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From the Private Secretary

9 July, 1984

cc:

Warnock Report

The Prime Minister has seen a copy of the Social Services Secretary's paper for H Committee on the Report of the Warnock Committee (H (84) 22).

The Prime Minister recognises that it may be difficult to avoid the establishment of a new statutory body, as proposed by the Committee, to license and inspect infertility services employing the new techniques, as well as any use of human embryos in research. Nevertheless, she would be grateful if the Committee could give some consideration to the alternative possibility of professional self-regulation in this area, in accordance with the precedent set by the Genetic Manipulation Advisory Group.

I am sending copies of this letter to the Private Secretaries of the other members of H Committee, and to Richard Hatfield (Cabinet Office).

DAVID BARCLAY

Miss Janet Lewis-Jones, Lord President's Office

54

PRIME MINISTER

Warnock Report

The Warnock Committee on Human Fertilisation and Embryology has submitted its report. The Social Services Secretary has circulated a paper to H Committee recommending publication as soon as possible, to be followed by a period of consultation lasting until the end of the year.

This is an emotive and difficult subject. Among the issues covered in the report are artificial insemination, test tube babies, surrogate motherhood, and research on human embryos.

The main recommendations are annexed at 'A'. Those on anonymity of donors, screening for genetic defects, and the legal status of children born as a result of artificial techniques, seem likely to command general support. But the majority view that research on artificially produced human embryos should be permitted in controlled circumstances will be fiercely opposed, not least by the churches, who resent not having had a place on the Committee. Robin Nicholson in his note at 'B' supports the majority view on the grounds that a ban on embryo research, in which this country leads the world, would deprive humanity of important medical and social benefits.

There is no need for the Government to reach a view on any of this before consultation - indeed, it would be perilous to do so.

But there is one key issue where the initial presentation could affect the outcome. The Warnock Committee recommended the establishment of a statutory body

to licence and inspect all infertility services where the new techniques are used, and also any use of human embryos in research. The alternative possibility, which Robin Nicholson for one prefers, would be professional self-regulation along the lines of, say, the Genetic Manipulation Advisory Group.

Agree to invite H Committee to consider including self-regulation, as an alternative to a statutory body, in consultation document? Us - but it will be with with one of the consultation of leave such consultation.

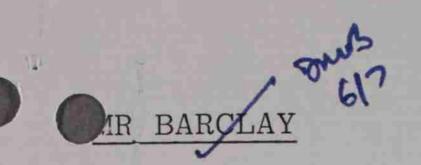
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Robin Nicholson, vine

6 July 1984

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5 July 1984

WARNOCK REPORT ON HUMAN FERTILISATION AND EMBRYOLOGY

- 1. This is a long and interesting report, full of recommendations. The principal conclusions are that:
 - i. subject to certain controls and exceptions, doctors should be allowed to help heterosexual couples (married and unmarried) give birth to children by:
 - artificially inseminating the woman either with her male partner's sperm, or with the sperm of another man;
 - removing eggs from the female partner or from another woman and fertilising these eggs in a test-tube with the male partner's sperm or with the sperm of another man, so that the resulting embryo can be placed in the female partner's uterus;
 - ii. where any such form of artificial birth takes place, the child should 'belong to' the woman who eventually has the pregnancy and to her male partner not to any other man and/or woman who has donated eggs and/or sperm;
 - iii. the practice of 'surrogacy' in which one woman carries a child for another with the intention to hand it over at birth should be banned by law;
 - iv. scientists should be allowed to conduct experiments on test-tube embryos up to 14 days old, regardless of whether these embryos are created as a by-product of techniques i. and ii. or specificially for the purposes of research;
 - v. a statutory authority, chaired by a layman but with scientific members and support staff, should be set up to oversee all activities in this field, to issue licenses, and to advise the government.

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- 2. Some of the reasoning by which the committee arrives at these recommendations is intellectually suspect. Why, for example, is it assumed throughout largely without argument that pregnancy, rather than conception, is the key to parenthood? Why is there no serious consideration of the problems arising, when doctors use these techniques on behalf of a couple who have a record of child abuse? (The single paragraph devoted to this topic (2.7) is a showpiece of sloppy argument). And why is there no discussion of the radical social implications of a refusal to distinguish between married and unmarried couples?
- 3. Points of this sort will be made by many commentators: there is nothing definitive about the report.
- 4. For that reason alone, the government would be very unwise to accept the report's recommendations without allowing time for public debate. And there are other reasons for abstaining from comment at this stage: Robin Nicholson points out that a statutory licensing authority is not the only option, and that the government needs time to consider others; moreover, popular opinion is likely to be divided, with strong views both for and against the report, so that the government may well make numerous enemies if it takes a decision before listening to the debate.
- 5. It would, however, be equally unwise to suppress the report.

 Many of the conclusions are already widely known; there is considerable interest in the media; and a refusal to publish will fuel accusations that the government is authoritarian.

We therefore recommend that the Prime Minister should agree to the publication of the report, but that she should urge colleagues to abstain from committing the government to any definite view or action at this stage. The bland statement suggested by Norman Fowler will suit this purpose admirably.

Oliver LETWIN

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Among the points of criticism which may be raised in the public debate are:

Composition of the committee: Although Mary Warnock says in the foreword, "Rightly you chose a membership which encompassed not only the many professions ... but the many religious traditions within society," the Churches were not asked to nominate representatives to the committee. The Catholic Church is particularly strong in its criticism of the way the committee was, in the words of one spokesman, "rigged".

When does life (or personhood) begin? The report's evasive and vague approach to this central question will be heavily criticised.

Causes of infertility: The report admits that the techniques it describes can help little more than 5% of infertile couples. But it fails to mention sexually transmitted diseases, abortions and use of intra-uterine contraceptive devices and abortifacient pills, all of which cause high percentages of temporary or permanent infertility. The committee's failure to insist on the compilation of proper data on the causes and incidence of infertility will be criticised, as will its failure to comment on the possibility of a well-researched programme of public education.

Remedies for infertility: The report scarcely considers some of the less morally dubious or biomedically dangerous methods which would have a greater success-rate as well as being cheaper and safer then test-tube fertilisation. For instance, a recently-developed technique, similar to test-tube fertilisation and suitable for the same types of infertility, but without its moral or medical dangers, is low tubal ovum transfer. The committee received evidence of this and other techniques, but will be criticised for failing to consider their advantages.

Medical dangers of test-tube fertilisation: The committee's treatment of these dangers will be criticised as skimpy. For example, the report underestimates the ratio of deaths to live births and the risk of foetal abnormality; and it fails to mention that the use of drugs which produce multiple ovulation for test-tube fertilisation may cause the formation of ovarian cysts, a further cause of infertility.

Ethics: NAT HEALTH. FeB'82.

Await Ditss submission CONFIDENTIAL 28 June 1984 W.0447 MR DAVID BARCLAY, No 10 WARNOCK REPORT ON HUMAN FERTILISATION AND EMBRYOLOGY I attach some comments on the Warnock report. I understand that its handling will be discussed at a forthcoming meeting of H and that the Prime Minister will receive a copy with the H papers. I would therefore be grateful if you could feed in my comments (copied also to Miss Lewis-Jones) at an appropriate stage. ROBIN B NICHOLSON Chief Scientific Adviser

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JUMMARY OF RECOMMENDATIONS

1. In all, the Inquiry make over sixty recommendations but the key one is that there should be a statutory body to license and inspect all infertility services where the new techniques are used and also any use of human embryos in research. This body would also provide on-going advice to Government about future developments in this field.

2. The Inquiry recommend that the statutory body should also be responsible for ensuring that the criteria of good practice which they recommend for the control of intertility services are implemented. These criteria include:

the anonymity of semen and egg donors;

the screening of donors for genetic defects;

the limitation to a maximum of ten children born as a result of donations from any one individual.

3. A number of legal changes are recommended in relation to the new treatments for infertility, notably:

where the husband has consented to the ATD;

that legislation should provide that in every case where a woman has given birth to a child she should be regarded as the mother of that child regardless of whether the birth resulted from egg or embryo donation.

4. Although the Inquiry are not unanimous on the possible use of human embryos in research, all members are agreed that any such use must be regulated by law. Those who accept research consider that it must be strictly controlled by the statutory body. They recommend:

an absolute limit of fourteen days after fertilisation as the maximum age to which embryos may be grown in vitro;

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that any use or handling of human embryos without a licence for the purpose to which the embryos are put should be prohibited;

that certain types of research should be prohibited for example, trans-species fertilisation should not be allowed to proceed beyond the two-cell stage of development;

should not be undertaken in any circumstances;

that the statutory body should have power to decide what types of research might be undertaken using in vitro human embryos, but that this should only be permitted where the information could not be obtained from research involving other animal species.

They recommend that any use of human embryos outside the above criteria should be a criminal offence.

- 5. A number of recommendations are made in relation to the collection of statistical information on existing infertility services and the rationalisation and development of infertility service provision within the National Health Service.
- 6. There is one method of treatment for infertility, namely surrogate motherhood, which all but two members of the Inquiry wish to see prohibited. To this end, the Inquiry have recommended a complete ban on provision of this type of treatment either by commercial, non-profit making agencies or individual doctors.

COMMENTS ON THE

REPORT OF THE GOVERNMENT INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY

- 1. I have now seen the report of the Inquiry chaired by Dame Mary Warnock. For ease of reference I attach as Annex 1 a summary of its recommendations and as Annex 2 a guide prepared by DHSS on the issues and terms involved. In general the report is a cautious and measured approach to an emotive area. The "life"lobby's claims that it is unduly permissive are, in my view, unwarranted. The report's approach is practical rather than philosophical; it does not address questions such as "when does life begin" but founds its recommendations upon practices already generally accepted by the public, such as contraceptive techniques and artificial insemination. But I shall confine my further comments to those recommendations relating to the conduct of research.
- 2. I support the view of the majority of the Committee of Inquiry that research on human embryos should continue, subject to effective controls and monitoring. It would be tragic if unjustified controls were to prevent this country from retaining the lead in yet another area of research where it has done the pioneering work and which has tremendous social benefits. The following advances are believed to be attainable if experimentation on early embryos is allowed:
 - a. To improve infertility treatment and fertility control
 - b. To prevent or rectify genetic defects

Going beyond the area of direct benefits to the embryo studied or to its parents:

c. To screen against potential "thalidomides"

^{*} This may seem a simple approach to the issue, but biology does not, unfortunately, give a helpful answer. Life does not begin at conception since the sperm and eggs are living cells, already alive in advance of fertilisation. All that can be said is that a genetically novel kind of cell comes into existence at fertilisation and that this cell has the potential, if it is successfully implanted in the lining of the womb, for becoming a human individual. It does not have that potential if it is not implanted.

- d. To improve understanding of cellular and developmental processes and hence understanding of inherited genetic disease, and perhaps also causes of cancer and other diseases.
- 3. If it is accepted that research on embryos must continue, three main issues need to be considered: (i) for how long is it reasonable to keep an embryo; (ii) the origins of embryos used for research; and (iii) how the research should be regulated.
- 4. The time limit proposed for keeping an embryo for experimental purposes is 14 days. This is around the stage that the embryo becomes implanted in the wall of the uterus - a stage prevented by some forms of contraception. This recommendation coincides with the advice of the Medical Research Council, the Royal College of Physicians and the British Medical Association. The Royal College of Obstetricians and Gynaecologists suggests a limit of 17 days, when early neural development begins. The recent report of a Working Party of the Council for Science and Society (Chairman Professor G R Dunstan) proposes a much longer period, 6 weeks, on the grounds that this would still be before the onset of functional activity of the nervous system and thus before an embryo could experience pain. The Inquiry therefore errs on the side of caution. The 14-day limit would exclude such important experiments as the grafting of embryonic stem cells into damaged adult organs to attempt their repair: for such experiments the embryo would need to survive for about 17 days. The time limit now proposed reflects current public attitudes and it is quite probable that these attitudes will change. AID was for some years considered to be an undesirable practice, and IVF when first practised was disapproved of, even by the profession. Now both techniques are generally regarded as acceptable. If the 14-day time limit were to be accepted by Government I hope that it would not be regarded as immutable, but would be kept under review.
- 5. Embryos for research have two different origins. Some are "spare" embryos, in excess of the number to be implanted in IVF. Others are produced from spare eggs and semen with the sole intention of using them for research. While the Inquiry recommended that research should be permitted on spare

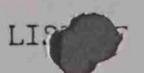
embryos, a minority did not accept the use of deliberately generated embryos. If the minority view were to prevail, the scope and value of research that could be undertaken would be greatly limited. The "best" embryos are implanted into the mother and the spares tend to be less good. And, as techniques become more successful, fewer spare embryos will be available for research.

- 6. The recommendation that a new statutory authority, with an inspectorate, should be set up to regulate and to grant licences for research (as well as infertility services) is the one that causes me difficulty. My reservations are as follows:
 - (i) the law would be unenforceable. In the case of animal experiments, Home Office inspectors can monitor the type of research being undertaken, the health and housing of the animals etc. In the case of embryos, inspectors would be reduced to inspecting research workers' notebooks and the size of the microscopic bodies that experimenters chose to reveal to them.
 - (ii) The degree of expertise required by inspectors would in any case be likely to make them parti pris.
 - (iii) At the moment there are only some six teams doing research in this area, and there is no immediate prospect of an escalation.
 - (iv) The real sanction against unethical experiments would be the inability to publish the results or, should there be the slightest hint that ethical guidelines had not been observed, to gain further support from funding bodies.
- 7. I therefore believe that professional self-regulation would be preferable. The Genetic Manipulation Advisory Group (GMAG) was a good example of the success of this type of control. When GMAG was set up, widespread concern about genetic manipulation was threatening the conduct of scientific research and the exploitation of that research in this country. There is now confidence that the risks are being properly

assessed and contained, and in consequence some of the leading research in the world in this area occurs in Britain. A comparable mechanism could be employed in the case of IVF. The report does not, however, consider alternative, non-statutory means of regulation - although it does mention in passing that Medical Research Council guidelines for the use of foetal material have worked well. I believe non-statutory options should be explored before a Government response is prepared. I would therefore urge that Ministers, in receiving the report, should not commit themselves to setting up a statutory body to regulate research, and that they should, for the moment, do no more than open the debate.

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CONFIDENTIAL



RECOMMENDATIONS OF THE INQUIRY

a. Licensing Body

- 1. We recommend the establishment of a new statutory authority to regulate both research and those infertility services which we have recommended should be subject to control.
- 2. We recommend that the licensing body promulgates guidance on which areas of research, apart from those precluded by law, would be likely to be considered as ethically unacceptable in any circumstances.
- 3. We recommend that there should be substantial lay representation and that the chairman must be a lay person.

b. The New Techniques

- 4. We recommend that artificial insemination by donor should be available to couples on a properly organised basis. To achieve this we recommend that provision should be subject to the licensing arrangements described in Chapter Thirteen.
- 5. We recommend that the service of IVF should continue to be available subject to licensing and inspection in the same way as we have recommended with regard to the regulation of AID.
- 6. We recommend that egg donation be accepted as a recognised technique in the treatment of infertility, with the principles of good practice we have already considered in relation to other techniques applied; these include the anonymity of the donor, a limit of ten children born form each donor, openness with the child about his genetic origins, the availability of counselling for all parties and informed consent.

- 7. We recommend the technique of embryo donation by lavage should not be used at the present time.
- 8. We recommend that the form of embryo donation involving donated semen and egg which are brought together in vitro be accepted.
- 9. We recommend that it should be accepted practice that donated embryos and gametes should be offered to those at risk of transmitting hereditary disorders.

c. Principles of Provision

- 10. We recommend that all practitioners offering the services that we have recommended should be subject to control, and all premises used as part of any such provision, including the provision of fresh semen and banks for the storage of frozen human eggs, semen and embryos should be licensed by the licensing body.
- 11. We recommend that counselling should be available to all infertile couples and third parties at any stage of their treatment both in the private sector and as an integral part of NHS provision.
- 12. We recommend that the formal giving of consent in writing by both partners should as a matter of good practice always be obtained before the treatment begins. A consent form should be used and thoroughly explained to both partners.
- 13. Our recommendation, following the English Law Commission is that it should be presumed that the husband has consented unless the contrary is proved.
- 14. We recommend a gradual move towards a system where donors should be given only their expenses.

- 15. We recommend a limit of ten children who can be fathered by one donor.
- 16. We further recommend that the NHS numbers of all donors be checked by the clinic where they make their donations against a new central maintained list of NHS numbers of existing donors which must be held separately from the NHS central register.
- 17. We therefore recommend that where trans-species fertilisation is used as a diagnostic tool, it shall be a condition of granting a licence that development of any resultant embryos should be terminated at the two-cell stage.
- 18. We recommend that the sale or purchse of human eggs, semen or embryos should only be permitted under conditions laid down by the licensing body and unauthorised sale or purchase should be a criminal offence.

d. Availability of NHS Services

- 19. We recommend the establishment of a working group at national level made up of central health departments, health authorities and those working in infertility, to draw up detailed guidance on the organisation of services.
- 20. We recommend that each health authority or board should review its facilities for the investigation and treatment of infertility and consider the establishment of a specialist infertility clinic providing a service separate from routine gynaecology. There should be close working relationships with specialised units, including genetic counselling services, at regional and supraregional level. We recommend that infertility patients should be seen separately from other types of gynaecological patient wherever possible.

- 21. We recommend that consideration be given to the inclusion of plans for infertility services as part of the next round of health authority strategic plans.
- 22. We recommend that funding should be made available for the collection of adequate statistics on the incidence of infertility and the provision of infertility services.
- 23. We recommend that IVF should continue to be available within the NHS.
- 24. We recommend that the first task of the working group whose establishment we recommend in 2.18 should be to consider how best IVF can be organised within the NHS.

e. Research

- 25. We recommend that research conducted on human in vitro embryos and the handling of such embryos should be permitted only under licence. We recommend that any unauthorised use of an in vitro embryo would in itself constitute a criminal offence.
- 26. We recommend that no live human embryo derived from in vitro fertilisation may be kept alive, if not implanted beyond fourteen days after fertilisation, not including any days during which it may have been frozen, nor may it be used as a research subject after that time. We further recommend that it shall be a criminal offence to handle or to use as a research subject any live human embryo derived from in vitro fertilisation beyond that limit.
- 27. We recommend that spare embryos may be used as subjects for research.

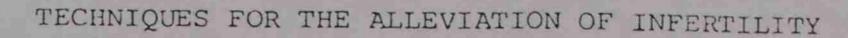
28. We recommend that as a matter of good practice no research should be carried out on any spare embryo without the informed consent of the couple for whom that embryo was generated, whenever this is possible.

f. Legal Changes.

- 29. We recommend that the AID child should in law be treated as the legitimate child of its mother and her husband where they have both consented to the treatment.
- 30. We recommend that the law should be changed so as to permit the husband of a woman who has conceived by AID to be registered as the father. We recommend that if the parents so wish the father's name may be followed in the birth register by the words 'by donation'.
- 31. We recommend a change in the law so that the donor will have no parental rights or duties no relation to the child.
- 32. We recommend that on reaching the age of eighteen the child should have access to basic information about the donor's ethnic origin and genetic health (4.21) and that legislation be enacted to provide the right of access to this.
- 33. We recommend that legislation should provide that when a child is born to a woman following donation of another's egg the mother giving birth should, for all purposes, be regarded in law as the mother of that child, and that the egg donor should have no rights or duties in respect of the child. We recommend that if the parents so wish, the mother's name may be followed in the birth register by the words 'by donation'.
- 34. We recommend that the legislation proposed in paragraphs 4.26 and 6.8 should cover children born following embryo donation.

- 35. We recommend that legislation should provide that for all purposes in law the woman giving birth to the child should be regarded as its mother as against the genetic mother where the two differ.
- 36. We recommend that it be provided by statute that all surrogacy agreements are illegal contracts and therefore unenforceable in the courts.
- 37. We recommend that legislation be introduced to render criminal the creation or the operation in the United Kingdom of agencies whose purposes include the recruitment of women for surrogate pregnancy or making arrangements for individuals or couples who wish to utilise the services of a carrying mother; such legislation should be wide enough to include both profit and non-profit making organisations. We further recommend that the legislation be sufficiently wide to render criminally liable the actions of professionals and other individuals who assist in the establishment of a surrogate pregnancy.
- 38. We recommend that the embryo of the human species should be afforded protection in law.
- 39. We recommend that legislation be introduced to regulate the use of human embryos and to establish a new statutory body to license research.
- 40. A majority of the Inquiry recommend that the legislation should provide that research may be carried out on any embryo resulting from in vitro fertilisation, whatever its provenance, up to the end of the fourteenth day after fertilisation, but subject to all other restrictions as may be imposed by the licensing body.

- 41. We recommend that trans-species fertilisation, involving the use of human gametes, should be a criminal offence, except in the context of the assessment and alleviation of infertility subject to the control of the licensing body.
- 42. We therefore recommend that the placing of a human embryo in the uterus of another species for gestation shall be a criminal offence.
- 43. We recommend that all potential types of 'Do-It-Yourself' sex selection kits should be brought within the ambit of the Medicines Act.



1. Artifical Insemination

The term artificial insemination (AI) is used to refer to the placing of semen inside a woman's vagina or uterus (womb) by means other than sexual intercourse.

a. Artificial Insemination by Husband (AIH)

The procedure by which a woman is artificially inseminated with her husband's sperm is known as AIH (artificial insemination by husband). The technique is used for some couples who cannot otherwise achieve sexual intercourse, for example where the husband is severely physically disabled or where the technique may enhance the chances that a subfertile man may procreate a pregnancy.

b. Artificial Insemination by Donor (AID)

AID - artificial insemination by donor - may be used when investigations have shown the husband to be sterile or to have significantly reduced fertility or it may be used for the avoidance of hereditary diseases when these are carried by the male. In this procedure the woman is inseminated with sperm from a donor.

2. In Vitro Fertilisation (IVF) (the test tube baby technique)

IVF is the technique whereby an egg or a number of eggs is recovered from a and woman fertilised with her husbands semen outside the body. If the fertilisation is successful the embryo is transferred to the mother's uterus with the intention that it will implant in the same way as an embryo fertilised in vivo and that a normal pregnancy will be achieved. The technique is used to treat women who can produce eggs and have a normal healthy uterus but have blocked or diseased fallopian tubes, so that the egg cannot pass from the ovary to the uterus in the usual way.

3. Egg Donation

Egg donation helps those women who cannot themselves produce an egg and also those who would be candidates for IVF except that in their case, egg collection is impossible. A mature egg is recovered from a fertile woman donor, for example during sterilisation, and is fertilised in vitro, using the semen of the husband of the infertile woman. The resulting embryo is then transferred to the uterus of recipient woman. If it implants she may then carry the pregnancy to term.

4. Embryo Donation

Embryo donation may take two forms. One involves the donation of both egg and semen. The donated egg is fertilised in vitro with donated semen and the resulting embryo implanted in a woman who is unable to produce an egg herself and whose husband is subfertile.

The second method does not involve removing the egg by surgical intervention. Instead the egg is released naturally from the ovary at the normal time in the donor's menstrual cycle. At the predicted time of ovulation she is artificially inseminated with semen from the husband of the infertile woman (or from a donor if the husband is also infertile), in the expectation that fertilisation will occur. Some three to four days later, but before the start of implantation, the donor's uterus is "washed out" and any embryo retrieved is then transferred to the uterus of the infertile woman. If the embryo implants successfully the recipient carries the pregnancy to term.

5. Surrogacy

Surrogacy is the practice whereby a woman carries a child for another with the intention that the child should be handed over after birth. The use of artificial insemination and the recent development of in vitro fertilisation have dispensed with the need for sexual intercourse in order to establish a surrogate pregnancy. The most likely type of surrogacy arrangements are:

- 1. surrogacy involving artificial insemination, where the woman who carries the pregnancy also provides the egg, and she is inseminated with semen from the male partner of the commissioning couple, who intend to bring up the child after it is born.
- 2. Surrogacy using in vitro fertilisation where both egg and semen come from the commissioning couple, and the resultant embryo is implanted in the uterus of the woman who is to carry the pregnancy.

The technique could be the only way to alleviate the infertility of certain couples, for example where the woman has no uterus.

6. Scientific Research

There are certain possible uses for human embryos in the field of scientific research. Some of these uses and techniques, such as the detection of abnormal genes in an embryo or the identification of an embryo's gender at a very early stage, may become realities in the fairly near future. However the possible techniques that arouse most public concern, such as ectogenesis (the growing of a human embryo for the whole of pregnancy in an artificial womb) or the transfer of a human embryo to the uterus of another species for gestation, are not likely to be developed in the foreseeable future.

