by lack of consent on A's part to matters which were more properly part of the treatment that her mother would have to have. In addition, A would have been happy to leave the question of sperm donor selection to her parents.

48. On Ms Richards' submission, there is nothing in the Code of Practice to say that A had to be informed about or take advice about these matters. It would be her mother who was receiving treatment on the issues in question. Ms Richards submits that the requirements of paragraph 4.2 of the Code of Practice did not cover the sort of information in this case. If there had been a failure to provide information, the Committee should have gone on to ask if the information was likely to have changed their mind. The Committee should seek to give effect to the wishes of the gamete provider. There was no reason to believe that information about US law would be likely to have changed A's mind. Moreover the statute has to be read as a whole. The information has to be considered by A in a schedule 3 case. But this is a case under Schedule 4. Section 5 of the Code merely reiterates matters. It does not say what information should be provided. A donor can place conditions on use, but she does not have to do so.

49. If A had signed the WD form, she could have inserted a condition that her mother should be the surrogate mother. But her signature of the form would have said nothing more than the Committee already knew from the evidence. Had this form been signed, the process would have been sufficient for treatment in the UK. The Committee misunderstood the position. The matters which troubled them were matters which were relevant to the woman receiving treatment which was never going to be A.

50. Accordingly, in summary, Ms Richards submits that the Decision was flawed. The cumulative impact of the evidence was not considered. It was a fundamental error on the part of the respondent to proceed on the basis that in order to manifest her wish she would have to produce serious practical evidence. The Committee failed to

consider the evidence in the context of posthumous use. It was overly stringent on informed consent. The suggestion that there was ample time between January 2010 and A's death in June 2011 to work out the details of the proposed surrogacy failed to take account of reality. A's consent once given remained effective. She did not know about the other consents required.

The HFEA's case distilled

51. The HFEA stresses the importance of fully informed consent in the structure of the HFE Act. The Committee acted lawfully within its powers in requiring evidence of informed consent from A. The appellants propose to use her eggs in ways to which A had not given her informed consent.

The detailed submissions on behalf of the HFEA

52. Ms Catherine Callaghan, for the HFEA, submits that the judge was not wrong to hold that the Committee was acting lawfully. The Court should accept the Committee's assessment of the evidence. Ms Callaghan submits that the Committee had a wealth of experience on the scope of their power.

53. Ms Callaghan submits that the appellants' case has changed and that for the first time on appeal the appellants sought to characterise the daughter's acts as giving her eggs to her mother, for her to use as she thought fit ("donation"), not surrogacy. The Committee considered that there was no sufficient evidence to show that A wished her own mother to be a surrogate mother. There is an important difference here which affected the way the Committee and the judge approached the evidence. Donation is not consistent with the evidence before the Committee and the judge. The position was as the mother's witness statement shows: the daughter wanted her own family and she was consumed by the effect of the cancer on her ability to have her own children. There was no reference to donation in the mother's statement. She called the eggs "my babies".

54. Ms Callaghan submits that one of the twin pillars of the HFE Act is consent. Consent creates a bright line and is required to ensure regulatory certainty. The question whether there had been consent was thus the correct starting point and it promoted the objects of the Act. The Committee did not have a free hand. They were not seeking more than the General Directions required. There was no failure to understand the scope of their legal powers.

55. Ms Callaghan submits that, contrary to Ms Richards' submission, it was relevant whether A had the requisite information. In addition there has to be the receipt of information: schedule 3, paragraphs 1, 3, 5 and 6. The Act contemplates that there will be an opportunity to be informed about the use of embryos. This can also be seen from the HFEA's Code of Practice.

56. Moreover, the Committee was entitled to consider the extent to which events departed from schedule 3. The General Conditions set a benchmark as to what is acceptable. The HFEA gives individual consideration to cases where the General Directions are not satisfied. Schedule 4 to the General Directions, therefore, requires there to be

effective consent under schedule 3 to the HFE Act. The General Directions are not challenged.

57. Ms Callaghan submits that while there is nothing in the HFE Act to prevent a Special Direction being given if there is no consent, this might well undermine the statutory purpose. A never gave written consent to either the use of her eggs by someone else or their use to create embryos. That is why the Centre could not use her eggs. Export was not permitted under the General Directions. There was no clear evidence that A wanted her mother to carry her child after her death. They were only eggs, and they required fertilisation, and therefore the Committee had to ask if she would have agreed to the particular method chosen by her parents. The sad fact was that A had had a long period in which to make these decisions but she had failed to do so.

58. Ms Callaghan submits that, as regards the clarity of evidence, the Committee was entitled to find that it was not sufficiently clear that A wanted her mother to carry her own child in the event of death. In any event, A's wishes about surrogacy were not sufficiently informed. Moreover the Committee was entitled to find she had not consented to that particular use. Ms Callaghan fairly accepts that export would not have been within A's reasonable contemplation.

59. Ms Callaghan submits that in January 2010 the conversation was not sufficiently clear to create an embryo to be used in the treatment of others. If it had been in writing, that might have tipped the balance but it was not an informed expression of wishes. The January 2010 conversation was in the Committee's assessment a general discussion without any sufficient specificity.

60. Ms Callaghan submits that the Committee did not know what A would have felt about her mother becoming the legal mother. There ought to have been discussion about whether the father's identity should be anonymous.

61. Ms Callaghan submits that this is not a case where inferences ought to be drawn. Likewise guesses should not be made.

MY REASONS FOR CONCLUDING THAT THE DECISION WAS FLAWED

62. In considering whether the Decision was flawed, I have been struck by a number of points in the HFEA's approach to this case which seemed to me revealing.

Revealing points

63. First, at paragraph 34 of the Decision (paragraph 29 above), in stating that there was no evidence to support the view that A wanted her mother to carry her child if she died, the Committee waved aside the conversation between A and her mother in January 2010 (paragraph 12 above). This explicitly dealt with this situation. Yet the HFEA continued to say on this appeal that the January 2010 conversation was simply a general discussion. However, A did say "I want you to carry my babies." Contrary to Ms Callaghan's submissions, that statement clearly contemplated the creation of an embryo. Contrary to Ms Callaghan's further submission that we should accept the

Committee's assessment of the evidence, this misstatement of the evidence discloses error in public law.

64. The second revealing point is the suggestion that the appellants are raising a new case on this appeal, that is, that A was donating her eggs to her mother rather than asking her mother to be a surrogate - a contention which the appellants deny. This suggestion indicates that the HFEA would adopt a different approach where a person is donating eggs to another person so that the other can have a child from the situation from the case where a donor of gametes asks someone to be a surrogate because of the donor's childlessness. This suggestion also reinforces the view that the Committee, in treating the arrangement between A and her mother as simply a surrogacy arrangement, failed to consider the possibility that A consented to her mother's use of the eggs for the purpose of bearing her child on the basis that her parents or her mother took all the detailed steps and brought up the child themselves.

65. In other words, the Committee simply did not consider the possibility that this is a case where A said something along these lines (if I may be bold as to attribute words to A that A never used and to which she is not capable of answering): "This is what I want to do. I want to do it whatever you want to tell me about what it involves. I trust my Mum and Dad to make the right decisions about all this when I am gone because they brought me up so well. It is my only chance." That possibility might explain why there was no detailed discussion involving A and her mother of the details of what would need to happen if A's eggs were to be used between January 2010 and her death. In fact there was some discussion very shortly before her death, to which the Committee failed to refer. The Committee did not consider whether the inherent probabilities of the case might lead to this sort of conclusion.

66. Third, it is also revealing that the HFEA has chosen to press a case that A did not consent to the use of anonymous donor sperm. It would be totally unrealistic to suppose that she was not aware that there would have to be a donor. Moreover, there is no suggestion that she had a preference for any donor known to her. The donor would have to be someone not known to her. In the normal case, the selection of the sperm donor will be important but the question was whether the inherent probability was that it was important in this case. It was possible that A wanted to leave the decision to her parents. There was no evidence that she wanted the father to have any particular traits, which is also consistent with A wanting all those decisions to be left to her parents. The Committee again did not consider whether, for her consent to be effective, she needed to have information on all the steps that would have to be taken after her death in these circumstances. Moreover, the name of the donor was relevant to the child's rights when the child reached majority. There was no evidence to suggest that A's consent to use of her eggs would be conditional on the child having this right.

67. The fourth revealing point in my judgment is that in the Decision the Committee attached significance to the fact that her eggs would have to be exported from the UK because she had not signed the relevant form before her death. As Ms Richards submits, that could hardly have been in A's reasonable expectation and Ms Callaghan fairly accepts before us (though not, as I understand it, before the judge) that that must be so. That must dispose in turn of the point that A needed to be told that, if the child was born abroad, there might be different laws about who was the mother. I can also see that this is a thoroughly rational concern in non-familial surrogacy but not

necessarily in this case, where A trusted her parents implicitly and where the child would be brought up as a grandchild. I agree with Ms Richards that, if the Committee was troubled by A's use of the words "my babies," it read too much into them. As a non-lawyer, A was likely to be talking about her babies in genetic, not legal, terms.

68. I have found these points instructive and I draw from them that the Decision contains three levels of error, as mentioned in paragraph 7 above, namely:

i) misstatements of material evidence;

ii) a failure to give reasons why the Committee considered A had to have certain information before she could give effective consent to the appellants' proposed actions;

iii) a failure to decide what relevant information the HFE Act required A to have.

Misstatements of the evidence

69. In paragraph 34 of its decision the Committee wrongly stated that it had no evidence that A had explicitly expressed a wish for her mother to carry her child after her death "with the possible exception of the comments made in January 2010". Disregarding for a moment the Committee's description of the January 2010 conversation as a "possible exception", the statement that there was no evidence on this point is, as I have said, a most surprising conclusion which flies in the face of A's mother's evidence, none of which was rejected. The January 2010 conversation did provide the Committee with evidence that A wanted her mother to be the surrogate mother of her child if she had died.

70. The judge generously interpreted this finding as one which had to be read with the Committee's view that A did not have sufficient information fully to understand the implications of her mother being her surrogate. This generous approach camouflages the presence of the misstatement.

71. The Committee also stated that there was no evidence to support the view that A would have consented to the use of anonymous donor sperm. As already stated, it would be perverse to conclude that A did not realise that there would have to be donor sperm. There was no evidence to suggest that she preferred a known donor. In those circumstances, to reach a rational decision, the Committee should have considered whether it was inherently probable that A would have refused her consent to an anonymous donor sperm if that is what her mother proposed or if that was the only way in which her wishes could be implemented.

72. The Committee also stated that there was no evidence that A consented to the use of her eggs after her death. This was a significant point and it is plainly inconsistent with the form of consent which A signed (paragraph 9 above).

73. As to Ms Callaghan's submission that the Committee should not make inferences in this case, I agree that the Committee should not make inferences which are not fairly capable of being made, but there is nothing in law to prevent it from making

appropriate inferences from the evidence or on the basis of the inherent probabilities of the case.

Failure to give reasons for the need for A to have each item of information

74. The Committee evidently considered that A could not give effective consent unless she received information on each of the steps that would have to be taken to give effect to her wish that her mother should carry her babies and consented to those steps. The Committee give no reasons for requiring information to be given about each of these steps which addressed the particular circumstances of this case.

75. The question of what information had to be provided to A was too serious a question to go without consideration and articulation in the Decision. By the time any use of A's eggs occurred, it was likely that A would be deceased and that it would be A's mother, and not A, who was receiving treatment. That fact also meant that there was a possibility that A did not want to prescribe matters herself, but left them to her parents to decide. The Committee apparently did not consider this possibility.

76. This point leads to the question of what information A had to receive, which the Decision did not explore. This was the reason which I identify as the third flaw.

Failure to decide what relevant information A was required to have

77. As I have said, the disclosure of relevant information is one of the cornerstones of the HFE Act, and nothing in this section of my judgment should be read as detracting from that. I see that requirement not just, as Ms Callaghan put it, to ensure regulatory certainty, but also as recognition of the importance of the autonomy of the person whose consent is required.

78. But the HFE Act does not say that a person must receive all relevant information in the abstract, only that a person must receive "such relevant information as is proper". An analogy can be drawn here with the question how much a doctor has to tell the patient to be satisfied that the patient has consented to medical treatment. A doctor has a duty to take reasonable care to ensure that the patient is aware of any material risks, not all risks, involved in proposed treatment. For this purpose, the test of materiality is whether, in the circumstances of a particular case, a reasonable person in the patient's position would be likely to attach significance to the risk (see the decision of the Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] 1 AC 1430 at [87]).

79. Although the test in that context is materiality, not relevance (which might conceivably be different), and although there may be differences between consent to treatment affecting the body and consent to the use of human material that is no longer a part of the body (see generally, *Yearworth v North Bristol NHS Trust* [2010] QB 1), the test established by the Supreme Court involves an assessment of what would be material to someone in the patient's position and depends on the facts and also to the characteristics of the patient. Therefore the information required may vary according to the particular circumstances. In my judgment, the expression "such information as is proper" in schedule 3 to the HFE Act also recognises that information may vary according to the particular circumstances of a case.

80. The problem is that the Committee assumed that A needed to know matters which on the face of it were not relevant to her situation. It went further than perform the exercise suggested by Ms Callaghan of considering what information would normally have to be supplied where a person was asking another to be a surrogate or what information was required under the General Directions. It applied the same test of sufficiency of information to this case as it would to that hypothetical case without examining the differences.

81. For instance in paragraph 35 of the Decision, the Committee drew particular attention to A's lack of information about the risks to her mother or the legal implications to such arrangements.

82. This is not, however, necessarily information which A required to decide what she wanted to do. As to the risks to her mother, there is no evidence that A would have known that she could have or should have some input on these matters. Further, her mother could decide for herself if she was willing to take the risks when the time came. In addition, those risks would have to be assessed after A's death and in the light of medical knowledge then available.

83. As to the legal implications, we are talking about a posthumous child and so it may not be a matter of such significance as outweighs the evidence of consent that is available whether in law the child was hers or her mother's. Since no other surrogate was envisaged, no one else could be the mother. Furthermore, A's mother has proposed a way in which a child could be recognised in everyday life to be A's baby because A's parents propose to bring up any child as their grandchild.

84. As I see it, the Committee had to weigh up these matters if it was to act rationally in completing the task it set for itself of deciding whether there was sufficient (meaning, effective) consent. It had to determine what level of information was appropriate. It had to do this on a proper assessment of the totality of the evidence in A's case. Only then could it decide whether A could, and did, give effective consent to the use of her eggs proposed in the application before it.

CONCLUSION

85. I do not need to decide any further issue, including the further submissions on Article 8 and the question whether gametes are property (as to which see *Yearworth*, above). I would allow this appeal.

LORD JUSTICE BURNETT

86. I agree.

THE PRESIDENT OF THE FAMILY DIVISION

87. I also agree.

Appendix

The legal framework as described by Ouseley J

[6] The HFE Authority was set up under s 5 of the HFE Act 1990. Section 4 prohibits the storage or use of any gamete, that is unfertilised egg or live sperm, except in pursuance of a licence. Licences are granted under s 11 by the HFE Authority. Section 12(1)(c) makes it a condition of every licence that Sch 3 to the Act is complied with by the licence holder. Schedule 3 is concerned with consent, which is a very important aspect of the HFE Authority's approach to the regulation of licensed activities under the Act.

[7] Schedule 3, para 1(1) provides that consent under the Schedule 'must be signed by the person giving it'. 'Effective consent' means consent which has not been withdrawn, ie written and continuing consent. Paragraph 2 provides:

> '2(1) A consent to the use of any embryo must specify one or more of the following purposes—
>
> > (a) use in providing treatment services to the person giving consent, or that person and another specified person together,
> >
> > (b) use in providing treatment services to persons not including the person giving consent …
>
> (2) A consent to the storage of any gametes, or any embryo or any human admixed embryo must—
>
> > (a) specify the maximum period of storage (if less than the statutory storage period),
> >
> > (b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it …

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.'

[8] Paragraph 3 imposes two separate requirements in relation to effective consent:

> '(1) Before a person gives consent under this Schedule—
>
> > (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
> >
> > (b) he must be provided with such relevant information as is proper.'

Thus effective consent must be fully informed as well.

[9] Paragraphs 5 and 6 and 8 apply here and are important:

> '5(1) A person's gametes must not be used for the purposes of treatment services or non-medical fertility services unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.
>
> (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.
>
> (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

…

> 6(1) A person's gametes or human cells must not be used to bring about the creation of any embryo *in vitro* unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes or human cells being used for one or more of the purposes mentioned in paragraph 2(1)(a), (b) and (c) above.

…

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

[10] I should also refer to the definition of 'mother' in s 28: 'the woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.' This applies wherever, in the UK or elsewhere, the mother was when the embryos, sperm or eggs were placed in her.

[11] In the UK, the child at 18 is entitled to know the identity of the sperm donor, and to establish contact; sperm is donated on that basis. I was told by counsel that, in New York, the sperm donor has the option of deciding whether that should occur.

[12] As Ms Callaghan for the HFE Authority submitted, the HFE Act prohibits the storage or use of gametes in the UK without effective, fully informed consent. The Act itself permits no exceptions. Posthumous use of gametes requires the effective consent of the gamete provider. The donor's next of kin, here AM's parents, the claimants, have no right under the Act to decide on the use or disposal of her gametes.

[13] The Act does contain some flexibility, however, over the import and export of gametes and embryos. Section 24(4) contains a general power to give directions and in relation to export provides:

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

[14] The reference to ss 12–14 means that Sch 3 conditions can be modified, including effective consent provisions.

[15] This power has been exercised by way of General Directions Ref 0006 'Import and export of gametes and embryos'. Its requirements in Sch 4 include, in para 1(d), that the person who provided the gametes 'has … given and not withdrawn consent in writing to the gametes … being exported to the country in which the receiving centre is situated', para 1(e) before giving that consent, that the gamete provider 'has been given a written notice stating that the law governing the use of gametes … and the parentage of any resulting child may not be the same as in the UK, and they have been given any further information which they may require', and para 1(h) that the gametes are not exported 'if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes … are used by the receiving centre'. These were the requirements of the General Directions which the Statutory Approvals Committee accepted, and it is agreed, were not met.

[16] The s 24(4) power can also be exercised to give Special Directions in relation to a case where the General Directions are not satisfied.

[17] Section 25 requires the defendant to maintain a code of practice, giving guidance about the 'proper conduct of activities carried on in pursuance of a licence under this Act'.

[18] The HFE Authority's Code gives guidance as to the information which is relevant and proper for the purposes of para 3(1) of Sch 3 to the Act. The seventh edition of the Code's guidance, in force in 2008, but the eighth edition is not significantly different, states that information should be given about the possible outcomes and limitations of the treatment, possible side effects and risks, and where a donor is used, relevant information about genetic inheritance, in particular about inheriting physical characteristics from the donor, and about legal parentage.

[19] It is the Code which explains that where the General Direction requirements are not fulfilled, or cannot be assured, a person can apply for a Special Direction.

[20] This is the power which the claimants applied to the defendant for it to exercise, recognising that the General Directions could not be satisfied by reference to the requirements of para 1(d), (e) and (h) of Sch 4 to the General Directions cited above. The defendant has delegated power to make a Special Direction permitting the export of gametes to the Committee.