The Committee to Consider the Social, Ethical and Legal Issues arising from In Vitro Fertilization

REPORT ON THE DISPOSITION OF EMBRYOS PRODUCED BY IN VITRO FERTILIZATION

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THE COMMITTEE TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILIZATION

REPORT ON THE DISPOSITION OF EMBRYOS PRODUCED BY IN VITRO FERTILIZATION

PREFACE

1. The Committee

The Committee to consider "the social, ethical and legal issues arising from in vitro fertilization" was established on 24 May 1982. Its members are:-

Professor Louis Waller, Sir Leo Cussen Professor of Law, Monash University, and presently Law Reform Commissioner, who is Chairman;

Reverend Dr. Francis Harman, Parish Priest of Clifton Hill and Presiding Judge of the National Tribunal of the Catholic Church;

Mrs. Jasna Hay, a former teacher with interests in migrant welfare and education;

Reverend Dr. John Henley, Lecturer in Christian Ethics and Dean of the Melbourne College of Divinity;

Professor Priscilla Kincaid-Smith, Professor of Medicine, University of Melbourne; Director, Department of Nephrology, Royal Melbourne Hospital;

Ms Eva Learner, social worker, formerly Director of the Human Resource Centre of LaTrobe University and the Lincoln Institute of Health Sciences, and presently Principal Staff Development Officer, Department of Youth and Community Services, New South Wales;

Dr. James McDonald, general practitioner, with a substantial practice in obstetrics and gynaecology, Area Co-ordinator for the Family Medicine Programme;

Miss Lynnette Opas, barrister-at-law of the Victorian Bar, practising in family law;

Professor Roger Pepperell, Professor of Obstetrics and Gynaecology, University of Melbourne.
2. **Terms of Reference**

The Committee's Terms of Reference are set out below:

To consider whether the process of in vitro fertilization (IVF) should be conducted in Victoria and, if so, the procedures and guidelines that should be implemented in respect of such processes in legislative form or otherwise.

In relation to this issue, particular consideration should be given to:

- whether the process and practice of IVF (whereby conception occurs outside normal physiological, emotional and social conditions and relationships) give rise to undesirable social and moral practices.

To consider whether the community and the parties (that is, the donors, the embryo and the medical and scientific personnel) involved in the process of IVF have any rights and/or obligations and, if so, whether such rights and/or obligations should be enforced, in legislative form or otherwise.

In relation to this issue, consideration should be included of the following aspects:

- the rights of infertile persons to take advantage of IVF processes.

- the criteria and selection procedures to be applied in determining persons who are to participate in these processes and the conditions to which such selection will be subject.
the manner of determining who should make the decision of selection.

- the methods of selection, treatment and protection of embryos prior to and after implantation and, if implantation does not proceed, the destruction or use of embryos for other purposes.

To make recommendations upon such related matters as the Committee considers appropriate.

To make an interim report to the Attorney-General within three months of the Committee first convening.

3. Published Reports

In accordance with its Terms of Reference, the Committee submitted an Interim Report to the Attorney-General in September 1982. An Issues Paper on Donor Gametes in IVF was published on 25 April 1983. The Report on Donor Gametes in IVF was published on 26 August 1983. That Report was considered by the Victorian Government, which invited the community to respond to the recommendations contained in it. On 13 December 1983 the Attorney-General stated that the Government had decided to accept the Committee's recommendations, and that legislation to give effect to them would be introduced into the Parliament as soon as possible. The provisions of the proposed legislation were to apply to the case where a person is living with another person of the opposite sex as his or her spouse on a bona fide domestic basis although not married to the other person, as well as to married couples. On 20 March 1984, the Attorney-General
introduced the Status of Children (Amendment) Bill 1984 and the Infertility (Medical Procedures) Bill 1984 in the Legislative Council. In his Second Reading Speech, he said that the Government had accepted the Committee's recommendation that a programme of information about the causes and incidence of infertility be initiated, and that through the Health Commission it would develop community education programmes to that end. The first measure became law on 15 May 1984, and was proclaimed on 1 August 1984. Debate on the Infertility (Medical Procedures) Bill 1984 was adjourned until the 1984 Spring Session of the Parliament.

In the Interim Report, and in the Report on Donor Gametes in IVF, the Committee made recommendations on the formation of embryos from parental and donor gametes and their disposition by transfer to women who, with their spouses, were seeking to establish a family through participation in an IVF programme.

The Committee, in its Interim Report, had identified other matters relating to the disposition of embryos which needed to be considered within its Terms of Reference. It decided that after the completion of the Report on Donor Gametes it would examine these, namely, the cryopreservation of embryos, the conduct of research and scientific experiments upon embryos, and the separate matter of surrogate motherhood in IVF.

4. Disposition of Embryos - Final Report

Since the publication of its Report on Donor Gametes in IVF, the Committee has met on sixteen occasions. It decided to invite submissions from the Victorian community in relation to the disposition of embryos, and
advertisements inviting submissions were published in Victorian newspapers in December 1983. Thirty-three submissions were received by the Committee in response to the advertisement, and twenty-nine submissions, comments and letters in response to more recent news reports about the Committee's work on issues relating to the formation of embryos and the two frozen embryos stored in Melbourne for a couple killed in an air crash overseas. Lists of these submissions and letters are published as Appendixes D and F to this Report. As well as considering these, the Committee invited a number of persons with expertise or special interest in the scientific, medical, ethical, social and legal issues relating to the disposition of embryos each to attend one of its meetings to discuss these matters and to respond to its inquiries. A list of those persons, with the dates and the general ambit of their presentations to the Committee, is published as Appendix E to this Report.

The Committee has received and read many publications, ranging from articles and reports in Australian and overseas newspapers to contributions in learned journals. It wishes to acknowledge the value to it of many of these, including the comprehensive reports on aspects of human fertilization prepared in Queensland and South Australia.

5. Acknowledgments

Ms Frances Harrison has continued to be Secretary to the Committee, in addition to her full-time responsibilities as Administrative Officer in the Law Department. The Committee expresses its deep gratitude to her for many kinds of help. She has helped to make the work of the Committee proceed smoothly and effectively. From May 1984, Mr. Mark Campbell of the Law Department has helped Ms Harrison in the preparation of
the Minutes of Meetings of the Committee, and has carried out other secretarial, research and administrative work. His help is gratefully acknowledged. Ms Iona MacNab prepared the Annotated Bibliography on Surrogate Mothering, under the Chairman's direction, which was published in March 1984, and has voluntarily continued to keep it up to date.

The Committee acknowledges with gratitude the help it has had, from the outset of its work, from the Law Reform Commissioner's Secretary, Miss Elizabeth Russell, and from the other members of his staff, especially Mrs. Patricia Tickner, who carried out all the word processing work for this Report.

15 August 1984.
1. UNTRANSFERRED EMBRYOS: FREEZING AND STORAGE

1.1 Introduction. In preparing its Reports the Committee has been conscious of its obligations to consider the rights and interests of all persons affected by IVF programmes. In particular, it has considered the rights of infertile persons to take advantage of these programmes, the rights and duties of the community, and of those who may be involved in the processes of IVF, including donors and medical and scientific personnel. It has also considered the best interests of those children who may be born as a result of the use of IVF. The Committee's responsibility has been to try to balance those rights and interests. Its Terms of Reference oblige it to consider specifically the interests, if any, of the embryo formed in the laboratory. This Report deals with the disposition of embryos formed in vitro. It is written to be read in conjunction with the Committee's previous Reports.

1.2 The Interim Report, September 1982. In that Report the Committee stated that it appreciated "the deep concern of a section of the Victorian community which considers that from the moment of fertilization an embryo is a human being to be accorded a substantial measure of respect and rights (some would say at the same level as persons born alive)." The Committee also stated that it knew that "not all sections of the community share this philosophical view of personhood and the attitude towards embryonic life that derives from it." This understanding of the various viewpoints expressed in the submissions the Committee received and in opinions expressed in newspapers and
on radio and television led the Committee to conclude that in the Victorian community "IVF and ET are acceptable if all fertilized oocytes are transferred to the uterus of the mother."

1.3 Where a couple asked that all ova recovered should be fertilized and there were then too many embryos to be safely transferred, a majority of the Committee decided that the wishes of that couple concerning the handling of such excess embryos should be respected. In coming to that decision, those members took into account evidence which indicated that there was a higher rate of successful pregnancies when all ova recovered were fertilized.

1.4 This led the majority of the Committee to decide that "the process of freeze thawing should be allowed to continue" pending further consideration of that matter by the Committee. The Chairman, Rev. Dr. Harman and Mrs. Hay were not in favour of this recommendation.

1.5 The Report on Donor Gametes in IVF, August 1983. In that Report a majority of the Committee decided that the use of donor sperm, donor ova and donor embryos in IVF programmes in Victoria should be permitted. Rev. Dr. Harman was not in favour of these recommendations, and Mrs. Hay was not in favour of the recommendation relating to donor embryos. The issue of the freezing and thawing of embryos was briefly considered in relation to the study of donor embryos. The Committee stated, in par 5.2 of the Report, that "A previously frozen embryo may become available, in a variety of circumstances." But the
Committee reiterated that it had not completed its study of the issue of freezing and thawing.

1.6 Freezing of Gametes

1.6.1 Sperm

After experimental work using animals, the freezing of human sperm has been successfully achieved. Frozen sperm is used in most AID clinics, including those in Melbourne: see par 2.4 of the Issues Paper on Donor Gametes in IVF.

1.6.2 Only about 50% of persons have sperm suitable for freezing and storage, and there is a reduction in motility of about 10% after thawing.

1.6.3 Ova

Attempts to freeze ova have so far been uniformly unsuccessful. There is a view that, because the chromosomes in a human ovum are aligned on a spindle-like structure which disappears during freezing, there is a strong risk of chromosomal damage in freezing. The concern is that, after thawing, the reconstituted spindle may not have the complete 23 chromosomes aligned properly on it; some chromosomes may not be aligned on it at all.
By contrast, the chromosomes in human sperm are tightly compacted and seem to suffer no damage as a result of freezing.

1.6.4 The Committee was advised by Dr. Alan Trounson, a member of the IVF group at the Queen Victoria Medical Centre, Melbourne, that experimental work on freezing mice ova was being conducted. There is now a report of these experiments by Dr. David Whittingham, of the British Medical Research Council's laboratories at Carshalton, which suggests that the freezing of mice ova may not cause damage to the genetic material of the ovum. The results of that research were that the incidence of loss of chromosomes in frozen-thawed ova was similar to that in freshly collected ova fertilized in vitro, and to that in ova fertilized naturally.

1.6.5 This is a strong impetus to further work on freezing human ova. Success in this endeavour would mean that a comprehensive reappraisal of the reasons for undertaking the freezing of embryos would need to be undertaken. This matter is considered further in pars 1.42 and 1.43, below.

1.7 Freezing, or Cryopreservation, of Embryos.

An embryo is formed when a single sperm penetrates the ovum. Evidence of entry may be seen between 10 to 18 hours after the
sperm is introduced into the petri dish containing the ovum. If fertilization has occurred, two or more pronuclei will be seen on light microscopy examination. Cell division, with the production of two cells or blastomeres, does not take place until 21 to 29 hours after penetration of the ovum.

1.8 Embryo freezing, whereby an embryo is frozen in liquid nitrogen, stored for a variable period of time, thawed and then transferred to the uterine cavity has been used for many years in veterinary practice. With the establishment of successful IVF programmes, the use of embryo freezing has been introduced into some of them, including that conducted at the Queen Victoria Medical Centre and in several institutions overseas.

1.9 Excess Embryos. Initially freezing was only applied to the minority of cases where surplus embryos resulted from excessive ovarian hyperstimulation, when the number of ova satisfactorily fertilized exceeded that appropriate for the transfer to the uterus of the intended mother. Refinements of the hyperstimulation technique or methods of determining the most appropriate ova to be fertilized may be developed, and there are some encouraging reports in this connexion. This will reduce the number of instances wherein an excess of embryos will be present. But it seems unlikely, in the opinion of the doctors and scientists engaged in the IVF programmes in Victoria, that the problem of having excess embryos will be completely solved in the very near future.
1.10 As already mentioned, cryopreservation is undertaken at the Queen Victoria Medical Centre, and in March 1984 the first successful birth resulting from a previously frozen embryo was announced. The Chairman of the Human Reproductive Biology Unit at the Royal Women's Hospital, Mr. Ian Johnston, has told the Committee that cryopreservation of embryos is not part of that Hospital's current IVF programme, pending the outcome of the Committee's deliberations and its Report. Any excess embryos produced at the Royal Women's Hospital are allowed to succumb.

1.11 **Postponement of Embryo Transfers.** There are other reasons that have been proposed for the need for embryo freezing within an IVF programme. These include

- a range of unforeseen occurrences whereby embryos should not be transferred immediately to the woman for whom they are intended, because of a sudden onset of illness in the woman, or accident or trauma in her family;

- recent evidence that pregnancy may occur more frequently when an embryo is able to be transferred into the uterus during a normal, non-stimulated cycle;

- removal of the need for synchronization of the donor's and the recipient's menstrual cycles where donor ova or embryos were to be used;
...and sparing the patient the risks of a further general anaesthetic and operative procedures if the immediate embryo transfer is unsuccessful. The introduction of ultrasonically-guided aspiration of ova as an alternative to laparoscopy could affect the last mentioned ground.

1.12 Animal studies suggest that a 7 cell embryo could be frozen while studies were being made on the 8th cell, in an attempt to recognize a foetal abnormality or defect. It is now well described that removal of 1 cell from an 8 cell embryo in animals will allow a variety of disease processes to be recognised. This does not, however, affect the capacity of the remaining 7 cells still to produce a normal animal. The single cell itself does not, in culture, produce an embryo.

1.13 Although such studies have not been done on human embryos, there is no reason to suppose that similar developments would not be possible in humans.

1.14 Where the single cell test indicated that a foetal abnormality was present, the 7 cell embryo would probably not be transferred to the recipient, but further attempts at the production of a normal embryo would be undertaken. As techniques of genetic manipulation progress, however, it may become possible for such embryos to be treated and cured. Such a technique would offer some hope to couples who are currently unable to produce normal offspring.
1.15 The Committee has been informed, however, that the application of these techniques to human embryos is most unlikely. This is because it is almost always the case that a couple will produce some normal embryos together with those which are abnormal. In the extremely rare case of a couple who produced only abnormal embryos, this could also be managed, if the couple agreed, by the use of donor gametes.

1.16 There are, of course, grave issues relating to this technique and to the whole question of genetic manipulation of untransferred embryos. Suggestions of enhancing embryos through genetic manipulation have been made, as well as suggestions about the treatment of genetic disorders.

1.17 Some members of the Committee regard developments in genetic manipulation of the kind to which brief reference has been made as leading to real benefits for some couples. Some members have grave reservations about any genetic manipulation, and some prefer to defer their judgment on the matter until a more detailed study of the subject may be completed. The Committee is, however, unanimously of the opinion that the subject of genetic manipulation of untransferred embryos should be carefully studied, and all of the implications of the proposal should be widely canvassed.

1.18 The Techniques of Cryopreservation, Thawing and Transfer. The 8 cell embryo is first immersed in a special liquid solution (dimethyl sulphoxide DMSO) designed to protect it from damage
as freezing occurs. Initially the temperature is reduced from room temperature to -6°C at a rate of 2°C per minute, at which stage ice nucleation is induced by touching the ampoule containing the embryo with cold forceps. After holding the temperature at -6°C for another 20-30 minutes, further cooling to between -60°C and -80°C is achieved at 0.3°C per minute. The ampoule is then placed in a canister of liquid nitrogen where storage occurs at -196°C.

1.19 The identity of each frozen embryo is indicated by a variety of means, including a tag attached to the tube, and markings on the tube itself. When a particular embryo is required for transfer it can thus be readily identified, removed from the canister, and gradually thawed at 10°C per minute from -80°C to 4°C. It is then allowed to reach room temperature and immediately transferred or continued in culture for a few hours before transfer.

1.20 Following thawing of the frozen embryo, embryo transfer is performed, providing the number of normal cells or blastomeres in the embryo is at least four. Despite the protective liquid in which it was immersed prior to the freezing process, damage is quite often done to one or more of the cells of the embryo, and this damage may be evident on microscopic examination after thawing.

1.21 The Committee has been informed that 75% of embryos show some evidence of cellular damage after thawing. Nonetheless, 3 of the first 6 pregnancies produced, following transfers of thawed
embryos, occurred from embryos showing such damage. This seems to confirm that at this early, undifferentiated stage of development embryos frequently overcome such damage, as the totipotent state which exists at that stage means the cells which remain undamaged take over and replace those which have been damaged to such an extent that they cannot subsequently divide.

1.22 It would currently appear that embryos with less than four surviving blastomeres are incapable of producing an ongoing pregnancy as all such embryos subjected to further culture in the laboratory have failed to undergo further cell division.

1.23 Current Results. As has been said, the only IVF programme in Victoria in which cryopreservation is employed is that conducted by the Queen Victoria Medical Centre/Epworth Hospital. Since the beginning of 1982, more than 300 embryos have been frozen. This includes 179 embryos frozen in 1983, and 116 between 1 January 1984 and 12 May 1984. Since January 1982, 130 embryos have been thawed, and 45 have been transferred. In 1983 there were 3 established pregnancies, of which 1 miscarried at 24 weeks. In 1984 there have been 4, one of which subsequently miscarried. Of the five surviving pregnancies, there has been one successful birth, on 28 March 1984. Another patient is nearing the end of her pregnancy, and the remainder are in the early or middle stages of pregnancy. There has been at least one successful birth resulting from a previously frozen embryo in an overseas IVF programme.
1.24 **Attitudes to Embryo Freezing.** The first successful birth after embryo freezing in Victoria engendered extensive, sustained publicity. The most recent Australian National Survey showed that over 80% of respondents had heard of freezing fertilized embryos for later use. The community seems almost equally divided in its attitude towards the procedure.

1.25 In mid-June 1984, there was extensive national and international publicity about two frozen embryos stored at the Queen Victoria Medical Centre since November 1981. These embryos were formed from ova collected from a patient who was admitted with her husband to the IVF programme in 1980. Donor sperm was employed. Both husband and wife died in an air crash in South America early in 1984. They were United States citizens. These events have clearly resulted in further community knowledge of and discussion about the freezing of embryos, and have served to emphasise some of the particular difficulties and problems associated with the procedures. These will be considered below.

1.26 **Should Freezing of Embryos be Permitted?** The Committee has received submissions which contain strong arguments against permitting the freezing of untransferred embryos, and submissions containing strong arguments in favour of freezing.

1.27 **The Case against Freezing** The arguments against freezing have as their core the view that the embryo - which comes into existence as soon as sperm and ovum fuse - is actually, not just potentially, a human being with the potential to develop that
The diploid embryo is not just a further progression of the haploids, the sperm and the ovum, but a new, distinct entity. As soon as it is implanted, the embryo will form a hormonal bond with its host, the woman who will, if all goes well, carry it to term. A human embryo is clearly not just a piece of human tissue, it is human life.

1.28 Rev. Dr. Harman has developed this argument to encompass the dimension of personality. In his view the quality or attribute which constitutes the radical identity of a human being is present in the embryo. Therefore to bring embryos into existence and freeze them, taking advantage of superovulation, and to store them as insurance against a failure of implantation is to derogate, grossly, from their intrinsic worth.

1.29 Dr. Harman considers that embryos should not be formed in an IVF programme in numbers in excess of those destined for the direct and immediate circumvention of a couple's infertility, and Mrs. Hay shares that view. Dr. Harman is opposed to the freezing of embryos in any circumstances, Mrs. Hay is not opposed to the freezing of embryos in the limited circumstances set out in par 1.38, below. Dr. Harman's statement of dissent on this subject is published as Appendix A.

1.30 There is a further argument which may be marshalled against cryopreservation and storage of embryos. The procedure is experimental, and there may be unacceptable risks of damage to the embryo. Beyond the physical damage which may be caused by
freezing and thawing, there must be a question about the impact on the child born after storage of the discovery that for a time he or she was in suspended animation. This is one reason why those members of the Committee who have decided that cryopreservation is acceptable in an IVF programme have also decided that the period of storage shall be as short as possible in each case.

1.31 The Case for Freezing Embryos. The main argument in favour of freezing embryos as part of an IVF programme is that the procedure is successful and it does presently facilitate the operations of a programme.

1.32 Freezing is not inimical to the interests of the embryo. Though there may be some interference with embryo development - as described in par 1.21 above - the evidence the Committee has had shows that a thawed embryo may be successfully transferred and that an uneventful pregnancy leading to a live birth can ensue.

1.33 The freezing of embryos clearly assists in those instances where couples in the most common situation are faced with the impossibility or the grave impracticality of an immediate transfer. This may be because of some medical or surgical occurrence in the course of laparoscopy or of ovum collection, or because of some unrelated medical condition. It could be because of an accident in which a member of the couple's family is injured or killed while the laboratory fertilization is taking place. While the Committee has been told that it is rarely necessary for
embryo transfer to be postponed on medical grounds, there has been one such case described to it and the possibility of other instances has clearly been acknowledged.

1.34 Freezing permits a couple participating in an IVF programme to avoid a further laparoscopy under general anaesthetic, sperm collection and laboratory fertilization if an immediate transfer of one or several presently fertilized embryos is unsuccessful. The information provided to the Committee shows that the majority of transfers does not result in the establishment of a pregnancy, and this has meant that couples must embark on another complete cycle of IVF treatment. The short-term freezing of embryos which are not immediately transferred not only avoids the burdens already described; it also reduces the costs to the couple, and to the community, of participation in an IVF programme.

1.35 Freezing makes donation of ova and donation of embryos, both of which the Committee has approved in its Report on Donor Gametes in IVF, more effective. The ovulatory synchronisation of the woman who is to receive the embryo may be more readily achieved if the embryo to be transferred is frozen for a short time.

1.36 There are more remote conditions where freezing is of specific value, especially since human ova cannot at present be frozen successfully. (The very recent reports on the successful freezing and thawing of mouse oocytes leads to the hope that the
successful freezing of human ova may also be undertaken.) Men who are required to undergo radiation therapy or chemotherapy which will or will probably cause sterility may deposit their sperm before undergoing such treatments. This sperm may be safely frozen, and subsequently the artificial insemination of their wives - AIH, not AID - may be carried out, so that the medical treatment does not mean the end of child bearing in that family. This is particularly important if the couple has had no children before such an illness strikes.

1.37 In the case of a woman who must undergo radiation or chemotherapy the freezing of embryos fertilized from her ova and her husband's sperm would permit the same family development to be attempted. Once the treatment was successfully completed, the thawed embryos could be transferred. Again, if human ova may be successfully frozen, this need would be met without fertilization and embryo freezing.

1.38 These are all important practical considerations which lead the Committee, other than Rev. Dr. Harman, to support the proposition that embryo freezing should be permitted as part of IVF programmes in Victoria. But Mrs. Hay only supports freezing in those cases where the health of the woman who is to receive the embryo does not permit an immediate embryo transfer. In those instances where medical complications such as peritonitis or acute bleeding prevent immediate embryo transfer, she believes that storage should continue only until the next ordinary
cycle of that woman. Mrs. Hay's reasons for her view are set out in Appendix B.

1.39 Those who support freezing of embryos, either in a very limited instance or in a variety of circumstances, may point out that the extent to which an embryo gains respect varies from group to group and indeed from person to person in our pluralist society. For many who accord it very significant respect, freezing is acceptable because the embryo is carefully preserved and its existence is perpetuated.

1.40 Recommendation: Freezing of Embryos in an IVF Programme.

The Committee considers that the freezing of embryos formed in an IVF programme should be permitted in Victoria at present. The freezing of embryos should be undertaken on the terms and in the circumstances which are set out in the next part of the Report.

1.41 For the reasons which appear in pars 1.27 to 1.29 of the Report, Rev. Dr. Harman is not in favour of the freezing of embryos in any circumstances. Mrs. Hay is in favour of the freezing of embryos only in the circumstances described in par 1.38. But both have joined with the rest of the Committee in the consideration of the terms upon and conditions under which freezing shall be permitted.

1.42 The Possibility of Freezing Ova. Many of the reasons which are offered to support the freezing of embryos would diminish in
force if it became possible to freeze human ova successfully. Until very recently, this has been thought to be impossible. But very recent research suggests that this may not be the case: see par 1.6.3 to 1.6.5, above. The results of that research done in Great Britain, must however, be viewed with caution, as well as with the greatest interest. There is rarely an exact transfer of results from the animal to the human situation. But the developments do rekindle the hope that safe methods of freezing and thawing human ova may be developed in the future.

1.43 The Committee considers that research on and development of techniques for the freezing and storage of human ova should be warmly encouraged. If that research and development is successful, then the whole subject of freezing and storing human embryos should appear as an item on the agenda of a standing review and advisory body on human fertility, reproduction and related subjects. The establishment of such a body is the subject of Part 5 of this Report.
2. THE REGULATION OF EMBRYO FREEZING AND STORAGE IN IVF PROGRAMMES

2.1 Freezing and Storage: The Present State.

The Committee considers that freezing and thawing of embryos must still be regarded as an experimental programme, even though there are established pregnancies and at least two successful live births. It views the process in the same light as the donor ova programme stood when the Committee completed its consideration of that subject in 1983. Accordingly, it considers that the greatest caution must be exercised in the management and control of that programme, and that the overriding consideration must be to restrict as far as possible the period of cryopreservation of each embryo received into that programme, while attending to the particular circumstances of the infertile couple in respect of whom the freezing has been undertaken.

2.2 Authorisation. The Committee recommends that freezing and storage of embryos shall only be undertaken in a hospital already approved to conduct an IVF programme, which is specially authorised by the Minister of Health to conduct such activities. Such an authorisation should clearly state terms and conditions, based on matters considered in this part of the Report.

2.3 Sperm banks have been developed as part of AID programmes. The Committee has decided that no hospital authorised to
conduct a cryopreservation programme shall maintain a bank or store of large numbers of frozen embryos from which embryos may be disposed of as the hospital thinks fit. Each embryo which is frozen shall be retained for a couple, to be used in the course of the treatment of their infertility. Where an embryo has been donated, it shall be used for a selected couple in the terms of the section on donor embryos in the Committee's last Report.

2.4 Information. The Committee repeats the recommendations it has already made in its earlier Reports about the importance of accurate, comprehensive information about freezing and storage of embryos being made available to the couples participating in IVF programmes. In addition this information should be part of what is disseminated in the community education and information programmes which the Committee has already advocated and which the Victorian Government has undertaken to establish.

2.5 Counselling. From the beginning of its work the Committee has been made aware of the great importance of expert counselling for couples embarking upon participation and participating in IVF programmes. It has made, and now reiterates, firm recommendations that counselling should be an integral part of every IVF programme, and it had been pleased to learn that those recommendations have been embodied in the provisions of the Infertility (Medical Procedures) Bill 1984. In describing counselling as an "integral part" of an IVF programme, the Committee is repeating its view that counselling, to be effective, should involve constant interchange of information and opinion.
between the counsellors who work with all the participants and
the medical and scientific members of each IVF group. Counselling for couples who have been informed about the
possibility of freezing and storing their untransferred embryos
should include counselling about the objects of freezing, and
should clearly cover all the matters which are considered in the
next sections of this Report.

2.6 The Committee also reiterates the suggestion made in the Report
on Donor Gametes in IVF, that information about IVF programmes
should be translated into as many community languages as
possible. The needs of those patients and would-be patients who
cannot, or cannot easily, understand and speak English must be
considered in relation to counselling. The Committee realise
that it is not easy to meet these needs, but it believes that they
must be recognized and addressed.

2.7 Consent. The Committee considers that understanding the
procedure and agreement to its conditions are at the core of the
regulation and the management of cryopreservation. An embryo
shall only be frozen and stored if the couple whose gametes have
been used in its formation agree to the procedure. That
agreement may only be made after they have received the
information and the expert counselling described in the preceding
paragraphs. The couple should be told that they may find it
useful to discuss the matter and the terms of the agreement with
their legal adviser or with a legal worker in a community legal
service. The agreement shall be recorded in an appropriate
document, which shall state clearly the purpose and the expected duration of the embryo storage. For instance, if the couple agree to the procedure to insure against an unsuccessful embryo transfer, and to avoid a further laparoscopy and attendant procedures, then that agreement should state those matters, and also clearly state that the storage will cease if a viable pregnancy is established. Documents used to record consents and agreements should be translated into those community languages used by patients or would-be patients in the IVF programme conducted by the relevant hospital.

2.8 The Committee does not regard the couple whose embryo is stored as owning or having dominion over that embryo. It considers that those concepts should not be imported into and have no place in a consideration of issues which focus on an individual and genetically unique human entity. It may be sensible to embody this conclusion in legislation dealing with the regulation of embryo freezing, storage and disposition. The Committee nevertheless does consider that the couple whose gametes are used to form the embryo in the context of an IVF programme should be recognized as having rights which are in some ways analogous to those recognized in parents of a child after its birth. The Committee does not consider that those rights are absolute, just as the rights of parents are limited by the rights and interests of the child, and by the larger concerns of the community in which they all live. Without attempting to enunciate precisely what the limits of those rights are in every instance, the Committee considers that the couple may not sell or
casually dispose of the embryo. But they may, after receiving comprehensive information and expert counselling, and perhaps legal advice, consent to donation or, subject to the matters set out in the next Part of this Report, to the embryo being made available for research or experimental work in connexion with an IVF programme.

2.9 In order to avoid any semblance or appearance of pressure or undue influence, the couple shall be required to make their decision about the disposition of the embryo which is to be stored before that procedure is initiated.

2.10 Consent to Donation. If a couple agree that an embryo may be donated, in the terms set out in Part 5 of the Report on Donor Gametes in IVF, then the Committee recommends that, with their consent, it shall be permissible for that embryo to be frozen and stored until the next appropriate reproductive cycle of the woman who is to receive that embryo in a donor ova or donor embryo programme conducted by the hospital. This will clearly facilitate the effective conduct of such programmes, and is in accordance with those matters set out in par 2.1., above.

2.11 Disposition of Untransferred Embryos After Short Term Storage.
Where an embryo is stored to insure against a failure of transfer or implantation, and the immediate transfer of a non-frozen embryo is successful with the establishment of a viable pregnancy (that is of 20 weeks duration) then the Committee recommends
that the decision made by the couple whose gametes have been used in the formation of the embryo should be given effect.

2.11.1 The couple may have decided that, if a viable pregnancy is established, their frozen stored embryos shall be donated to another couple in the IVF programme.

2.11.2 The couple may have decided that if a viable pregnancy is established, the stored embryo or embryos shall be made available for research or experiment.

2.11.3 The couple may have decided that if a viable pregnancy is established, storage of frozen embryos shall cease.

2.12 Removal from Storage. The Committee recommends that, in those cases set out in par 2.11, the embryo shall be removed from storage as soon as possible. If the couple has decided that storage shall cease (par 2.11.3), the embryo, after removal, should not be destroyed in any deliberate fashion, but the ampoule should be set aside in the laboratory. The removal of the frozen embryo from storage is in some ways similar to the removal of life-support systems from a mortally ill person. Life is allowed to end. This does seem to accord the embryo a measure of that respect which is so often spoken of in relation to it.
2.13 **Prolonged Storage.** The Committee has stated that in general storage shall be for very short periods. In a few instances it may need to be for a comparatively long time, as where the woman whose ova have been used is undergoing prolonged chemotherapy: see par. 1.32, above. In that time the view of the couple, and their circumstances, may change. The Committee recommends that where a couple consents to long term storage, the consent shall be reviewed after 5 years, and may then be renewed.

2.14 **Accident, Death or Dissolution.** The much publicised case of the death of a husband and wife whose ova were used to form embryos then stored in the Queen Victoria Medical Centre, which was reported in June 1984, has served to focus attention on the problem of disposition in a case where one or both parties whose gametes have been used die, or disappear, or the woman becomes incapacitated in a way which makes transfer impossible. It also focusses attention on the problem of disposition if the couple separate, with no real intention of resuming their relationship, or institute proceedings for dissolution of their marriage. The Committee had identified all these matters as problems which needed consideration well before the reports about the frozen embryo case mentioned at the beginning of this paragraph. It has been given an account of the participation by the couple in the IVF programme at the Queen Victoria Medical Centre, and of the subsequent decision by the couple that two untransferred embryos be stored with a view to later transfer to the wife. The lengthy interval between the beginning of storage and the accident in
which the couple died underlines very heavily the Committee's view, already expressed, that storage shall be for as short a period as possible in terms of the reason for the storage of that embryo or those embryos.

2.15 The Committee has considered a variety of solutions to the problems which arise in these cases. It has debated carefully the suggestion that the survivor of a couple should be empowered to determine what shall happen to the stored embryo. Considerable sympathy was expressed by some members of the Committee for the view that where the survivor was the woman intended to receive the embryo then it should be transferred if she so wished. This was analogous, it was said, to the posthumously established pregnancy of a woman whose husband dies soon after their child is conceived or at any time before its birth. On the other hand, it was argued that it should not be public policy to provide technological assistance and scientific and medical help to ensure the birth of a child to a single parent. Given that there is a choice, it is difficult to maintain that the interests of a possible child are well served by bringing it into existence in such circumstances.

2.16 The Committee has decided that the disposition of the stored embryo shall not be determined by the hospital in which it is held. This could readily lead to the establishment of an embryo bank managed and controlled by the hospital. The Committee believes that such a development is unacceptable in Victoria, and points out that the presentations made and the submissions
delivered by the directors and staff of the IVF programmes in this State give no support to the view that the establishment of embryo banks be permitted.

2.17 After the most serious consideration, and in view of the public interest that a proposal for dealing with these cases should be as clear and as straightforward as possible, the Committee recommends that the couple who agree to storage shall be required to determine at that time what disposition shall be made if any of the events mentioned occur. That conditional disposition shall be incorporated as part of the consent document to which they agree. They may agree to donation of the embryo, on condition that its transfer is effected as soon as possible after any one of those events: see pars 2.10 and 2.12, above. They may agree that the embryo be made available for research. They may agree that it shall be removed from storage.

2.18 In any cases where by mischance or for any other reason, an embryo is stored which cannot be transferred as planned, and no agreed provision has been made at the time of storage, the Committee recommends that the embryo shall be removed from storage. This is in accordance with the Committee's earlier determinations on the donation of gametes, and also with its concern to uphold the primary responsibility of the couple whose gametes have been used to form the embryo, and so to respect the embryo as an independent and unique human entity, and not as a mere means to an end.
2.19 The Committee takes the view, as its earlier recommendations imply, that an untransferred embryo should not be regarded as possessing rights or claims to inheritance. But the earlier recommendations also make it clear that the Committee considers that safe storage of the embryo, under the conditions specified in each case, may be protected, where necessary, by legal action.
3. **EMBRYO RESEARCH IN AN IVF PROGRAMME**

3.1 **The History of Embryo Research in an IVF Programme.** In its Interim Report, the Committee set out the brief history and the initial attempts at IVF. All of these could be classified as research, as a continuing pregnancy was not achieved until 1979, although embryos were produced from 1973 onwards. Initially research was necessary on these embryos to prove fertilization and subsequent normal development of the embryo had occurred. Failure of fertilization initially was common. Subsequently the fertilization rate was able to be improved dramatically by changes in culture media and fertilization conditions, and by delaying attempts at fertilization until the ovum had been cultured in the laboratory for 5 to 6 hours after aspiration at the time of laparoscopy.

3.2 Abnormal development of the embryo, often due to fertilization by more than one sperm, was also common. Such embryos were not transferred to the uterus of the recipient but were subjected to further analysis in an attempt to determine the cause of the abnormality. It is now recognised that where too many sperm are used at the time of fertilization of the ovum, an abnormal embryo is more likely, with the fetus likely to be born with a disturbed chromosome constitution, or the pregnancy lost as a miscarriage. The rate of cell division of the newly formed embryo was also found to be an important factor in determining the subsequent success of embryo transfer. Embryos in which cell
division was occurring too slowly did not produce continuing pregnancies. Without embryo research in the early days of IVF the technique, which today is producing many hundreds of pregnancies per year throughout the world, would never have been successful.

3.3 Following release of the Interim Report all research on excess embryos produced by IVF ceased, except where these excess embryos had been frozen. The Monash University Department of Obstetrics and Gynaecology at the Queen Victoria Medical Centre was specifically allowed to proceed with its embryo freezing programme, which had already received the approval of the N.H. & M.R.C. and the Ethics Committees of both the University and the Centre, and aspects of this programme entailed assessment of some of the embryos following thawing and further culture in the laboratory. Even where the embryo was not destroyed as a result of this assessment, prolonged culture in the laboratory to ensure that normal development would occur, precluded successful embryo transfer subsequently.

3.4 The Royal Women's Hospital group has performed research on ova obtained specifically for this purpose, that is, from patients who were not participants in the clinical IVF programme, but had their ova removed at the time of an operation such as a hysterectomy, or sterilization. Each patient gave informed written consent that the ova so removed could be used for research and, if an embryo did result, this was not to be transferred into a patient or allowed to grow in the laboratory past the morula stage: that is 3 or
4 days. Initially, such research was aimed at improving the success rate of the IVF programme, whereby prolonged culture of immature eggs prior to fertilization was attempted. After September 1982 this research ceased. Since that time research on such ova has been confined to an assessment of the process of sperm attachment and fertilization of the ova, with the research being completed before there is any evidence of cell division and the product of the research then being destroyed. All these projects involving the use of ova had first received the approval of the N.H. & M.R.C. and the Ethics Committee of the Royal Women's Hospital.

3.5 Future Research. Scientists involved in many areas of research, including IVF, contraception, and genetic counselling, see many applications of the use of IVF in their own areas, including research on embryos produced by the method referred to in par 3.4.

3.6 IVF Programmes. The directors of these programmes and their colleagues see continuing research as necessary to improve the overall success rate of their clinical programmes. Such research includes the possibility of freezing ova prior to fertilization in order that excess embryos are not produced. Such a result would be comparable to the technique of freezing human sperm for AID, a technique which has considerable community support and ethical approval: see pars 1.6.1 to 1.6.5, above.
3.7 It also includes methods of improving the capacitation of the human sperm to improve the fertilization rate and subsequent pregnancy rate. Methods may also be developed to enable the sperm of infertile men to be able to be used to achieve fertilization in an IVF programme. Currently the results of the use of sperm from such men are very poor.

3.8 Further research would include that on methods of preventing fertilization of the ovum by more than one sperm, thus preventing abnormal embryo production, and on improving the fertilizability of the immature egg, since many of these may be obtained together with mature eggs at the time of laparoscopy in a clinical IVF programme. Currently fertilization anomalies occur when such eggs are penetrated by sperm.

3.9 None of the above research areas involves embryo research in the first instance. The success of the research, however, may only be tested by allowing ovum fertilization with subsequent assessment of the embryo produced. Where such an embryo was shown to be dividing normally, to look normal by microscopic assessment and to have a normal chromosome analysis, the technique could then be applied to clinical practice. Clinical application, without such proof, may well mean children with congenital malformations would be produced.

3.10 Chromosome abnormalities have been thought to follow ovum freezing; see pars. 1.6.3 and 1.6.4, above. This is not the case for sperm frozen and used in successful AID programmes. It is
also possible that freezing may cause damage to the zona pellucida around the ovum, and this may result in more than one sperm fertilizing the ovum with an abnormal embryo resulting. The successful research on mouse ova provides great impetus to research of freezing human ova: see pars 1.6.3 to 1.6.5, above.

3.11 Embryo freezing. Although success has been achieved following transfer of a thawed frozen embryo, the optimum techniques for freezing and thawing have probably not been established. Changes in technique will require the assessment of a small number of embryos to ensure embryo survival and lack of damage due to the freezing process.

3.12 Embryo division. Division of embryos may be undertaken deliberately to produce identical twins. In cattle, division of the embryo in half has increased pregnancy rates from 60% to 105% of the original number of embryos collected. A similar increase in pregnancy rate could be expected in the human, but it would need to be proven that such embryo division did no harm. Such a technique could be used when only single oocytes were obtained from patients in an IVF programme, as it is well known that transfer of two embryos has a much higher pregnancy rate than transfer of one.

3.13 Research in Contraception. Extension of research referred to in pars. 3.7 and 3.8 may well result in the development of new contraceptive techniques for the male and female partner respectively.
3.14 Genetic Counselling Research. As already mentioned in par 1.12, above, assessment of a single cell of an 8 cell embryo in animals allows a variety of disease processes to be recognized. It does not, however, affect the capacity of the remaining 7 cells to produce a normal individual.

3.15 It is also known that 8 cell human embryos in which only 5-6 cells appear normal after freeze-thawing are able to produce perfectly normal children, so the removal of one cell for appropriate analysis in the human is certainly a theoretical possibility. Where the single cell test indicated an abnormality was present in a human embryo, the 7 cell embryo which remained could either not be transferred to the recipient uterus or, if appropriate techniques were to be developed, could be treated and 'cured' prior to transfer. Research in this area might thus have enormous potential for curing or preventing a wide variety of disease processes or congenital abnormalities.

3.16 The above research assumes all of the cells in an 8 cell embryo are identical and that analysis of one gives an accurate assessment of the whole embryo. It is known that all cells of an embryo are not identical, however, and research on some embryos, whereby half or even all of the cells were subjected to analysis, would be required before the clinical use of single cell assessment could be instituted.
Certainly the success of correction of an abnormality could not be evaluated unless subsequent embryo growth and assessment was allowed with, in the early stages of this research at least, the loss of embryos resulting.

3.17 Review of Embryo Research. The use and application of embryo research has been considered by a number of responsible bodies during the period in which the Committee has been sitting. These bodies, many of which have wide ranging representation from the community, include the National Health and Medical Research Council of Australia (N.H. & M.R.C.), the Medical Research Council of Great Britain (M.R.C.), the IVF Working Party of the South Australian Health Commission, the Special Committee of Inquiry into Artificial Insemination and IVF in Queensland, and most recently the U.K. Committee of Inquiry into Human Fertilisation and Embryology (the Warnock Committee). Their guidelines or recommendations are listed below.

3.18 N.H. & M.R.C., 1982

Research with sperm, ova or fertilized ova has been and remains inseparable from the development of safe and effective IVF and ET: as part of this research other important scientific information concerning human...
reproductive biology may emerge. However continuation of embryonic development in vitro beyond the stage at which implantation would normally occur is not acceptable.

Cloning experiments designed to produce from human tissues viable or potentially viable offspring that are multiple and genetically identical are ethically unacceptable.

In this as in other experimental fields those who conscientiously object to research projects or therapeutic programmes conducted by institutions that employ them should not be obliged to participate in those projects or programmes to which they object, nor should they be put at a disadvantage because of their objection.

3.19 M.R.C.1982 The guidelines for research related to human fertilization and embryology released by the M.R.C. are:

Scientifically sound research involving experiments on the processes and products of in vitro fertilization between

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1. Members of the M.R.C. Advisory Group to review policy on research involving in vitro fertilization and embryos transfer in humans:

- Professor C. S. Dawe, F.R.S. (Chairman),
  Nuffield Institute for Medical Research, Oxford.
- The Rt. Rev. the Bishop of Durham.
- Professor H. J. Evans,
  M.R.C. Clinical and Population Cytogenetics Unit, Edinburgh.
- Professor C. A. Faire,
  Veterinary Physiology, University of Liverpool.
- Professor J. F. Hearns,
  Institute of Zoology, London.
- Dr. J. D. D. London (Observer),
  Royal College of Obstetricians and Gynaecologists.
- Dr. Anne McLaren, F.R.S.,
  M.R.C. Mammalian Development Unit, London.
- Professor J. C. Macken, Obitrates and Gynaecology, University of Glasgow.
- Dr. E. F. Mackett,
  M.R.C. Clinical Research Centre, Harrow.
- Professor P. E. Polani, F.R.S.,
  Paediatric Research Unit,
  Guy's Hospital Medical School, London.
- Professor A. C. Turnbull,
  Obstetrics and Gynaecology, University of Oxford.
- Professor R. Williamson,
  Biochemistry, St. Mary's Hospital Medical School, London.

and observers from the Health Departments.
human gametes is ethically acceptable and should be allowed to proceed on condition both that there is no intent to transfer to the uterus any embryo resulting from or used in such experiments and also that the aim of the research is clearly defined and directly relevant to clinical problems such as contraception or the differential diagnosis and treatment of infertility and inherited diseases.

Informed consent to research involving human ova or sperm should be obtained in every case from the donor(s); sperm from sperm banks should not be used unless collected and preserved specifically for a research purpose. Approval for each experiment should be obtained from the appropriate scientific and local ethical committees.

When human ova have been obtained and fertilized in vitro for a therapeutic purpose and are no longer required for that purpose it would be ethical to use them for soundly based research provided that the informed consent of both donors was obtained.

Human ova fertilized with human sperm should not be cultured in vitro beyond the implantation stage; and should not be stored for unspecified research use.
Although it is not always possible to extrapolate results from animal work to the human situation, studies of animal gametes and embryos are useful to elucidate the potential risks of in vitro fertilization and embryo transfer. Tests of animal embryos in appropriate animal models are necessary before it can be assumed that freezing and storage of the embryo does not cause harm to the conceptus.

Studies on interspecies fertilization are valuable in providing information on the penetration capacity and chromosome complement of sperm from subfertile males, and should be supported. The fertilized ova should not be allowed to develop beyond the early cleavage stage.

3.20 **South Australian Health Commission - Working Party, 1984.***

Recommendation 18: That fertilized gamete(s) of human beings should never be used for scientific or genetic experimentation.

3.21 **Queensland Special Committee of Enquiry, 1984.***

Recommendation 20: An embryo should not be created for the purposes of experimentation.

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1. The members of the Working Party were:
   - Dr. Allan F. Cowie, Medical Coordinator, South Australian Health Commission (Chief, Obstetrics and Gynaecology).
   - Mr. Philippe Kelle, Legal Officer, Attorney-General's Office, S.A.

2. The members of the Special Committee were:
   - Mr. Justice A. Dennis (Chairman), a Judge of the Supreme Court of Queensland.
   - Professor E. Ryan, O.C., Past Chair, Supreme Court of Queensland.
   - Sister Mary Doreen, S.S.N., Director of the Ethics Centre for the Catholic Church in Queensland.
   - Rev. Dr. June Morgan, Vicar General, St. John's College, University of Queensland.
   - Dr. Jean Collins, Director, Division of Research and Planning, Department of Health.
   - Professor Eric Markey, Professor of Obstetrics & Gynaecology, University of Queensland.
   - Dr. Allen McIlrath, Senior Lecturer in Social Work, University of Queensland.
3.22 Warnock Committee, 1984. A majority of the Committee recommended that legislation should provide that research may be carried out on any embryo resulting from IVF, whatever its provenance, up to the end of the fourteenth day after fertilization. Three members of the Committee were wholly opposed to experimentation on the human embryo.* Four members were opposed to the formation of embryos specifically for research, or on those coming into existence as a result of other research.**

3.23 The Position in Victoria. Although some aspects of IVF are well known and accepted by the community, embryo research has not been widely publicised, nor has its acceptance by the community been extensively evaluated. The members of the Committee are not in agreement regarding a recommendation concerning embryo research, although a majority favours some forms of embryo research.

The options available in relation to embryo research are complete prohibition, research allowed only on excess or spare embryos,
which come into existence as part of IVF programmes for the treatment of infertility, or research on embryos formed specifically for that purpose.

3.24 Complete Prohibition. The Committee appreciates the deep concern of a section of the Victorian community which considers that, from the moment of fertilization, an embryo is a human being to be accorded a substantial measure of respect and rights. Under such circumstances any research on embryos which prevents implantation, or reduces the success rate of such implantation, is unacceptable, as is the creation of embryos specifically for research where there is no intention that the embryo created should be transferred to a recipient uterus. Rev. Dr. Harman and Mrs. Hay support this view.

3.25 Acceptability of Research on Embryos. The remaining seven members of the Committee have come to the conclusion that embryo research should be allowed in order that the success rate of the clinical IVF programme may be improved and advances in genetic research referred to in par 3.14 and the following paragraphs may be evaluated. The development of techniques of ovum freezing would also mean that the morally difficult decisions regarding the use of excess embryos - to allow to succumb in culture, to use for research, to use for embryo donation, or to freeze for subsequent use - would arise less frequently. The total number of ova subjected to fertilization could in many cases be limited to the total of embryos acceptable for transfer, with the excess ova stored for subsequent use in a
non-fertilized state, as may be done with sperm. On the other hand, if freezing and thawing of embryos should improve the success rate of IVF, the problems of dealing with untransferred embryos may not decline.

3.26 The Chairman, Dr. Henley, Ms Learner, Dr. McDonald and Ms Opas have decided that embryo research shall be limited to the excess embryos produced by patients in an IVF programme. Where the number of embryos produced exceeds the number acceptable for transfer, the couple who produced the embryo shall make a decision about their use, in terms of the options listed in par. 2.11, above. It is possible that some couples will agree to make some available for research purposes, or that some of the originally frozen embryos may be made available or become available for research purposes for the reasons listed in pars. 2.11 and 2.17 above.

3.27 These members consider that formation of embryos solely for research or experimentation is not acceptable in Victoria today. From a moral perspective, it may be said that, regardless of the particular level of respect which different sections of the community would accord an embryo, this individual and genetically unique human entity may not be formed solely and from the outset to be used as a means for any other human purpose, however laudable. Where the formation occurs in the course of an IVF procedure for the treatment of infertility, the reasons which lead to the embryo's existence are not "means to an end" ones.
3.28 In making this decision, these members of the Committee recognize that developments in IVF such as freezing and thawing of ova and the use of sperm of otherwise infertile men could lead to the formation of embryos the examination of which may give rise to reasonable doubts about their normality. In these circumstances, they consider, it would not be responsible behaviour on the part of those conducting IVF programmes to proceed with embryo transfers, and that, provided appropriate consents had been given, such embryos could be used for research. Clearly these would not have been formed solely for that purpose.

3.29 The Committee considers that the use of any embryo for research shall be immediate, and in an approved and current project in which the embryo shall not be allowed to develop beyond the stage of implantation, which is completed 14 days after fertilization. It is after this stage that the primitive streak is formed, and differentiation of the embryo is clearly evident. In no circumstances shall any embryo which has been made available for research be frozen for some unspecified future purpose.

3.30 Professor Kincaid-Smith and Professor Pepperell agree with the recommendations of the NH & MRC, set out in par 3.18, above, that embryo research should not be limited to excess embryos. In their view, it is ethically acceptable for embryos to be created purely for research purposes, as they believe that restriction to
the use of excess embryos would mean many aspects of research would be impossible.

3.31 This particularly applies to the techniques of ovum freezing, improving the fertilizing capacity of sperm from infertile men, improving the fertilizability of the immature ovum, embryo division and genetic research. In each of these instances the ovum must be fertilized and the normality of fertilization and subsequent development proven before embryo transfer may be allowed. As has been pointed out in par 3.9, above, transfer of embryos before normality has been proven by preliminary embryo research procedures, could well be associated with an increased number of congenital malformations. Professor Kincaid-Smith and Professor Pepperell have elaborated their views in more detail in a Dissenting Statement published as Appendix C.

3.32 **Control and Supervision of Research.** The Committee recommends that, because of the very great public interest in and concern about research on human embryos all such research shall be regularly scrutinised by the Health Commission or the standing review and advisory body which is the subject of Part 5 of this Report.
4. **SURROGATE MOTHER ARRANGEMENTS IN IVF.**

4.1 **A Definition.** Surrogate motherhood or surrogacy is the name applied to an arrangement where one woman bears a child for another woman, with the intention that the child is handed over to the other immediately or very soon after its birth.

4.2 The practice has received extensive publicity in North America, Great Britain and Australia in the last three or four years. There have been, the Committee has been informed, instances in Victoria where women have had sexual intercourse with the fertile husband of an infertile woman and the child born as a result has been handed over to its father and his wife. In some instances it may be presumed that after a time adoption proceedings were completed in order to establish the legal relationship of mother and child.

4.3 With the employment of artificial insemination it has become possible to achieve a surrogate pregnancy without what is sometimes euphemistically called "natural insemination by donor". This has led to the development of surrogacy agencies in the United States of America, and very recently in England, where women prepared to act as child bearers are recruited, agreements prepared, and substantial fees charged to the couple who desire a child. Part of the fee is paid to the surrogate, and the remainder represents the agency's charges.
4.4 There have been reports of several cases where the surrogate has refused to hand over the child she has carried, and of one case in early 1983 where the man who supplied the sperm for a surrogate fertilization refused to accept the defective child said to have been born as a result. A case of a surrogate refusing to hand over the baby she bore has now occurred in New South Wales, and has received extensive publicity.

4.5 These aspects of surrogacy are relevant to, but specifically outside, the Committee's terms of reference; these are restricted to surrogacy in IVF. The Committee decided, however, that the extensive and growing literature on the whole subject should be reviewed as part of its work on this issue. As a consequence An Annotated Bibliography on Surrogate Mothering was published by the Committee in March 1984.

4.6 The Committee has come to the conclusion that surrogate mother arrangements where fees are paid are, in reality, agreements for the purchase of a child, and should not be countenanced. It has also accepted the advice that where such agreements contemplate the adoption of the child by the infertile wife, they are probably criminal conspiracies to controvert the provisions of the Adoption of Children Act 1964. The Committee has also been told that many lawyers consider that, because of these and related considerations, any surrogacy agreement would not be enforceable, should legal proceedings be instituted.
4.7 The advertisements seeking a surrogate published in *The Age* in January and May 1984 have served to focus attention on these aspects of the matter. It may be sensible, in the Committee's opinion, for those provisions of the adoption legislation which deal with agreements for private adoptions, advertisements which clearly involve the prospect or possibility of a private adoption, and payments in relation to adoptions, to be carefully examined and reviewed, with a view to the introduction of amendments to clarify, and if thought necessary, to strengthen the law of Victoria. Some members of the Committee consider that the criminal law should be amended to make it clearly an offence to enter into, or contribute in any way to, a commercial surrogacy agreement.

4.8 **Surrogacy in IVF.** IVF has made it possible for some infertile women to be helped to achieve not a pregnancy but a child which was genetically theirs. Women with functioning ovaries but without wombs, or with non-functioning wombs, could undergo laperoscopies for ovum recovery. The ova could be fertilized in vitro, and the embryo or embryos transferred to a surrogate mother who had agreed to carry and deliver, in every sense, the child.

4.9 The Committee has been informed that there are several infertile couples who have sought to make or enter into surrogacy arrangements in an IVF programme in Melbourne. The director and staff of the programme have told these couples that such arrangements cannot at present be made. The Committee has
also been informed of a couple in an IVF programme who had agreed to the cryopreservation and storage of an embryo formed from their gametes, after unsuccessful transfers. Soon after the last such transfer, the wife underwent surgery for the removal of a malignant tumour, and subsequently required radiotherapy. She was advised that she should not become pregnant. The wife's two sisters-in-law, who both have established families and do not intend to have more children, have each offered to receive the thawed embryo and if a pregnancy is established, to bear the child and hand it to the woman who would be its genetic mother.

4.10 The Committee notes that surrogacy in IVF may commend itself more than the use of donor gametes in IVF to some couples. A child born would be genetically theirs, and ethical problems about disclosure and identity would be avoided.

4.11 Surrogacy and Commercial Arrangements. The Committee has decided that commercial surrogacy arrangements, that is, where a fee is to be paid to the woman who bears the child, are completely unacceptable as part of an IVF programme in the Victorian community. If the sale of human gametes is characterised as inhuman, then these agreements to bear and then convey a child for a fee are the more so. Whatever terms are employed it seems clear, as has already been stated, that it is the buying and selling of a baby which is really the core of the arrangement. The buying and selling of children has been condemned and proscribed for generations. It should not be allowed to reappear, and no technological assistance, available to
infertile couples, should be afforded to any such arrangements. A hospital licensed to conduct an IVF programme shall not be permitted to make any commercial surrogacy arrangements as part of that programme.

4.12 Volunteer Surrogates. There may be women, besides those who are referred to in the case mentioned in par 4.9, above, who are prepared to bear a child for another woman for reasons of family affection or duty or simply as an act of altruistic service for an infertile member of the same sex. An arrangement that such a woman's medical, hospital and travelling expenses be paid would not result in it being labelled as commercial.

4.13 The Committee realises that such a possibility, within an IVF programme, deserves the most careful consideration. Some members of the Committee have pointed out how the altruistic volunteer may contribute to her own and to the patient's short- and long-term well-being.

4.14 But the Committee has also come to the conclusion that even in this situation very serious problems may arise, and as a consequence, grave harm could be caused to any child born as a result of the arrangement. When the baby is born the woman who carried and gave birth may decide that she cannot, or will not, relinquish. The experiences of some relinquishing mothers in adoption are a clear pointer to what may occur. So are the now much publicised cases of the surrogate mothers who have refused to relinquish the children they bore, in England and very recently
in New South Wales. If there are refusals to hand the child to its father and his wife, the child's genetic mother, these may lead to the kinds of custody conflicts which have already been before the courts in England as a result of a commercial surrogacy arrangement.

4.15 Similarly, if the child is born defective or deformed, or is simply disliked by the couple for some stated or unstated reason, they may reject it. Are they to be legally constrained? It is glib to say then that the Department of Community Welfare Services should be made the responsible guardian. There can be no reasonable comparison between a foundling or abandoned baby and one born after the planned use of advanced scientific and medical techniques employed in an approved programme used to circumvent infertility in a public or private hospital.

4.16 In addition to these concerns, some members of the Committee believe that even where a true volunteer is employed as surrogate and no element of commerce is involved, there is still the deliberate manufacture of a child for others. The Committee has grave doubts whether any such surrogacy arrangements are in the best interests of the child whose birth is so planned.

4.17 The Committee therefore recommends that surrogacy arrangements shall in no circumstances be made at present as part of an IVF programme in Victoria.
5. THE FUTURE.

5.1 Further Issues. The Committee has not been able to consider in any detailed fashion a number of matters identified in its Interim Report, though what appears in Part 3 of the Report will go some way to provide an indication of its views and the attitudes on some matters. Nor has it been able to examine several matters which are related to but separate from IVF. Of these perhaps the most urgent is in vivo fertilization or embryo flushing, a practice already being employed in one infertility clinic in the U.S.A., which one of the IVF groups in Victoria has stated it would be ready to employ if authorised to do so.

5.2 Nor does the Committee consider that its examination of those matters which are the subject of this or its earlier Reports represents the last word on these grave and controversial subjects. In its Report on Donor Gametes in IVF, the Committee said that its "assessment of the understanding and acceptance of the use of donor gametes in IVF in Victoria by the Victorian community is one made as those programmes are either in their earliest stages or just being launched.... Developments in scientific research and in medical and surgical practice may rapidly influence the future conduct of programmes to provide treatment for the infertile, and these may also be influenced by community attitudes." What has happened since that was written leads the Committee to repeat and underscore that statement. The whole range of IVF programmes and practices, and associated
research, continues to produce discussion and debate in the Victorian community and beyond it.

5.3 Managing Developments. The Committee was established at a time when the IVF programmes in Victoria were already firmly in place. Its work, especially its invitations to the Victorian community to provide submissions on the several matters examined in its three Reports, has provided opportunities for public discussion about those IVF techniques already being employed. The publication of its Reports has itself helped to enlarge and deepen that public discussion. What should happen now?

5.4 A Standing Review and Advisory Body on Fertility, Reproduction and Related Matters. The Committee considers that it would be in the best interests of the Victorian community if the Government established a standing review and advisory body which would continue and broaden the work it has already done. It should be empowered to examine and report on all matters in the field of the scientific and medical management of infertility, and related issues. The question of embryo flushing or in vivo fertilization should be one matter considered by such a body, and should not be permitted unless the body so recommends. Other matters which it should consider are embryo cleavage, embryo surgery, and genetic manipulation. The Committee recommends that the Government should proceed to its establishment as soon as possible. This recommendation is in line with similar advice
given in Queensland, and by the Warnock Committee in the United Kingdom.

5.5 The Committee considers that it should not attempt to advise the Government in any detail about the composition of the standing review and advisory body. It should be a multi-disciplinary group, whose members represent a variety of interests in the Victorian community. If it is to be effective it will need the support of an efficient and innovative research, secretarial and administrative unit.

5.6 The standing review and advisory body should be encouraged, within its broad terms of reference, to have both formal and informal meetings not only with scientists and medical personnel working in the areas of its concern but also with a range of interest groups concerned with infertility and reproduction, and with other groups such as those representing the ethnic communities in Victoria. It may be able to play a most important part in the development of the information and education programmes on infertility and its treatment the establishment of which the Committee has so strongly advocated from the outset.

5.7 The Committee advocates that cooperation and collaboration be fostered between the standing review and advisory body and similar bodies in other States and Territories in Australia.
6. SUMMARY OF RECOMMENDATIONS.

6.1 The freezing of embryos formed in an IVF programme shall be permitted in Victoria at present. (par 1.40).

* Rev. Dr. Harman is not in favour of this recommendation: see pars 1.27 to 1.29, and Appendix A.

** Mrs. Hay is only in favour of this recommendation in those circumstances described in par 1.38. And see Appendix B.

6.2 Research on and development of techniques for the freezing and storage of human ova should be warmly encouraged. (par 1.43).

6.3 Freezing and storage of embryos shall only be undertaken in a hospital already approved to conduct an IVF programme, which is specially authorised by the Minister of Health to conduct such activities. (par 2.2).

6.4 No hospital authorised to conduct a cryopreservation programme shall maintain a bank or store of large numbers of frozen embryos from which embryos may be disposed of as the hospital thinks fit. (par 2.3).

6.5 Information and counselling on freezing and storage of embryos shall be made available to couples participating in IVF programmes. (pars 2.4 and 2.5).
6.6 An embryo shall only be frozen and stored if the couple whose gametes have been used in its formation agree to the procedure. The agreement shall be recorded in an appropriate document, which shall state clearly the purpose and the expected duration of the embryo storage. (par 2.7).

6.7 The couple whose gametes are used may not sell or casually dispose of the embryo. (par 2.8).

6.8 The couple shall be required to make their decision about the disposition of the embryo which is to be stored before the procedure is initiated. (par 2.8).

6.9 If the couple agree that an embryo may be donated (in terms of Part 5 of the Report on Donor Gametes in IVF), it shall be permissible, with their consent for that embryo to be stored until the next appropriate reproductive cycle of the woman who is to receive that embryo. (par 2.10).

6.10 Where frozen embryos remain in storage after the establishment of a viable pregnancy, the prior decision of the couple concerning their disposition shall be given effect as soon as possible. (pars 2.11 and 2.12).
6.11 Where a couple consents to long-term storage, that consent shall be reviewed after 5 years, and may then be renewed. (par 2.13).

6.12 The couple shall be required to indicate, by means of the consent document, what the disposition of the stored embryo or embryos shall be in the event of accident, death or dissolution. (par 2.17).

6.13 In any case of accident, death or dissolution where an indication concerning disposition has not been given, the stored embryo or embryos shall be removed from storage. (par 2.18).

6.14 Embryo research shall be limited to the excess embryos produced by patients in an IVF programme. (par 3.26).

* Rev. Dr. Harman and Mrs. Hay are not in favour of this recommendation. They believe that embryos shall not be used for research. (par 3.24 and Appendix A).

** Professor Kincaid-Smith and Professor Pepperell are not in favour of this recommendation. They believe that embryo research should not be limited to excess embryos. (par 3.30 and Appendix C).

6.15 The use of any embryo for research shall be immediate, and in an approved and current project in which the embryo shall not be allowed to develop beyond the stage of implantation, which is completed 14 days after fertilization. (par 3.29).
6.16 All research on human embryos shall be regularly scrutinised by the Health Commission or by a standing review and advisory body. (par 3.32).

6.17 A hospital licensed to conduct an IVF programme shall not be permitted to make any commercial surrogacy arrangements as part of that programme. (par 4.11).

6.18 Surrogacy arrangements shall in no circumstances be made at present as part of an IVF programme. (par 4.17).

6.19 A standing review and advisory body shall be established to examine and report on all matters in the scientific and medical management of infertility, and related issues. (par 5.4).
APPENDIX A

STATEMENT OF DISSENT

BY REVEREND DR. FRANCIS HARMAN

A1.1 For the second time in the life of this Committee I find myself 'alone lorn creetur' like Dickens's Mrs. Gummidge, pleading the human embryo's case for inclusion amongst the liberation movements of our day.

A1.2 The plea is set amidst the dilemmas which the technological imperative is creating, not so much by the speed of developments as by their direction which, like that of a cyclone, determines where the havoc is wrought. When the Committee dealt with the simple IVF case in its Interim Report we were at least still in the area of the human: our central problem was the degree of rupture between the unitive and procreative aspects of the marriage covenant. Later, in the Report on Donor Gametes in IVF, the dividing line between the human and the veterinary, although blurred, was still recognisable. Now the question is whether we should allow that dividing line to be erased and we are being urged to do so by the prospect of eugenic selection and an assurance that the progeny of the petri dish are already super-children.

A1.3 In the context of the Committee's discussions, by the term 'embryo' is understood the entity deriving from the fusion (whether intra-uterine or extra-uterine) of human sperm and ovum throughout that phase of its existence which runs from the
moment of fusion up until the moment of delivery or of death if unfortunately that should precede delivery.

\[ A2.1 \]

Many would hold that this embryo is simply an indeterminate mass of cells with the potential to become human and that this potential cannot translate into actuality until there is some degree of fetal development. This view fragments into a wide spectrum of opinions when it comes to specifying the precise stage of development, with some placing it at implantation, others favouring a time when twinning and recombination are no longer possible, yet others looking to the formation of the cerebral substratum for human thought, and finally others who demand the presence of 'interests' and 'preferences' and require "a concept of self as a continuing subject of experiences and other mental states" and a belief "that it itself is such a continuing entity". This last viewpoint clearly challenges the human biological status not only of the embryo but of anyone who lacks "morally relevant characteristics" (e.g. rationality, self-consciousness, awareness, autonomy, pleasure and pain), or who suffers a substantial decline in or loss of such characteristics at any time after birth. Thus the way is paved for infanticide and euthanasia.

\[ A2.2.1 \]

In my alternative position the early embryo is actually a human cell with the inherent potential to develop that humanness. This diploid is not just a further progression of the haploids (sperm/ovum) but a new entity as distinct ontologically from each haploid as water is distinct from hydrogen and oxygen, and in the
earliest (pre-implantation) phase subsistent in itself but already forming a hormonal bond of a specifically human type with its maternal host. To this basic biological data, rational processes lead theists to add the concepts of creation, ensoulment and immortality; reason enlightened by faith leads Christians to add the concept of redemption; but the common denominator for all is that "intuitively we do not equate a fertilised egg with a hamster or a piece of mouse tissue": (Professor Ian Kennedy in The Times, 26 June 1984). Intuitive that reaction may be, but it does not lose any of its force for that reason since in any moral judgement in the area of basic human values there is a certain prethematic and instinctive component which cannot be totally reflected in analytical discourse or legally accountable terms but which is nonetheless real.

Hence the finding of the New Zealand Royal Commission of Inquiry into Contraception, Sterilization and Abortion (1977): "From a biological point of view there is no argument as to when life begins. Evidence was given to us by eminent scientists from all over the world. None of them suggested that human life begins at any time other than at conception." (At p.184).

If therefore I put the question "What is an embryo?", I am in good philosophical and scientific company by answering "a human life". Can I go further and add another dimension to that question by asking "Who is this embryo?" The element of personhood is now introduced - not personhood in the sense of manifestations of individual temperament and its development into character
(= personality), but personhood in the sense of that quality or attribute which constitutes the radical identity for every human entity. I submit that there are both intra-entity and inter-entity elements which give a high degree of probability, if not certainty, to incipient or rudimentary personhood in the embryo.

A2.3.2 The intra-entity elements are seen in the data supplied by molecular genetics. As soon as the 23 paternally derived chromosomes are united through fertilization to the 23 maternal chromosomes the full genetic information necessary and sufficient to express all the inborn qualities of the new individual is gathered irrevocably in its DNA. In accordance with its code and by interacting with its environment the DNA controls every phase of the development of the individual from conception to death: coloring of eyes, coloring of hair, height and all the other identifying characteristics are already programmed in a cell which truly merits the qualifying adjective "progenitor".

A2.3.3 The inter-entity or relational element derives from the fact that the early embryo is already involved in fundamental human relationships (paternity, maternity, affiliation) which should develop in due course into a network of familial and social links, rights and responsibilities as person-in-community.

A2.3.4 The progenitor cell is therefore already on the way to the fuller expression of personhood, directed by its own nature to a progression or continuum through implantation and gestation to delivery and beyond even if through other factors it fails to reach
term. In other words, such terms as 'zygote', 'embryo', 'fetus' merely indicate successive stages of development in exactly the same way as do the terms 'infancy', 'childhood', 'adolescence': in fact, it has been observed that the dramatic changes and outpouring of 'new' chemical signals at puberty is no less amazing than the multiplication and differentiation of the cells from a single fertilized ovum, but no-one asserts that a 'different' being is formed. During the individual's progressive biography the underlying life is a constant. Morphological structure may change; consciousness may fluctuate; the potential may develop in one way or another; but the identity remains the same. Philosophically therefore, and with a sound scientific basis, it is at least highly probable that the combination of human biological entity plus sharply identified individual genetic characteristics plus basic relational framework constitutes rudimentary or incipient personhood and justifies putting about the early embryo the question "Who is it?".

A3.1 Next we can move from the area of fact into the area of values and ask what moral (as distinct from biological) status the human embryo merits. Those who deny it humanness up until a particular stage of fetal development will not concede moral status up until at least the same stage; in fact, the most recent suggestion amongst those who look to a pre-natal moment is the beginning of the growth of head and limbs (See The Age 23 June 1984).
Because of the important role played by the National Health and Medical Research Council (NH&MRC) on the Australian scene, one cannot fail to take cognisance of and comment on the formula prepared for and accepted by that body, viz.: "Embryos derived from human sperm and ova should be treated with respect, but that respect need not encompass the full rights attributed to persons." With respect I submit the following observations:

A3.2.1 The NH&MRC formula is negative and nebulous in its expression, offering no clear determination in positive terms of the respect it professes.

A3.2.2 It is proferred gratuitously with no supporting argumentation of any profundity to indicate why it concedes an indeterminate respect and why it draws an indeterminate limit on that respect.

A3.2.3 It conflicts with the basic principles of the art of logic insofar as it accepts as an underlying premise something unproven and unprovable viz.: that the embryo does not possess incipient personhood.

A3.2.4 In its applications it adopts arbitrarily a fluid concept of humanness, as though a post-implantation embryo could somehow be 'more human' than it was in the pre-implantation phase and become progressively 'more human' as gestation continues. Ian Kennedy in The Times article already quoted shows graphically how fundamentally offensive to our human instincts is this sort of
suggestion: "Let us accept for the moment the minimum criterion of humanness now commanding agreement, namely the capacity for sentience or the development of the nervous system. Let us further imagine that a technique was developed which could inhibit or prevent the development of the brain or nervous system but otherwise allow for normal development of the embryo. Would it then be morally licit to experiment on such embryos, intentionally crippled so that they could never meet the criterion of humanness? The response would undoubtedly be one of outrage. On analysis such outrage would seem to rest on the wrongness of interference with the potentiality to develop further."

As an alternative to any unsubstantiated devaluation of the worth or moral status of the embryo, I recall firstly the biological fact that embryos are not tumours nor amoebae nor fish nor quadrupeds but human lives and secondly the high probability, if not certainty, that they possess ab initio rudimentary or incipient personhood. Because of the biological fact the element of justice must be inherent in all dealings on embryos; because of the probability of personhood the element of prudence or reasonable care must likewise be inherent in all those dealings. This means, negatively, that embryos cannot be considered as chattels, and any intervention of the law of property other than to protect their entitlements, e.g. of inheritance, would be incongruous;
positively it would appear to indicate that the appropriate control
over embryos in our culture and law should be that of trustee,
with the corollary that trusteeship must always be exercised in
the interests of the object of the trust and in accordance with the
prudence or reasonable care of the common man.

A3.3.2 If we try to fit the concept of the embryo's humanness and
rudimentary personhood into the context of law we will find not
full confirmation but at least in civil law a recognition that the
embryo's membership of the species *homo sapiens* is a radical
basis of rights, and in criminal law an admittedly minimal but
nonetheless discernible degree of protection from the first
moment of gynaecologically recognisable existence which, in the
present state of the art, means relatively soon after implantation
and certainly some time prior to sentience or cortical formation.

A4.1 We can now proceed to ask for what purposes may those embryos
be used which are formed in excess of the number required for
the immediate and direct circumvention of infertility? As
current discussion in the community indicates, the question is far
from oratorical and has refreshed in our minds Shakespeare's
dictum that unnatural deeds do breed unnatural troubles.
Perhaps, however, there has been some injustice in placing only
the research scientists at the centre of the discussion. If their
ethical decisions have, to use a phrase from Ian Kennedy's
*Unmasking of Medicine*, "been made in a rather haphazard and
idiosyncratic way", responsibility must also be shared by the
NH&MRC, whose guidelines permit such research and by
institutional ethics committees which have approved it. It would be an interesting exercise in the domain of freedom of information for the community to learn just what projects in the general area of genetic experimentation have in fact been submitted or suggested.

A4.2 Some of the experimental issues have already been dealt with in the Committee's earlier Report on the use of donor embryos for synchronised implantation into an alien womb. In the present context I would submit that to bring embryos into existence and freeze them for the purpose of taking advantage of the outcome of superovulation and holding them as an insurance against actual or conjectural infertility is to derogate grossly from their intrinsic worth; it reduces them to the level of objects for the satisfaction of others (who may or may not have contributed genetically) while simultaneously placing their vital continuance in serious jeopardy, as the statistics show. To bring them into existence solely for the purpose of experimentation would be still more reprehensible, giving grimmer meaning than he ever contemplated to Thomas Hood's lines:

"Oh God! that bread should be so dear,
and flesh and blood so cheap!"

A4.3 The argument of the NH&MRC and of those who endorse its guidelines is strictly utilitarian. The NH&MRC does indeed have the grace to recognise that there is an alternative ethical framework but then proceeds to ignore its criteria even though they are held by a broad cross-section of the community. I
believe that philosophically utilitarianism is vitiated by the inherent logical defect of trying to commensurate incommensurables. But even on the utilitarian calculus "society is still required to weigh up its commitment to humanness: do we prefer the interests of future children or of science against the interests of a miniscule entity just because it is miniscule and intensely vulnerable?": (Ian Kennedy, The Times, 1.c.).

A4.4 A correspondent in The Australian (4 January 1984) quoted George Bernard Shaw as having said "atrocities are not less atrocities when they occur in laboratories and are called medical research". The correspondent was defending animal rights. I do not know if GBS in fact used the phrase, but if it is worth quoting in the cause of humanity's duties towards other species it is a fortiori worth quoting in the cause of humanity's duties to its own.

A5 If, therefore, the technological formation of embryos is to be allowed, should it be in numbers in excess of those destined for the direct and immediate circumvention of infertility? The simple answer is "No"!
APPENDIX B

STATEMENT OF DISSENT ON FREEZING AND STORAGE OF EMBRYOS

BY MRS. JASNA HAY

B1.1 I have personal reservations about the ethical issues related to freezing. My reasons for restricting embryo freezing to those specific cases where immediate transfer is not possible due to medical complications, such as bleeding, are based on a firm belief that long-term freezing of embryos and the development of embryo banks is not in the best interests of the community nor of the child. In those very limited instances, the storage of the embryo would be only until the next normal cycle of the woman.

B1.2 This view is largely supported by the Committee which has stated that there shall be no banks or store of frozen embryos, and that storage is to be for the shortest possible time. The recommended limitations proposed, however, by the Committee do not, in my opinion, adequately ensure that the objectives stated will be achieved. It seems to me inevitable that frozen embryo banks will develop as a result of the Committee's recommendation which states that if transfer is successful (or in the event of accident death or dissolution), the couple's decision that the embryo should be donated, or used in relation to experimental work in connection with an I.V.F. programme, or removed from storage, will be implemented.
B1.3 The number of embryos which will be made available under the first two options will be unpredictable, but the most likely outcome will be a gradual build up of frozen embryos, because in respect to the first disposition option, it allows for a couple to donate embryos without a specific nominated recipient.

B2.1 The Committee has concluded that storage should be for the shortest possible time in relation to the circumstances of the couple who have agreed that their embryo be stored. That period will be determined, however, by medical and/or non-medical grounds which could be very subjective. Such a recommendation leaves open a most elastic interpretation, which may inadvertently bring about a development quite contrary to the statement of opposition to long-term storage.

B2.2 Whatever recommendations are finally accepted in respect of freezing and storage will materially influence the direction of IVF programmes in the future.

B3.1 Current developments using ultrasound for ovum collection, which could render laparoscopies unnecessary, together with the recent discovery that the freezing of ova may be possible, without significant damage being caused to them, suggest that freezing of embryos may soon be unnecessary except in the very limited instances where I support its use. There is a significant danger that freezing and storage will become the focus and an integral part of IVF programmes and these other options which seem so promising may be disregarded or forgotten.
Freeze-thawing techniques have long term broader implication for future human reproduction, and for this reason any recommendations must be viewed in the widest context.
APPENDIX C

STATEMENT OF DISSENT ON EMBRYO RESEARCH

BY PROFESSOR PRISCILLA KINCAID-SMITH AND

PROFESSOR ROGER PEPPERELL

C1.1 We believe that embryo research should not be limited to excess embryos, but that it is ethically acceptable for embryos to be created purely for research purposes.

C1.2 The number of excess of embryos available for embryo research is insufficient to enable embryo research to proceed. With the success of embryo freezing, most patients in IVF programmes now want all of their excess embryos frozen for future use by themselves. Prior to successful embryo freezing, many were happy for some of their excess to be used for research purposes.

C1.3 Restriction to the use of excess embryos would mean that most aspects of research could not proceed. This particularly applies to the techniques of ovum freezing, improving the fertilizing capacity of sperm from infertile men, improving the fertilizability of the immature ovum, embryo division and genetic research. In each of these instances the ovum must be fertilized and the normality of fertilization and subsequent development proven before embryo transfer may be allowed. As has been pointed out in the Report, transfer of embryos before normality has been proven by preliminary embryo research procedures could well be associated with an increased number of congenital malformations.
Although IVF in animal models, for example in the mouse or the rhesus monkey, may allow the above research areas to be evaluated, even the rhesus monkey is different from the human, and direct interspecies extrapolation is not necessarily possible and is often misleading.

The IVF teams in Victoria have been responsible in their research on embryos and there is no reason to suspect this state of affairs will change. In the past, the use of embryos has been restricted to the bare minimum required to answer the scientific question posed, with the main objective of the research being to improve the results of the clinical IVF programme. Had such research not been done, successful IVF and embryo transfer would probably not exist and certainly successful pregnancies following embryo freezing would not have occurred.

To prevent the continued advance in the improvement of IVF, including the advances referred to in Part 3 of the Report, would itself be contrary to a humanitarian view on the value of human life. This particularly applies where techniques for prevention or correction of disease or congenital malformation, or attempts to improve the pregnancy chances for the infertile male and female, are unable to proceed.

While accepting that experiments on human embryos are necessary for the advancement of medical knowledge in important areas for the benefit of mankind, we endorse the
principle of the sanctity of human life at all stages, and consider that experiments involving the destruction of human embryos should never be undertaken lightly, but should be performed so that the scientific information being derived is commensurable with the procedures adopted. To this end, it is recommended that the detailed planning and execution of such experiments should remain, as at present, under the continual surveillance of expert scientific and ethical committees so that the procedures are carried out to achieve the maximum scientific gain with the minimum number of embryos involved.

C2.4 Ethical regulation of scientifically sound research is possible, with culture of the embryo produced in vitro beyond the implantation stage being made unlawful: see the Warnock Committee's majority recommendation, referred to in Part 3 of the Report. Such regulation could be in the hands of the standing review and advisory body the establishment of which is recommended in Part 5 of the Report. Informed consent must play an important part in every aspect of human gamete and embryo research and guidelines for such research and for the protection of egg-sperm donors, scientists, doctors and the hospitals involved must and may be readily developed.

C2.5 Finally, it should be pointed out a pluralist society such as that found in Victoria is understandably divided in its views about the status of a human embryo, and about the extent to which it commands respect and protection. In these circumstances it
would seem inappropriate to prevent scientists from acting in good conscience to form embryos for research from which the whole community may well benefit.
APPENDIX D

SUBMISSIONS RECEIVED

ALDONS, Mr. T., East Malvern, Victoria.
ALLEN, Mrs. A., Brighton, S.A.
ANDERSON, Ms. S., Fairfield, N.S.W.
ANGLICAN CHURCH OF AUSTRALIA, Social Responsibilities Commission, Melbourne.
ANGLICAN DIOCESE OF MELBOURNE, Social Questions Committee;
St. Paul's Cathedral, Melbourne.
ARCHBISHOP SIR FRANK LITTLE - On behalf of the Catholic Bishops of Victoria.

BERMAN, Mrs. C., Kilaben Bay, N.S.W.
BRUMBY, Dr. M., Faculty of Education, Monash University,
                     Clayton, Victoria.
BURTON, Mr. and Mrs. R., Round Corner, N.S.W.

CATHOLIC WOMEN'S LEAGUE of VICTORIA and WAGGA WAGGA - Social Questions Committee.
CATHOLIC WOMEN'S SOCIAL LEAGUE, Cohuna, Victoria.
CHRISTIAN PRO-FAMILY FORUM, Ringwood, Victoria.
COLE, Ms. P., Avalon, N.S.W.
COTTERILL, Mr. and Mrs. S. M., Werribee. Victoria.

FERME, Mrs. M., Elsternwick, Victoria.
FORTSCH, Ms. P., Eastwood, N.S.W.
GILL, Mr. J., Mt. Waverley, Victoria.

HAMILTON, Dr. P. A., East Malvern, Victoria.

HARLOCK, Ms. R., South Morang, Victoria.

HAY, Dr. D. A., Department of Genetics and Human Variation, La Trobe University, Bundoora, Victoria.

HICKEY, MRS. T., North Croydon, Victoria.

IVF FRIENDS, Round Corner, Sydney, N.S.W.

JOSHUA, Dr. P., Box Hill.

MAHER, MR. F. K. H., Former Reader in Law, Melbourne University.

MARSHALL, Rev. Dr. S., Essendon, Victoria.

MENDES, Mr. D., Parkdale, Victoria.

MENDOZA, Mr. S., Heidelberg, Victoria.

MIHAN, Mrs. D., Meeniyan, Victoria.

NATIONAL COUNCIL OF WOMEN of VICTORIA, Melbourne.

PACKER, Mrs. C. T., Bethanga, Victoria.

PRO-LIFE, Victoria. (2)

RIGHT TO LIFE, Victoria. (2)

RYAN, Mr. A. J., East Bentleigh, Victoria.

ST. VINCENT'S BIO-ETHICS CENTRE, Melbourne.
SANTAMARIA, Dr. J.N., Chairman, St. Vincent's Bio-Ethics Centre, Melbourne.

SALESIAN THEOLOGICAL COLLEGE, Oakleigh, Victoria.

SIEWRUK, Mr. V., Newnham, Tasmania.

SINCLAIR, Mr. and Mrs., Glen Waverly, Victoria.

SINGER, Professor P., Monash University, Clayton, Victoria.

VILKELIS-CURAS, Mr. M., Mildura, Victoria.

WOMEN WHO WANT TO BE WOMEN, Melbourne.

WOMEN'S REFUGE REFERRAL SERVICE, North Melbourne, Victoria.

WOOD, Professor C., Department of Obstetrics and Gynaecology,

Monash University, Queen Victoria Medical Centre, Melbourne.
## APPENDIX E

**PRESENTATIONS MADE TO THE COMMITTEE**

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<thead>
<tr>
<th><strong>DR. A. LOPATA</strong></th>
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<tr>
<td><strong>Date of Presentation:</strong></td>
<td>1 December, 1983.</td>
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<tr>
<td><strong>Position:</strong></td>
<td>Human Reproductive Biology Unit, Royal Women's Hospital.</td>
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<tr>
<td><strong>Subject:</strong></td>
<td>Embryo formation and medical research.</td>
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<th><strong>REV. DR. J. D. McCaughey</strong></th>
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<td>1 December, 1983.</td>
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<tr>
<td><strong>Position:</strong></td>
<td>Theologian, Melbourne (Member of the NH&amp;MRC's Medical Research Ethics Committee).</td>
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<tr>
<td><strong>Subject:</strong></td>
<td>Ethical issues in relation to embryos.</td>
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<tr>
<td><strong>Position:</strong></td>
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<tr>
<td><strong>Subject:</strong></td>
<td>Ethical and legal issues in relation to embryos.</td>
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<td><strong>Date of Presentation:</strong></td>
<td>1 December, 1983.</td>
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<tr>
<td><strong>Position:</strong></td>
<td>Scientific Director, Infertility Services, Queen Victoria Medical Centre.</td>
</tr>
<tr>
<td><strong>Subject:</strong></td>
<td>Embryo formation and medical research.</td>
</tr>
</tbody>
</table>
PROFESSOR B. MORRIS.

Date of Presentation: 22 February, 1984.
Position: Professor of Immunology,
           John Curtin School of Medical Research,
           Australian National University, Canberra.
Subject: Embryology and genetic research.

DR. R. ROWLAND

Date of Presentation: 14 June, 1984.
Position: School of Humanities, Deakin University.
Subject: Moral and social issues in embryo research and IVF.
APPENDIX F
LETTERS RECEIVED BY THE COMMITTEE
IN THE COURSE OF ITS WORK ON THE REPORT

ANDRAYLE, Ms. K., Mulgrave, Victoria.
BAKER, Mr. A., Pro-Life, Victoria.
BOURKE, Mr. & Mrs. F., Charlton, Victoria.
BOYD, Mrs. P., Women Who Want To Be Women, Victoria.
BURTON, Mrs. B., Round Corner, N.S.W.
BYRNE, Mrs. J., Rupanyup, Victoria.
CARSON, Mrs. A. Thornbury, Victoria.
CLEARY, Mrs. G., Bunyip, Victoria.
CLIFFORD, Ms. N., East Preston, Victoria.
COUGHLAN, Ms. A., Hawthorn, Victoria.
CROFT, Ms. B., Frankston, Victoria.
DEVER, Mr. F., Wallabi Point, N.S.W.
DESHER, Ms. A., Brunswick, Victoria.
DUFFY, Mrs. M., Garfield, Victoria.
FALLOW, Ms. H., Albert Park, Victoria.
FEENY, Mrs. N., St. Arnaud, Victoria.
FOSTER, Mrs. B., Reservoir, Victoria.
FELTHAM, Ms. V. J., Bunyip, Victoria.
FOSTER, Mrs. B., Reservoir, Victoria.
FULLER, Mr. G., Melbourne, Victoria.
GREAVES, Mrs. R., Reservoir, Victoria.
HANRAHAN, Mrs. A., Reservoir, Victoria.
HOWELLS, Rev. J. St. Q., Newtown, Victoria.
HUDSON, Dr. K., Briar Hill, Victoria.
HULL, Ms. J. M., Glen Iris, Victoria.
JOHNSON, Ms. H., Northcote, Victoria.
JONES, Dr. C. G., Clifton Hill, Victoria,
JOY, Ms. R., Women's Refuge Referral Service, North Melbourne, Victoria.
LADSON, Ms A., Cohuna, Victoria.
LYNN, Ms. A., East Preston, Victoria.
McALISTER, Mrs. M. J., Wagga Wagga, N.S.W.
McCARTHY, Ms. K., Glen Iris, Victoria.
McEACHERN, Mrs. T. M., Albury, N.S.W.
McKAY, Ms. F. R., Launceston, Tasmania.
MORONEY, Ms. H. W., Rye, Victoria.
NATIONAL COUNCIL OF WOMEN OF VICTORIA, Melbourne, Victoria.
NEWMAN, Mr. J., Ayr, Queensland.
O'CONNOR, Ms. A., East Brunswick, Victoria.
O'CONNOR, Mrs. B., Bunyip, Victoria.
O'KEEFFE, Ms M., Terang, Victoria.
PAGON, Ms. L., Reservoir, Victoria.
PAUL, Ms. B., Newtown, Victoria.
PEARSON, Mrs. B., Gunbower, Victoria.
PHYLAND, Mrs. L. Phyland, Cohuna, Victoria.
RAMP, Ms. E., Northcote, Victoria.
RICHMOND, Mrs. K., Watchem, Victoria.
RODAUGHAN, Mr. & Ms. M., Reservoir, Victoria.
ROSS, Ms. P., Brunswick, Victoria.
RYAN, Mrs. A., New Gisborne, Victoria.
RYAN, Mrs. E., Old Bar, N.S.W.
SMITH, Ms. L., Northcote, Victoria.
SNELL, Mrs. L., Mulgrave, Victoria.
SOFO, Ms. M., Address not disclosed.
SULLIVAN, Mrs. J., Yarrawonga, Victoria.

TASKIS, Mrs. J. M., Pakenhan, Victoria.

TYLER, Mrs. P., Maryknoll, Victoria.

WILSON, Mr. P. J., General Manager, Epworth Hospital, Richmond, Victoria.

WOOD, Professor C., Melbourne, Victoria.

WOPPENKAMP, Mrs. F., Clayton, Victoria.
APPENDIX G

PAPERS and ARTICLES TABLED and RECEIVED


BRUMBY, Dr. M., "Australian Community Attitudes to Embryo Freezing and Experimentation". 1984.*


DOWNING, B., ROGERS, P., TROUNSON, A., WOOD, C., "Clinical Implications of Developments Associated With the Technique of In Vitro Fertilization".*


KENNEDY, Professor I., "Let the law take on the test-tube", The Times, 26 May, 1984.


MORRIS, Prof. B., "Unnatural Selection and the Destiny of Humanity".*

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, Medical Research Ethics Committee, "Report on Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue", October 1983.


TROUNSON, Dr. A., "Annual Report to Queen Victoria Medical Centre, Epworth Medical Centre, Monash University Ethics Committees as required by the N.H. and M.R.C. Guidelines (Supplementary Note 4)".

WALLER, Professor L., "Borne for Another", Eighth Oscar Mendelsohn Lecture, Monash University, 1 March 1984.*

WARNOCK, M., "In Vitro Fertilization: The Ethical Issues (II)", The Philosophical Quarterly, Vol. 33 No. 132.

WOOD, Prof. C., "Embryo Research in Perspective."*

*All references marked with an asterisk were unpublished at the time of preparation of this Appendix.