

NSW Law Reform Commission

REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

Table of Contents

Table of Contents	1
Terms of Reference and Participants	2
Artificial Conception Reference Publications	5
Table of Abbreviations	6
Glossary	8
Membership of the Commission	10
1. Background to Report	11
2. The Current State of IVF Regulation	14
3. Submissions, Debate and Principles	20
4. A NSW Model for Regulation	30
5. Recommendations	34
Appendix A - Minority Opinion on Embryo Research	57
Appendix B - Schedule of Organisations and Persons Who Made Submissions	67
Appendix C - Select Bibliography	70

Terms of Reference and Participants

New South Wales Law Reform Commission

To the Honourable J R A Dowd LLB, MP,

Attorney General for New South Wales

ARTIFICIAL CONCEPTION

IN VITRO FERTILIZATION

Dear Attorney General,

We make this Report pursuant to the reference from the late Honourable D P Landa LLB, MP Attorney General for New South Wales, to this Commission dated 5 October 1983.

Helen Gamble

(Chairman)

Eva Learner

(Commissioner)

Keith Mason QC

(Commissioner)

Susan Fleming

(Commissioner)

TERMS OF REFERENCE

1. To inquire into and report on the need to make laws on:

(i) Human artificial insemination (AI).

(ii) In vitro fertilization of human ova with human sperm (IVF) and transfer of the resulting embryo to the human uterus (ET).

(iii) Any other procedure whereby human ova may be fertilized otherwise than by sexual intercourse.

(iv) Any other procedure whereby the process of human reproduction may be commenced, continued or completed otherwise than in the body of a human female.

(v) The preservation of human ova, human sperm and human embryo outside the human body.

(vi) "Surrogate mothering" arrangements (arrangements under which a woman agrees to bear a child for another person or persons).

(vii) Any other related matter.

2. To include in its report recommendations on the extent and nature of any recommended laws.

3. In making its inquiry and report the Commission may take into account the extent that it decides is necessary or desirable:

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

- (i) Social, ethical and legal issues related to the subjects described above.
- (ii) Any form of artificial conception of a human child that it considers relevant.
- (iii) The public interest and the interests of children, parents, infertile couples, and any other relevant person.
- (iv) The nature of and issues raised by arrangements and agreements relating to any of the subjects described above, and to any child that may be born as a result.
- (v) The legal rights and liabilities of medical and other personnel involved in such practices and other related practices.
- (vi) Present laws including laws concerning children, including custody, adoption, inheritance and anti-discrimination, ownership of and dominion over human tissues, and the treatment of human infertility.
- (vii) Proposals and activities in relation to the subjects described above under consideration by the Standing Committee of Attorneys General, and by any Committee or other Organisation established in Australia by a State or Territory or by the Commonwealth.

D P Landa

Attorney General and Minister of Justice

5 October 1983

PARTICIPANTS

Commissioner-in-charge of Reference

Russell Scott (until 17 June 1988)

Ms Helen Gamble (from 17 June 1988)

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Artificial Conception Reference Publications

The following have been published in the course of the Artificial Conception Reference.

Discussion Papers

New South Wales Law Reform Commission, *Human Artificial Insemination: Discussion Paper 1* (DP 11, 1984).

New South Wales Law Reform Commission, *In Vitro Fertilization: Discussion Paper 2* (DP 15, 1987)

Booklets

New South Wales Law Reform Commission, [*Human Artificial Insemination Public Hearings \(Sydney, 16 April 1985\)*](#)

New South Wales Law Reform Commission, [*In Vitro Fertilization Public Hearing \(Sydney, 15 April 1988\)*](#)

Report

New South Wales Law Reform Commission, [*Human Artificial Insemination \(LRC 49, 1986\)*](#).

Research Report

New South Wales Law Reform Commission, *Surrogate Motherhood: Australian Public Opinion* (RR2, 1987).

Table of Abbreviations

AI	Human artificial insemination
AI Discussion Paper	New South Wales Law Reform Commission Discussion Paper 1 <i>Human Artificial Insemination: Discussion Paper 1</i> (DP 11, 1984)
AI Report	New South Wales Law Reform Commission Report <i>Human Artificial Insemination Report</i> (LRC 49, 1986)
Family Law Council	A sub-committee of the Family Law Council was established in 1984 to prepare a report relating to AID, IVF, Embryo Transfer, surrogate arrangements and related matters, chaired by the Honourable Mr Justice Asche. The Family Law Council is currently chaired by the Honourable Mr Justice Nygh
Family Law Council	Family Law Council <i>Creating Children: Report A uniform approach to the law and practice of reproductive technology in Australia</i> (July 1985)
ET	Embryo Transfer
IVF	Human in vitro fertilization
IVF Audit Report	National Health and Medical Research Council In Vitro Fertilization Centres in Australia: Their Observance of the National Health and Medical Research Council Guidelines (1987)
IVF Discussion Paper	New South Wales Law Reform Commission Discussion Paper 2 <i>In Vitro Fertilization</i> (DP 15, 1987)
MREC	Medical Research Ethics Committee of the National Health and Medical Research Council
NHMRC	National Health and Medical Research Council
National Perinatal Statistics Unit Report (1984)	National Perinatal Statistics Unit/ Fertility Society of Australia In Vitro (1984) <i>Fertilization Pregnancies Australia 1980-1983</i> (1984)
National Perinatal Statistics Unit Report (1984)	National Perinatal National Perinatal Statistics Unit/ Fertility Society of Australia <i>IVF Pregnancies Australia and New Zealand</i> (1985)
National Perinatal Statistics Unit Report (1987)	National Perinatal National Perinatal Statistics Unit/ Fertility Society of Australia <i>In Vitro Fertilization Pregnancies Australia and New Zealand 1979-1985</i> (1987)
Ontario Report	Ontario Law Reform Commission <i>Report on Human Artificial Reproduction and Related Matters</i> Volumes I and II (1985)

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

Senate Select Committee Report	Senate Select Committee on the Human Embryo Experimentation Bill 1985 <i>Human Embryo Experimentation in Australia</i> (September 1980)
South Australian Report	Select Committee of the Legislative Council on Artificial Insemination by Donor, In-Vitro Fertilization and Embryo Transfer Procedures and related matters in South Australia. <i>Report</i> , (April 1987)
United Kingdom Committee	Committee of Inquiry into Human Fertilization and Embryology, chaired by Dame Mary Warnock DBE
United Kingdom Report	Report of the Committee of Inquiry into Report <i>Human Fertilization and Embryology</i> July 1984)
Victorian Committee	Report of the Committee to Consider the Social, Ethical and Legal Issues Arising From In Vitro Fertilization, chaired by Professor Louis Waller
Victorian Report (1982)	The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization <i>Interim Report</i> (September 1982)
Victorian Report (1983)	The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization <i>Report on Donor Gametes in IVF</i> (August 1983)
Victorian Report (1984)	The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization <i>Report on The Disposition of Embryos Produced by In Vitro Fertilization</i> (August 1984)

Glossary

AI

The placement of sperm or semen within the vagina or cervix of a woman by artificial means.

Conception

Traditionally, used to refer to "the act of becoming pregnant" without further particularity. In this Paper, we use this term to refer to the fertilization of an ovum by a sperm.

Cryopreservation

In this Report, the freezing of reproductive tissue for storage purposes.

Ectopic Pregnancy

Implantation of the fertilized ovum outside the cavity of the uterus.

Embryo

Strictly, the term "embryo" refers to that period of development between the fourth and eighth weeks after fertilization has occurred. However, in the debate surrounding IVF it has been used to describe the fertilized ovum.

Fallopian Tube

Uterine tube through which an ovum released from the ovary is conveyed to the uterus, and where conception normally takes place.

Fertilization

The process which begins when a single sperm passes through the outer coat of the ovum. This process is not instantaneous, but can take 22 to 30 hours to complete.

Foetus

The developing human life from the end of the eighth week after fertilization to the moment of birth.

Follicle

A small sac within the ovary which contains the developing ovum.

Gamete

An ovum or a sperm.

Gamete Intra-Fallopian Transfer (GIFT)

Medical procedure of placing ova and sperm in the Fallopian tubes of a woman to bring about fertilisation.

Gynaecology

A branch of medicine dealing with the female reproductive tract.

In Vitro Fertilization

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

Human fertilization outside the body, and includes recently developed techniques for transferring fertilized eggs and early embryos to the fallopian tubes instead of the uterus, such as zygote intra fallopian transfer (ZIFT), pro-nuclear stage ovum transfer (PROST), tubal embryo stage transfer (TEST) and fallopian embryo transfer (FET).

Ovary

One of the paired reproductive glands in the female, containing the ova.

Ovum

The female sex cell produced in the ovary (plural, ova).

Semen

Fluid secretion containing sperm that is emitted during ejaculation.

Sperm

The male gamete(s) produced in the testicle. Strictly, spermatozoon (singular) and spermatozoa (plural).

Uterus

The womb, a hollow muscular organ in which the fertilized ovum may implant and develop into a foetus.

Membership of the Commission

The Law Reform Commission is constituted by the Law Reform Commission Act 1967. The members of the Commission are:

Full-time Commissioners

Ms Helen Gamble (Chairman)

Russell Scott (Deputy Chairman to 17 June 1988)

Paul Byrne

Part-time Commissioners

Dr Susan Fleming

Dr John Carter

Mr J L R Davis

Professor Brent Fisse

Greg James QC

Eva Learner

Mr Keith Mason QC

The Honourable Justice Jane Mathews

Professor Colin Phegan

The Honourable Mr Justice Andrew Rogers

Mr Ronald Sackville

Mr H D Sperling QC

The Honourable Mr Justice J R T Wood

1. Background to Report

I. INTRODUCTION

A. The Reference

1.1 On 5 October 1983 the then Attorney General, the Hon D P Landa, MP, referred to this Commission a number of matters that the Commission has collectively entitled *Artificial Conception*. The terms of reference are set out in the preliminary pages to this report.¹ The reference arose out of previous work done by the New South Wales Advisor; Committee on Human Artificial Insemination,² and the Commission decided to divide its subject matter into three parts:

human artificial insemination;

in vitro fertilization; and

surrogate motherhood.³

1.2 The first project, human artificial insemination (AI), has been completed. The report *Human Artificial Insemination*⁴ was presented to the Attorney General in June 1986 and was preceded by a substantial discussion paper published in December 1984.⁵ The report was published by the Commission with the consent of the Attorney General in July 1986 and tabled by him in Parliament on 28 May 1987. It was accompanied by draft legislation. The surrogate motherhood project is still in progress. In May 1987 the Commission published a research report on Australian public opinion on surrogate motherhood.⁶ A discussion paper on the matter is due to be released in late July 1988.

1.3 In July 1987 the Commission published a substantial discussion paper entitled *In Vitro Fertilization*.⁷ The paper provided background information relating to the medical practice of IVF, outlined legislative and non-legislative responses to IVF in Australia, reviewed the moral, ethical and social arguments for and against and presented in detail issues for law reform. The paper sought submissions from the public.

1.4 The Commission's policy in the inquiry into in vitro fertilization has been to integrate three major events, namely publication of the discussion paper, the consultation period which was formally concluded by a public hearing and this report. Accordingly, there is extensive reference in this report to the IVF discussion paper and an attempt has been made to keep repetition of material to a minimum.

B. Principles of Reference

1.5 The principles on which the Commission has conducted the reference were settled in the report on Artificial Conception.⁸ Those principles continue to guide our work. They are:

It is desirable, where possible, to alleviate the consequences of infertility through practices such as AI and IVF.

The paramount consideration in the practice of AI and IVF shall be the welfare of the child.

The formation of stable families is socially desirable and necessary.

Personal freedom and individual autonomy should, so far as possible, be respected.⁹

C. Membership of the Commission

1.6 The members of the Artificial Conception Division of the New South Wales Law Reform Commission who have produced this report are:

Ms Helen Gamble, Chairman of the Commission and Commissioner-in-charge of the Artificial Conception reference.

Dr Susan Fleming, Obstetrician and Gynaecologist.

Eva Learner, Social Worker.

Mr Keith Mason QC, Solicitor General for New South Wales.

1.7 Mr Russell Scott resigned as Deputy Chairman of the Commission on 17 June 1989 in order to take up a consultancy in the private legal profession. He was Commissioner-in-charge of the Artificial Conception reference from its inception in October 1983 until the date of his resignation. He presided over the Human Artificial Insemination project (now completed) and had a considerable influence on the direction and content of the IVF project.

1.8 Mr Scott was a member of the Commission when most of the recommendations in this report were formulated. Where recommendations have been altered or added after Mr Scott's departure, this is indicated in the report. Otherwise, the recommendations are reported as having come from the Division as it was constituted at 17 June 1988. As the writing of this report had not been completed before Mr Scott left the Commission, the reasons given for the recommendations do not necessarily represent his views.

1.9 The Hon Justice Peter Nygh was a member of the Division until his resignation on 12 November 1986 upon his appointment as Chairman of the Family Law Council.

II. PUBLIC CONSULTATION

1.10 Copies of the IVF Discussion Paper were distributed in July 1987. A public hearing was conducted by the Commission at the Assembly Hall, University of Sydney Law School on 15 April 1988. The hearing was well publicized and attended by members of the public and interested groups. Twenty five oral submissions were delivered and a full transcript of the proceedings was made. The public hearing provided a forum in which members of the public could express views and make a direct contribution to the process of law reform. The Commission has carefully considered the views expressed both at the hearing and in the written submissions and is grateful for the efforts of and interest shown by those individuals and interested groups who made submissions.

III. THE RESEARCH PROGRAM

1.11 In formulating its opinions, the Commission has also sought to inform itself from several additional sources including:

Literature Search: We have collected and examined a large amount of written material from Australian and overseas sources, ranging from scholarly and scientific publications to press reports which have been systematically accumulated and recorded. A select bibliography of this material appears in Appendix C.

IVF Questionnaire: In order to obtain up-to-date information on the incidence and practice of IVF, the Commission distributed questionnaires to IVF clinics in both NSW and interstate.

Observation Visits: Apart from the direct acquisition of information by letter and telephone, we also visited a number of prominent IVF clinics and interviewed the principals and staff involved in the program.

Examination of Existing Laws: We have collected information about legislation on IVF enacted in Australia and overseas and have made comparative studies. This comparative work has also involved examination of reports of a number of official and government inquiries into IVF conducted in Australia, North America, Europe and the United Kingdom.

IV. THE PRACTICE OF IVF

1.12 In vitro fertilization is a medical procedure, whereby a human ovum is surgically recovered from a woman's ovary and fertilized by human sperm in a laboratory dish. The resultant fertilized ovum is then transferred to the woman's uterus in the expectation that it will thereafter implant and develop as in a normal pregnancy. The

procedure and its techniques depend for success upon many factors including careful monitoring of the patient's hormonal levels, and the timing both of the ovum removal and its transfer after fertilization.

1.13 The practice of IVF often involves a husband and wife supplying their own reproductive tissues. The fertilized ovum (embryo) will be transferred to the uterus of the wife in the expectation that she will become pregnant. Variations may occur such as the use of donated gametes or the involvement of unmarried couples or individuals.¹⁰ Recently techniques have been developed in which fertilized eggs or early embryos are transferred to the fallopian tubes instead of to the uterus. These procedures have been called ZIFT (zygote intra fallopian transfer), PROST (pro-nuclear stage ovum transfer), TEST (tubal embryo stage transfer) and FET (fallopian embryo transfer). A related technique, GIFT (gamete intra fallopian transfer) involves transfer of the gametes to the fallopian tube prior to fertilization. It is therefore different from IVF in that fertilization does not occur in vitro but similar in that it utilizes related technology.

FOOTNOTES

1. Above xv-xvi.

2. See particularly NSW Advisory Committee on Human Artificial Insemination, *Australian Attitudes to Human Artificial Insemination* prepared by G Rawson (NSW Govt Printer 1984).

3. New South Wales Law Reform Commission *Human Artificial Insemination: Discussion Paper 1*. (DP 11 1984) at V.

4. New South Wales Law Reform Commission *Human Artificial Insemination* (LRC 49 1986).

5. New South Wales Law Reform Commission *Human Artificial Insemination* (DP 11 1984).

6. New South Wales Law Reform Commission *Surrogate Motherhood: Australian Public Opinion* (RR 2, 1987).

7. (DP 15 1987).

8. Note 4 at 18.

9. For fuller discussion see para 3.32 below.

10. For a more detailed account see Chapter 2, DP 15, 1987.

2. The Current State of IVF Regulation

I. INTRODUCTION

2.1 The birth of children conceived as the result of IVF is a recent phenomenon. Australia's first IVF baby, Candice Reid, was born in 1980.¹ The application of traditional legal principles to this new medical procedure was likely to produce results that were unexpected and often unwanted. For example, common law principles for determining paternity, maternity and legal personality were formulated long before IVF technology was developed and based on assumptions about conception and parenting which are no longer valid.

2.2 As IVF techniques have developed, attempts have been made to apply legal rules and principles to the problems created by the process as well as developing new legislation and regulatory schemes. This Chapter will assess the current state of IVF regulation on three different levels:

Common law

Legislative responses to IVF

Non-legislative responses to IVF

II. COMMON LAW STATUS OF THE HUMAN EMBRYO

2.3 At common law, it has traditionally been the act of "live birth" - the complete extrusion of the foetus from the body of the mother - which endows a foetus with a legal personality and the rights and responsibilities associated with being a person. There is a substantial list of authorities in which the courts have refused to confer legal rights on a human embryo or foetus unless, and until, it is born and has a separate existence from its mother.²

2.4 This is not to say that the foetus is denied all legal rights. The foetus is considered to have potential or contingent legal interests which will only vest and become enforceable upon its live birth.³ Two areas in which the foetus is accorded contingent legal rights are the law of succession and tort law. The question whether the IVF embryo should be given a special status at law on the basis of its unique nature and potentiality is discussed in Chapter 3.⁴

III. LEGISLATIVE RESPONSES TO IVF

A. Introduction

2.6 Our discussion paper set out a detailed description of the law in NSW and Australia as it applies to IVF.⁵ As shown there, the law applicable to IVF covers a wide range of questions including the maternity and paternity of IVF children, the ownership and storage of human reproductive tissues, as well as the important question of regulation of IVF practices and research. In this report we merely bring our description of the law up to date.

B. Maternity and Paternity

2.7 Problems can arise as to the maternity and paternity of children born on an IVF program, where donated reproductive "issues are used. At common law a child conceived following the use of donated gametes would be considered illegitimate. It is likely that the donor would be legally considered the father or mother of the child, and have all the rights and obligations attendant upon such a status.⁶

2.8 The common law rules governing legitimacy of children have been modified in most Australian jurisdictions by legislation. In New South Wales, the Children (Equality of Status) Act 1976 effectively abolishes the concept of illegitimacy and removes the stigma of being born *ex nuptial*.⁷

2.9 Status of children legislation has also been enacted at both federal and State levels to accommodate many of the legal problems created by artificial conception techniques. Under the legislation, new notions of paternity have been created:

Where a married woman, in accordance with the consent of her husband, has undergone a fertilization procedure [using donor sperm] as a result of which she has become pregnant, the husband shall be presumed, for all purposes, to have caused the pregnancy and to be the father of any child born as a result of the pregnancy.⁸

2.10 All Australian jurisdictions,⁹ apart from New South Wales and Queensland,¹⁰ also provide that when a woman gives birth to a child following IVF using donated ova, the birth mother is presumed to be the mother of that child. In New South Wales, the position of a child born from donor ova is still unclear. With no statutory or common law guidance to assist, a child so conceived can have up to three “mothers”:

a genetic mother (the ovum donor)

a gestational mother (who carries and gives birth to the child)

a social mother (who nurtures and cares for the child from birth).

C. Ownership and Control of Reproductive Tissues

2.11 The common law makes no distinction between reproductive and other human tissues. The general rule is that there can be no proprietary interest in human tissues and organs, and the person who possesses tissue controls it. Statutory modification of the common law is found in the Human Tissue Act 1983 which governs the acquisition and donation of human tissues for therapeutic purposes. The Act restricts the use of human tissue in the following ways:

Section 32 expressly prohibits commerce in “human tissue”. Human tissue is defined to include both ova and semen.

Section 21C provides that where semen has been obtained from a donor for a specific purpose it must be used for that purpose unless the donor has signed a certificate relating to its “medical suitability” for a different purpose.

D. Legislation Regulating the Practice of IVF

2.12 So far in Australia only Victoria and South Australia have enacted comprehensive legislation to deal directly with the practice of IVF.

1. Victoria

2.13 The effect of the Infertility (Medical Procedures) Act 1984 was described in the IVF discussion paper.¹¹ Enacted in November 1984, the main provisions were proclaimed to commence on 1 July 1988.¹² The Victorian Act provides three means of regulating IVF:

(i) by limiting its practice to approved hospitals and practitioners;

(ii) by limiting those who may have access to it;

(iii) by requiring the keeping of detailed records and registers by both clinics and government.

2.14 Since the discussion paper was written, the Victorian Parliament has also passed the Infertility (Medical Services) Amendment Act 1987. This Act, a response to the newly developed micro-injection technique, allows limited experimentation on the fertilized ovum in the first 22 hours following fertilization.¹³ This amendment was proclaimed to commence operation on 1 July 1988.¹⁴

2. South Australia

2.15 In September 1987, following the Report of a Committee on Artificial Conception¹⁵ the bill for the Reproductive Technology Act 1987 was introduced. This Act aims to regulate “the use of reproductive technology and research involving experimentation with human reproductive material”. The Act:

1. Establishes a Council on Reproductive Technology to monitor the practice of IVF and IVF research.¹⁶ It will also advise the Minister for Health on issues of reproductive technologies.¹⁷ Membership will be multi-disciplinary with equal representation of men and women.¹⁸
2. Sets down provisions to guide the Council in formulating a code of IVF ethical practice.¹⁹
3. Provides for separate licensing systems for both IVF practice and research.²⁰ These systems will be administered by the South Australian Health Commission and the Council respectively.
4. Creates a number of compulsory conditions to be written into licences, including provisions limiting access to rograms and the types of procedures available.²¹
5. Prohibits any research which “may be detrimental to an embryo.”²²
6. Makes it an offence to divulge confidential information other than as provided by the Act.²³

Like the Victorian Infertility (Medical Procedures) Act, the Reproductive Technology Act creates offences which are punishable by fines and imprisonment.²⁴

IV. NON-LEGISLATIVE REGULATION OF THE PRACTICE OF IVF

2.16 In States like New South Wales where no comprehensive legislation has been enacted the practice of IVF is currently regulated by non-legislative means. The NSW Department of Health has officially endorsed the principles for IVF practice adopted by the National Health and Medical Research Council (NHMRC).²⁵ The work of this body was set out in some detail in the discussion paper.²⁶ The principles set out by the NHMRC in relation to IVF practice include the following:

- (i) each clinic offering IVF “should have all aspects of the program approved by an institutional ethics committee”, and registers recording data relating to all attempts at IVF should be kept by the clinic;
- (ii) research with ova, sperm and fertilized ova should be allowed, but continuation of embryonic development in vitro beyond the stage at which implantation usually takes place should not be permitted;
- (iii) sperm and ova should be considered to belong to the donors, and the wishes of donors regarding disposal of their gametes should be respected as far as possible; and
- (iv) only early “undifferentiated” embryos should be stored, and time limits should be imposed on the duration of storage.

While this scheme has no legal sanctions, it provides advantages over strict legislative schemes by allowing much greater flexibility in responding to changing developments in IVF.

2.17 In addition Australian medical and scientific communities involved in the practice of IVF are subject to professional self-regulation. A breach of medical ethics may expose a medical practitioner to disciplinary proceedings under the Medical Practitioners Act 1938 which provides that a medical practitioner who has been found guilty of “misconduct in a professional respect” may be disqualified from continuing to practise medicine if the breach has been sufficiently serious.²⁷ Other sanctions include reprimands, suspensions from practising medicine and fines.²⁸

2.18 A new federal committee advising the Australian Health Ministers’ Conference (AHMC) on important bioethical issues such as IVF and embryo research was announced by the Minister for Health recently and endorsed at the annual meeting of the Health Ministers. Called the National Bioethics Consultative Committee,

(NBCC) its aim is to bring a more coordinated, national approach to significant bioethical questions. The Committee will provide advice and undertake studies on matters requested by the AHMC on ethical, legal and social issues in the biomedical area. Requests for advice and research may also be made by the Standing Committee of Attorneys General and the Council of Social Welfare Ministers through the AHMC. The composition of the committee seeks to obtain a balance of expertise, community views, gender, age and geographical region. The 13 members were appointed in March 1988 and represent the following areas:

Biomedical research

Community representation

Economics

Health care provision (other than medicine)

Law

Medicine

Moral theology

Philosophy/ethics

Social science

Women's health

V. RECENT INTERNATIONAL DEVELOPMENTS

2.19 Responses to IVF on an international level were outlined in detail in the IVF discussion paper.²⁹ Since the release of that document, two further developments have occurred which should be noted here.

A. United Kingdom

2.20 In July 1984 the report of the Committee of Inquiry into Human Fertilization and Embryology (the Warnock Committee), outlined a number of recommendations bearing on IVF. At the time of writing, only one of the recommendations had been implemented in the Surrogacy Arrangements Act 1985. This Act deals exclusively with surrogacy, banning the use of intermediaries. It does not extend to IVF.

2.21 In November 1987 the Department of Health and Social Security issued a White Paper³⁰ intended to clear the way for eventual implementation of the Warnock Report. The Paper covers statutory IVF licensing, embryo research, surrogacy, counselling, and registration. It is envisaged that after it is debated in both Houses a draft bill will be tabled in Parliament in the 1988-89 session.

B. The Council of Europe

2.22 The Council of Europe began work in 1984 to prepare a model code for the regulation of human artificial reproduction. Since 1984, regular meetings have been held of the Council's Committee of Experts in Medical Research on Human Beings (CAHBI), at which each of the Council's 21 member nations is represented, together with delegations from invited observer nations and international bodies. In April 1987 draft principles were completed by CAHBI. If approved by all members, these draft principles will be recommended by the Council to their member governments for adoption either by legislation or otherwise.

FOOTNOTES

1. Twelve of the world's first 16 IVF babies were born in Australia; D Overdiun and J Fleming, *Life in a Test Tube* (1982) at 63.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

2. See *Attorney General for the State of Queensland (Ex rel Kerr v T)* (1983) 57 ALJR 285 at 286: "As at present advise....a foetus has no right of its own until it is born and has a separate existence from its mother"; and see *In re F (in utero)* [1988] 2 WLR 1288; see also *Paton v British Pregnancy Advisory Service* [1979] QB 276.

3. *Ibid.*

4. At paras 3.12-3.15, see also Reasons for Recommendations, Chapter 5 paras 5.38 to S.40.

5. NSW Law Reform Commission, *In Vitro Fertilization* (DP 15, 1987) at para 3.1-3.14.

6. *Id* at para 3.S-3.6; also S Mason "Abnormal Conception" (1982) 56 *Australian Law Journal* 347 at 348-349.

7. Section 10.

8. Artificial Conception Act 1984 (NSW),s5.

9. Status of Children Act 1984 (Vic); Family Relations (Amendment) Act 1984 (SA); Status of Children (Amendment) Act 1984 (Tas); Artificial Conception Act 1984 (WA); Artificial Conception Ordinance 1985 (ACT); Status of Children Amendment Act 1985 (NT); Family Law Amendment Act 1983 (Cth); Marriage Amendment Act 1985 (Cth).

10. At the time of writing, legislation covering both maternity and paternity was before the Queensland Parliament.

11. NSW Law Reform Commission, *In Vitro Fertilization* (DP 15 1987) at para 5.11-5.12.

12. Victorian Government Gazette (4.S.88) at 1123.

13. Section 9A.

14. *Victorian Government Gazette* (4.5.88) at 1123.

15. Select Committee of the Legislative Council on Artificial Insemination by Donor, *In Vitro Fertilization and Embryo Transfer Procedures and Related Matters in South Australia, Report* (April 1987).

16. Section 5(l).

17. Section 10.

18. Section S(3).

19. Sections 10(3) and 10(4).

20. Sections 13 (Practice Licences) and section 14 (Research Licences).

21. Section 13(3)(b) and 13(3)(d).

22. Section 14(2)(b).

23. Section 18.

24. *Ibid.* The penalty for unauthorised disclosure of information is \$5000 or imprisonment for six months.

25. National Health and Medical Research Council, *Ethics in Medical Research* (1983), Supplementary Note 4 at 26; Fertility Society of Australia "Programme standards for in vitro fertilisation units in Australia" (1985) 3(4) *Artificial Reproduction and Fertility* 349; New South Wales Department of Health *Policy Statement: In Vitro Fertilisation* (December 1985).

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

26. At 3.12.

27. Section 27.

28. Medical Practitioners Act 1938, s27.

29. Paragraphs 5.19-5.11; 5.13-15.

30. *Human Fertilization and Embryology: A Framework for Legislation*, Cm 259.

3. Submissions, Debate and Principles

I. INTRODUCTION

3.1 The unique and unprecedented features of IVF place substantial obstacles in the way of achieving just and effective regulation of its procedures. It is not an established medical practice whose regulation is being updated. It is an entirely new treatment whose first success was recorded barely ten years ago. The law as it stands is barely equipped to deal with the issues it raises. IVF brings about human reproduction, and the attitudes of many people to it are influenced by strongly held moral, ethical and religious views concerning sexual behaviour, family formation and the bearing and raising of children.

3.2 Such views tend to make artificial conception techniques such as Artificial Insemination (AI) and IVF, the subject of concern and dispute in the community. This is in part evidenced by the large number of official inquiries set up to investigate the techniques, and is reflected in the substantial public interest we have found in the development of this reference.

II. SUBMISSIONS TO THE COMMISSION

3.3 Chapter 1 outlined how our work on artificial conception has been conducted to allow substantial participation by the public.¹ This has included wide publication of discussion papers² which invited public comment, the organization of public hearings prior to the publication of this report and the Commission's earlier report on Artificial Insemination, and extensive research by the Commission's staff. In relation to the Discussion paper on IVF, the Commission received 30 written submissions in the initial consultation period, and a further 16 in the wake of the public hearing, making a total of 46. These submissions came from individuals, community groups and church groups and contained a wide variety of viewpoints. Some responded favourably to the discussion paper, while others were critical. All submissions were carefully analysed, tabulated and summarised,³ and consideration was given to all views expressed in the formulation of our final recommendations. Reference is made to the submissions in Part III of this Chapter.

3.4 Many of the issues arising from IVF are shared with AI and are considered at length in the AI Report. However, IVF presents its own discrete issues, some of which overshadow the concerns of AI. In vitro fertilization is technically a much more complex Procedure than artificial insemination. As well, it involves the fertilization of an ovum outside the human body and, typically, the storage of embryos and the possibility of their disposal. These aspects have generated much of the IVF debate. Matters dealing with the recording of information raise few new considerations. However, certain issues such as donation and storage of reproductive tissue and research go far beyond their counterparts in AI, presenting wider moral and ethical problems. The Commission noted in its AI report⁴ the opinion that general acceptance of our recommendations for reform in this area will be governed to a significant extent by the acceptance and credibility of the principles underlying them.

3.5 This Chapter will again outline the basic principles that have guided the Commission in its work on this reference. They are the same as those described in our discussion paper on AI, the AI report and the discussion paper on In Vitro Fertilization. We will also outline some of the objections to IVF voiced in the literature and some of the arguments put to the Commission in the submissions received.

III. THE IVF DEBATE

A. Concerns raised by IVF

3.6 The relationship between the law and IVF cannot be discussed without reference being made to the moral debate surrounding the new birth technologies. As well as questioning the mean used in IVF, and often IVF itself, this debate is concerned with the ethics and morality of the practice of IVF. It began before the birth of the first IVF child in England,⁵ and has intensified as new developments occur in the technology.⁶ A full account of the state of the debate was given in the IVF discussion paper.

3.7 The Commission cannot attempt to resolve this debate nor to make any final statement on the moral issues.⁷ They are too diverse and do not lend themselves to compromise. Our terms of reference permit us to take the social, ethical and legal issues into account.⁸ This we have done through our consultation and

research programs. In this Chapter we present the results of that work before drawing it together in Chapters 4 and 5 to form the basis of our recommendations. Our primary task, has been to consider these issues in order to be able to make recommendations on the means appropriate to regulate the new birth technologies. In this process we have considered both legislative and non-legislative solutions. We believe we have achieved a reasonable balance between the two. We also believe that the strongly held moral views of most can be accommodated within the scheme we propose. It is sufficiently flexible so that no individual should be forced to make a compromise of his or her ideals and does not close the door to further debate. However, we believe our recommendations also offer sufficient structure to overcome the need to reopen the fundamentals of the debate.

3.8 One ingredient in our attempts to ascertain community attitudes has been the reference made to the results of public opinion surveys. These reveal that there is no public consensus or "identifiable community morality"⁹ on the issues involved in IVF. While we can agree with several of the submissions made to us, that no great significance can be given to the results of these surveys, we also believe it would be foolhardy to simply ignore them.¹⁰ Between 1981 and 1987, 8 separate surveys were conducted by the Roy Morgan Research Centre into Australian attitudes to IVF.¹¹ All showed that a substantial majority approved of IVF as a procedure to relieve infertility in cases in which the sperm and ova of a husband and wife are used to make the wife pregnant by IVF. Separate surveys in 1983¹² and 1986¹³ yielded similar results. In relation to some of the more controversial aspects of the process, results were predictably mixed.¹⁴ What we take from the results of these surveys is the added caution that in formulating our recommendations we should be careful to avoid imposing prohibitory or regulatory solutions where no clear community consensus exists to support them.¹⁵

3.9 The diversity of views in the community on IVF is also made clear in the submissions received by the Commission. Their individual emphasis varies greatly. What is agreed, or accepted in critically or expressly by one, is strongly criticized by another. For example, the discussion paper's treatment of eligibility for IVF procedures,¹⁶ is regarded by some as undermining the traditional family unit because of its willingness to include de facto couples.¹⁷ At the same time, the proposals were condemned by other groups for placing too much emphasis on the traditional family to the exclusion of single-sex and single-parent families.¹⁸ Several submissions commended the discussion paper's full discussion of IVF, and its balanced approach to the issues,¹⁹ while others thought it was unnecessarily sympathetic to the medical profession and did not sufficiently represent some of the more telling criticisms of the IVF procedure.²⁰ This divergence of opinion reflects not only an absence of agreement on the issues, but also a deep division in attitudes in those responding to the discussion paper. In what follows we present a brief overview of the arguments and views which have been put to us.

B. Major Objections to IVF

3.10 Many of the strongest criticisms of the IVF program can be attributed to a distrust of science and scientific research. This attitude arises from the perceived failure of science and scientist- to live up to earlier promises, as well as an increasing recognition of many negative by-products of what is seen to be inadequately controlled scientific development.²¹

3.11 In vitro fertilization, conspicuous among developments in the New Biology, and relating to the means of human procreation, which is a condition of human survival, has received more than a small share of this criticism. Some opponents argue that IVF is built on the destruction of human life and that it threatens the traditional family;²² others question the social and psychological implications²³ and criticize the process as one which makes women objects of scientific curiosity and subjects of scientific experimentation.²⁴ The real problem, it is argued, is infertility, and scientists should be aiming to prevent this, rather than seeking to perfect artificial conception techniques. Allied to this argument is a very real concern that patients on IVF programs are in a vulnerable position, reliant on the advice of their doctors, and therefore may be easily persuaded to agree to treatments without being fully aware of all the consequences.

1. Status of the Human Embryo

3.12 The target of the strongest criticism of IVF is the moral argument concerning the status of embryos created by use of the technique. The legal status of the embryo was discussed in our discussion paper where it was shown that while the embryo and the foetus have received from the law a degree of respect, neither has been given legal recognition as a human person, at least until after live birth. Numbers of recent attempts in courts in Australia and the United Kingdom to obtain rulings that would endow an embryo or foetus -with legal personhood have failed.²⁵

3.13 There is no ground in the common law to recommend that an IVF embryo should be given legal status as a person in any proposed legislation on IVF.²⁶ The call to accord the embryo status must therefore be based on moral and ethical grounds which are generally accepted by the community if we are to feel justified in reversing the established trend of the law. A number of these moral and ethical arguments were described in our IVF discussion paper.²⁷ They have been clarified and expanded in many of the submissions received by the Commission. Their main thrust is that at and from the time of conception a person exists who should be accorded the rights and status of a human. There is also said to be a related duty owed by those involved in IVF programs, to allow embryos to develop fully to become human beings. On this reasoning there is, morally, no difference between a fully-developed human person, a new born baby, a 7-month foetus and a single-cell fertilized ovum.²⁸ These, however, are not the only views which the Commission must accommodate. It has also been put to us that the recognition of foetal rights and the assignment of a legal status to the embryo, would have a serious and detrimental effect on the interests of women involved. The granting of legal status to an embryo, and consideration of its interests- in isolation from the woman who is to carry it, reduces women to mere "vessels" to contain embryos.²⁹ In most of the arguments outlined above women and women's roles are rarely mentioned, or are given little importance.³⁰ If enacted in legislation it is argued the grant of legal status to the embryo would see a further deterioration in the rights of women to control their own bodies, the interests of the embryo conflicting with those of the women.

3.14 As stated in the discussion paper, the Commission subscribes to the views put by the Ethics Advisory Board of the United States Department of Health.³¹ The Board, in its report in 1979, recognized the special nature of the embryo and accepted that it should be treated as different from other human tissue. The embryo, according to the EAB, was entitled to "profound respect", but this did not mean it was entitled to the "full legal moral rights attributed to persons".³² Because of its uniqueness, and its capacity to develop into a human being, it ought to be "accorded respect" as a symbol of respect for human life generally.³³ This opinion was influential in the formulation of the Australian national guidelines on IVF published in 1982 by the National Health and Medical Research Council.³⁴

3.15 This approach accepts the special status of the embryo, and recognizes that its handling - whether for implantation, storage or for research - should be a matter of special consideration. That the embryo can be distinguished from other human tissues is not in doubt. At the same time, however, this approach is not in conflict with the current law, which denies the embryo the legal status of a human person.

2. Costs of IVF Treatment

3.16 Disquiet over the cost of IVF programs, both to the community and the individuals involved, is another major concern the Commission has addressed. It is argued that the benefits of the IVF programs cannot outweigh the costs of the treatments: both financial and personal.

3.17 The actual financial cost to an average IVF patient undergoing a single treatment cycle is approximately \$3,000-\$4,000.³⁵ This was examined at some length in the discussion paper. Some consider this calculation misleading, as the individual price is only a small part of the overall cost to the health system.³⁶ In May 1988, the Federal Minister for Health, Dr Blewett, released a report outlining the costs of IVF treatment.³⁷ The estimates made in this report of the cost of an average treatment cycle, were similar to those made in the discussion paper.³⁸ The most publicized of its findings, however, was the statement that each child born through the use of IVF techniques had cost the Australian community \$40,500.³⁹ Critics of IVF present these financial costs in conjunction with the extremely low success rate of IVF, in a health system where there is increasing competition for a decreasing number of resources, to raise serious doubts as to its viability. It is argued that IVF is a luxury that few individuals can afford, and which our society should not support,

amounting to a misallocation of resources that should be addressed by diverting more funds to establishing the actual causes of infertility, and investigating treatment for it.⁴⁰

3.18 The Commission doubts the utility of applying this economic argument to in vitro fertilization. The costing in the Blewett report related the charges made for each medical procedure to the cost of developing the IVF program. Such figures could be calculated for any medical treatment or area of scientific endeavour, from cancer research to cosmetic surgery. They could be used to demonstrate the poor economic viability, of many medical programs. Liver and heart-lung transplants for example are also very expensive, and benefit only a small minority of the population, yet they are strongly supported by the community as worthwhile. The question ultimately must be the value placed on the end result of the treatment; in the case of IVF the value seen could be the new human life or it could be the relief of infertility. Those who would prohibit IVF because of its monetary cost must be prepared to persuade the community that the children born by the IVF procedure are not worth the money.

3.19 These financial costs are not the only costs of IVF treatment. Also disturbing are the criticisms made of its physical and psychological side effects. It has been established that a child born following IVF is more likely to suffer physical disability than a child born following sexual intercourse.⁴¹ There are also fears on the part of some concerning the possible psychological problems for the children and their families which may stem from a donor assisted conception, something which can only be fully assessed in the future.⁴² Amongst other important costs to be considered are the physical and emotional effects on the woman undergoing IVF treatment. Many patients have commented on the intrusive nature of the technology.⁴³ It is both tiring and stressful, and the low success rate means that most women never become pregnant. Those who do must often undergo at least two or three treatment cycles.⁴⁴ Even when the procedure is successful, IVF patients face a much greater than normal risk of premature births and multiple pregnancies,⁴⁵ with the attendant risks.

3.20 Finally, there is increasing evidence of prejudicial side effects suffered by some patients from the drugs and processes used in artificial conception techniques. Of particular concern is the link between the super-ovulatory drugs used and cancer, and the dangers involved in the laparoscopy procedure.⁴⁶ IVF procedures use a variety of super-ovulatory drugs. At the 1988 ANZAAS Conference⁴⁷ a number of serious side effects were listed in relation to these drugs, including dizziness, nausea and loss of vision. At the IVF Public Hearing Dr Ditta Bartels referred to reports which gave examples of women who developed cancer of the ovaries after treatment with super-ovulatory drugs.⁴⁸ As yet, the nature and extent of the link is unclear. It is argued, however, that until the full effects are known, these super-ovulatory drugs should not be used. It is also important to note that the problem extends beyond the individual IVF patient, as women encouraged to volunteer to donate ova are also given hormone treatment to superovulate.⁴⁹

3. Other Implications

3.21 Another attitude evident in some submissions to the Commission is unease about the aims and morality of the scientific community.⁵⁰ Often ill defined, this unease focuses in part on the alleged “dehumanizing” effects of IVF, the degradation of parenthood⁵¹ and the traditional family, the destruction of “human life”⁵² and the loss of control by individual human beings over their basic rights.⁵³ Several submissions listed a number of abhorrent (and currently impossible) adaptations, including cross breeding of human beings with animals, the creation of a “super race”, and the use of IVF and gene therapy to create a race of subhuman drudges to do dangerous work or to be used as “spare parts” for the more privileged.⁵⁴ Some of the other social implications of IVF which have been suggested to the Commission are not so far off in the future. One such view is that IVF, and the media publicity it generates, reinforces a view of women as being somehow incomplete without children. This means increasing social pressure on the infertile to undergo treatment in order to conform to a social stereotype, and degrades the choice to remain childless. Another danger for the near future is the use of IVF in combination with gene therapy. There is already discussion of using reproductive technology to eliminate genes which cause a number of serious genetic diseases. The fear expressed is that these processes could be developed into fully-fledged eugenics programs, in which parents could use IVF to create the perfect child.⁵⁵ Another concern increasing in the wake of recent IVF-surrogacy cases is the potential for use of IVF in conjunction with surrogacy as a tool to exploit women from poor countries or lower classes, who would be used as surrogates for wealthier families.⁵⁶

3.22 These concerns are serious, but they are difficult to assess. It is clear, however, that fear of the long-term consequences of the intrusion of technology into human procreation has influenced some of the views described above, particularly those concerning the costs and status of the embryo. In formulating its recommendations the Commission has tried to ensure that the views of all have been treated fairly. The impact each submission has had is reflected, we hope, in the reasons we give for them.

4. The Debate on Embryo Research

3.23 The debate on IVF is often reduced to a debate on IVF research. The spectre of research and experimentation on human embryos is the basis of many arguments asserting a legal status for the embryo. The Commission has considered these arguments in detail. As outlined in Chapter 5, we have decided by a majority of the Commission on each recommendation:

- (i) not to prohibit research on the IVF embryo.
- (ii) to allow the creation of IVF embryos solely for the purpose of research.
- (iii) to allow the transfer to a woman of an embryo that has been the subject of research.

3.24 Our reason is for these decisions accompany our recommendations on research in Chapter 5 at paragraphs 5.24 to 5.42. The minority opinion relating to (i) and (ii) appears in Appendix A. The major reason for these decisions is that the Commission has not been persuaded by the arguments put to it, and those contained in the Senate Select Committee Report, that the human embryo should be accorded such status that no research should be permitted on it at any time in the future. As noted above, we have taken the view of the Ethics Advisory Board of the United States Department of Health,⁵⁷ that an embryo is entitled to a profound degree of respect, but in our view this should not prevent research on the embryo until the fourteenth day of development in vitro.

3.25 The basis of the Commission's view is twofold. We feel that as IVF technology is in its very early stages of development, further research is essential to permit advances in knowledge and to allow the development of more effective, less dangerous and more cost efficient processes. It may be that some of the concerns voiced in this Chapter will be resolved as the science develops. Secondly, the recommendations in Chapter 5 contain a very strict regime for the regulation and control of research by an independent organization, to be called the New South Wales Biomedical Council. With such a system imposed, in addition to existing ethics committee and NHMRC guidelines, fears of unnecessary or exploitative research should be allayed.

3.26 As the council we propose will be making decisions on the basis of its knowledge of scientific development and community attitudes current at the time approval for a research project is sought, its decisions should be better grounded and more reliable than those we can make now. The council will have a clear responsibility to keep itself well informed of these matters, for it is only by maintaining its knowledge at this level that it will be able properly to protect the interests of the public. For details of our reasoning on the issue of research see paragraphs 5.24-4.42 and also Appendix A.

5. Conclusion

3.27 These brief passages cannot reflect the depth and complexity of many of the arguments put to us nor the skill and care with which they were put. They have, however, enabled us to conclude that IVF ought to be regulated and controlled as evenhandedly as possible, and without an unduly restrictive approach which itself could result in serious consequences for the community. Ultimately any law, whether prohibitive or permissive, will only be as effective as its social context will permit.

IV. UNDERLYING PRINCIPLES

3.28 At the outset of its work in the Artificial Conception reference, the Commission established four principles to guide its progress. These have been referred to in all our earlier publications, and in greater detail in our AI report. They are as follows:

It is desirable, where possible, to alleviate the consequences of infertility through practices such as AI and IVF.

The formation of stable families is socially desirable and necessary.

The paramount consideration in the practice of AI and IVF shall be the welfare of the child.

Personal freedom and individual autonomy should, so far as possible be respected.⁵⁸

3.29 Of these four principles, the last two received the most comment in the submissions on IVF.

A. Paramount Welfare of the Child and the Formation of Families

3.30 The laws of New South Wales and Australia have long reflected a commitment to the principle that the welfare of children should be the paramount consideration in relation to legal questions concerning their guardianship and custody. Expressions of this principle are to be found throughout family and adoption law. The interpretation of the meaning of the welfare of the child may have changed over the centuries but its basis has remained the same, namely, that the interests of the child are to prevail over those of other people involved in litigation.

3.31 In relation to the "formation of stable families" the Commission has been criticized both for being too conservative and too liberal. As stated by the AI Report we remain of the view that:

Stable family formation whether in marriage, a de facto relationship, an extended family or some other household has generally been considered by the community as necessary to provide a child with the best conditions in which to grow up. Even with divorce and family breakdown the law attempts to foster continuity and security in the child's life through stable custody arrangements. It is therefore appropriate that the Commission pay due regard to the desirable goal of stable family formation and encourage this so far as possible.⁵⁹

B. Personal Freedom and Individual Autonomy

3.32 One of the basic features of Western democracy since the 18th century has been respect for personal freedom and the autonomy of the individual.⁶⁰ In relation to IVF programs and treatment, the principle has been described as follows:

Our society recognises the general moral notion that all people are autonomous beings who have a right to, and indeed should, make their own decisions. In the field of medical treatment this means that a competent adult person is entitled to decide what shall be done with his or her own body. The law reflects this principle.⁶¹

3.33 When an increase in legislative control is being considered, allowing government more power over individual affairs, this principle should not be ignored. The law is limited in what it can and should do in enforcing views of private human conduct, and in our view it has been generally accepted that on this subject strict legislative solutions are not always the most appropriate.

V. CONCLUSION

3.34 In the formulation of the recommendations in this report, the Commission has attempted to weigh, and to give room for the operation of, genuinely held moral legal and social concerns put to us through the period of public consultation. In some cases it has not been possible to balance quite contradictory views. We have also tried to follow the principles described above as well as to maintain an awareness of the practicalities of law making and law reform.

FOOTNOTES

1. See paras 1.4, 1.10.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

2. The Commission has published two discussion papers in the course of this reference, these being: *Human Artificial Insemination* (DP 11, 1984); *In Vitro Fertilization* (DP 15 1987); a third Discussion Paper, *Surrogate Motherhood* (DP 18 1988) is to be released in late July 1988.

3. Each submission was read, analyzed and summarized according to the issues it addresses, and the chapter referred to. A final summary, running over 200 pages was then produced, and used by members of the Division in conjunction with the discussion paper when the Commission formulated its recommendations.

4. *Human Artificial Insemination* (LRC 49 1986) at para 3.2.

5. The practice and intentions of the Dr Patrick Steptoe were widely criticized in the lead up to the birth of the first IVF Child. R Edwards and P Steptoe, *A Matter of Life* (1980).

6. See for example, the recent intensification of the debate following the use of the micro-injection technique in Victoria. "Latest IVF process jumps gun on law", *Sydney Morning Herald* (5/4/88) at 4; "Laboratory Embryos banned", *Sunday Telegraph* (3/4/88); "New In-vitro technique tested in Sydney" *Sydney Morning Herald* 10/7/88 at 4.

7. Some comments in the submissions to the Commission have suggested that this should have been a part of our task; see *Transcript of Proceedings*, NSW Law Reform Commission Public Hearing on In Vitro Fertilization. See especially speakers on behalf of Right to Life (NSW) and the Women's Advisory Council; See as for n9, also Submission of Ms R M Albury (SB 2, 1987); Rev Fr T V Daly, "NSW Law Reform Commission Invites Discussion on the Embryo" (1987) 5, and see also *St Vincent's Bioethics Centre Newsletter* 9 (SB 26, 1987).

8. See xv; paragraph 3(l) of the Commission's Terms of Reference on Artificial Conception allows the Commission to take into account "social, ethical and legal issues" relating to AI, IVF and surrogate motherhood.

9. This is a term used by Lord Devlin, to identify a "community sense of what is right and what is wrong", which he argued the law ought to reflect. See P Devlin, *The Enforcement of Morals* (1965) at 15-18. Also see the opposing view set out in HLA Hart *Law Liberty and Morality* (1963).

10. See Women's Advisory Council (SB 4, 1987) at 7-8; Uniting Church of Australia (SB 6, 1987) at ; Submission by Mr Brian Maher (SB 20, 1987) ; Right to Life (NSW) (SB 2S, 1987) at 12.

11. Roy Morgan Gallop Poll (9 April 1987, finding No 1550). For details see summary in *In Vitro Fertilization* (DP 15 1987) at para 4.6.

12. R Rowland and C Duffin, "Community Attitudes to Artificial Insemination by Husband or Donor, In Vitro Fertilization, and adoption" (1983) 2 *Clinical Reproduction and Fertility* 195.

13. M Brumby and M Levine "Australian Attitudes Towards IVF: A Comparison of the Values of Supporters and Opponents. (1986) 11 *Australian Journal of Early Childhood* 24.

14. For details see *In Vitro Fertilization* (DP 15 1987) 4.6-4.7.

15. Several submissions were critical of this approach. See Right to Life (NSW) (SB 25, 1987) at 12; Australian Catholic Social Welfare Commission (SB 29, 1987); Council of Churches in NSW (SB 18; 1987).

16. At 6.3.

17. See Knights of the Southern Cross (SB 3, 1987) at 25; Presbyterian Women's Association (SB 16, 1987) at 2.

18. See Women's Legal Resources Centre (SB 1, 1987) ; Ms R M Albury (SB 2 1987)

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

19. See Seventh Day Adventist Hospital (SB 28, 1987) CONCERN (SB 17, 1987); Ms L Sullivan (Parents Centre Australia (SB 23, 1987).
20. Most notably Right to Life NSW (SB 2 S , 1 9 8 7)see especially introductory pages.
21. This is especially true in the area of medical science, where increasing numbers of treatments and prescribed drugs are shown to have serious negative effects. T Roszak, *Where the Wasteland Ends: Politics and Transcendence in Post Industrial Society* (1972); Leo Marx, "Reflections on the Neo-Romantic Critique of Science", *Daedalus* (1978) 107, 61; both cited by Gustav Nossal, "The Impact of Genetic Engineering on Modern Medicine" Text of the first Ian McLennan Oration of the Melbourne University Engineering School, Centenary Foundation (Melbourne, 4 October 1983) *Quadrant* November 1983 22 at 26.
22. SB 25; SB 19.
23. Australian Family Association "Submission to the Committee of Inquiry on In Vitro Fertilization" (1982) 3 *The Australian Family* 6; but see also J F Hollinger "From Coitus to Commerce: Legal and Social consequences of Non Coital Reproduction" [1985] 18 *Journal of Law Reform* 865 at 923.
24. M O'Brien, *The Politics of Reproduction* (1984); R Koval, "Women Birth and Power" (1985) 4 *Australian Society* 6.
25. *Attorney General for the State of Queensland (Ex rel Kerr) v T* (1983) 57 ALJR 285; *Re K; C v S; Paton v British Pregnancies Advisory Service* [1979] QB 276. See also the recent decision of the UK Court of Appeal in *Re F (in utero)* (1988) 2 WLR 1288 May, Balcombe and Staughton LJJ.
26. The Senate Select Committee Report, however, thought it "prudent" to treat an embryo as a "human subject"; Senate Select Committee on the Human Experimentation Bill 1985, Human Embryo Experimentation in Australia (September 1986), 3.18. See also the treatment of the subject in the Minority Opinion in Appendix A, para 2 *et reg.*
27. See Chapter 4.
28. Submission No: 25.
29. Barbara Ehrenreich, "The Heart of the Matter", *Ms* (May 1988) 20.
30. See especially Knights of the Southern Cross (SB 3 1987); Right to Life (NSW) (SB 25 1987).
31. See *In Vitro Fertilization* (DP 15, 1987) at 8-12-13.
32. Ethics Advisorv Board, Department of Health, Education and Welfare, *HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (4 May 19/9) at 101.
33. J A Robertson "Embryo, Families and Procreative Liberty: The Legal Structure of the New Reproduction". (1986) 59 *Southern California Law Review* 942 at 971.
34. National Health and Medical Research Council, *Ethics in Medical Research* (1983), Supplementary Note 4.
35. See IVF Discussion Paper at 3.22 based on information supplied by Dr B Burton; Also *IVF Friends* (April 1988) at 3-4.
36. See especially Presbyterian Womens Association (SBI6 1987); Womens Advisory Council (SB 4 1987); Right to Life (NSW) (SB25 1987).
37. Department of Community Services and Health (Cth), *Commonwealth Perspectives on IVF Funding: A Discussion Taper A (Summary)* at 4.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

38. IVF Discussion Paper 2.22.
39. Note 37 at 4.
40. Rebecca M Albury (SB 2 1987); Womens Advisory Council (SB 4 1987); G Corea "Priorities", paper delivered at the New South Wales Law Reform Commission, 6 May 1986. See also G Corea *The Mother Machine* (198S).
41. The incidence of major congenital malformations in liveborn and stillborn IVF infants was 2.6% compared to a national incidence for non-IVF infants of 1.5%. National Perinatal Statistics Unit Report (1987) at 13; IVF Dangerous for mother and child" SMH (3 May 1988) 3.
42. IVF Discussion Paper 4.23-4.24.
43. "Ten Years on IVF: is it worth it?" Leta Keens, *Australian Womens Weekly* (May 1988) at 91, 93.
44. "The Gruelline Baby Chase" Jean Seligmann, et al *Newsweek* January 1988 144-146.
45. See note 41.
46. "Teratogenic Effects of Clomiphene, Tamoxifen, and Diethylstilbestrol on the Developing Human Female Genital Tract". G R Cunha et al, *Human Pathology* Vol 18 No 11 (November 1987); "Warning on in-vitro drug effects" *Sydney Morning Herald* (17.5.88) 8.
47. Dr R Klein, "The Exploitation of Infertility: The New Reproductive Technologies and their Impact on Women"; Dr R Rowland, "Living Laboratories: The New Reproductive Technologies and their Threat to Women's Autonomy"; both papers given 16/5/88 at the ANZAAS Centenary, Congress, University of Sydney, 16-20 May 1988.
48. Transcript of Proceedings, NSW Law Reform Commission Public Hearing on In Vitro Fertilization.
49. See note 47.
50. Right to Life (NSW) (SB 25, 1987) at 2-4; Submission of Women's Advisory Council (SB 4, 1987) at 1; Submission of the Knights of the Southern Cross (SB 3, 1987).
51. Australian Catholic Welfare Commission, (SB 29, 1987).
52. *Ibid.* Also United Church in Australia (SB6 1987); Council of Churches NSW (SB 18 1987).
53. Rebecca M Albury (SB 2 1987); Womens Advisory Council (SB 4 1987).
54. Right to Life (NSW) (SB 25 1987).
55. C Ewing, "IVF Genetic Engineering and Eugenics" paper given 16/5/88 at the ANZAAS Centenary Congress, see note 47.
56. "Woman to bear her sister's baby" *SMH* 8/4/88; "Doubts over legal parentage of IVF baby" *AGE* 8/T788; "Victoria's first be IVF Surrogate Mother may also the last" *AGE* 20/4/88; "Surrogacy: Adultery by remote control" *AUST* (13/6/88).
57. Ethics advisory Board Department of Health, Education and Welfare, *HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (4 May 1979) at 101.
58. NSW Law Reform Commission, *Human Artificial Insemination* (Discussion Paper 1) (DP 11 1984) at 34; *Report on Human Artificial Insemination* (LRC 49 1986) at 3.4, also 3.10—3.15.
59. *Ibid.*

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

60. J S Mill *On Liberty*, Chapter 1.

61. Law Reform Commission of Victoria *Informed Consent to Medical Treatment* (DP 7 1987) at 1.

4. A NSW Model for Regulation

I. INTRODUCTION

4.1 one of the, Commission's chief concerns in this inquiry, has been an awareness of the need to respond to and reflect the concerns felt in the community about IVF and associated issues. This has resulted in the legislative framework for regulation and control which is described below and in the Recommendations for Reform in Chapter 5. The Commission recognizes that many in the community see a pressing need for immediate action. It has become obvious to the Commission, however, that there are major problems in applying legal norms and solutions to IVF. One of the major difficulties lies in accommodating what is often revolutionary scientific development within the normally static system of law which we have in Australia. Constant changes and discoveries, as well as the learning of new techniques, combine to make any strict legislative scheme almost immediately obsolete.

4.2 The Commission has come to the conclusion that it should not attempt to settle all the issues raised by practice and research in IVF at present. We can propose a framework for decision making and establish the principles against which future developments can be assessed, but many matters are better left for decision in the future when their context is better defined. Thus, we have not recommended prohibition of either the practice of IVF or research into it, but we have recommended that before any new projects are embarked upon they should be fully assessed and their worth evaluated by an independent group of people representing all the major areas of interest in the technology, including members of the general community. We believe that this group can develop the expertise necessary to protect society's interests better than we can now by proposing the passage of detailed legislation.

4.3 Some matters we have not left for determination by the representative group, however. These are the issues which we regard of such fundamental importance that they should be included in the initial legislation. Amongst them are our recommendations that only medical practitioners should be permitted to practise IVF and that any licence issued should contain a description of the type of practice it permits. These matters are discussed in 5.13.

4.4 All the major reports on the topic of IVF have recognized that it is an area where there are no correct answers.¹ The public has not made up its mind on the new technology and the scientists have not completed their work. The Warnock Committee was well aware of these problems, and recommended the creation of a licensing authority with a wide membership and a major advisory function. Other European states have taken a similar approach.² Within Australia, the reports of the Senate Select Committee, the Family Law Council and the Waller Committee all call for the establishment of similar bodies.

II. THE REGULATORY SCHEME

A. Establishment of the New South Wales Biomedical Council

4.5 The Commission considers that part of its role is to provide guidance for the future development of IVF. it therefore recommends that Parliament establish a permanent body to oversee the development of IVF and to monitor community opinion. This body should be called the Biomedical Council. As it is important for such an organization to represent all interests in the community, we have recommended a multi-disciplinary membership, with representatives from the general community as well. Also important is our recommendation that a substantial number of women sit on the Council. Because of the fundamental impact IVF practice and technology may have on their lives, the Commission believes that women should make up half of the Council's membership.

B. Functions of Council

1. To Advise the Minister

4.6 The new Council's first task should be to inform itself thoroughly so as to be able to advise the Minister for Health on all matters related to reproductive technology and biomedicine. The Council should also have a duty to report to Parliament annually through the Minister for Health. These reports should provide up to date information on IVF practice and research in the State as well as advising Parliament of likely

developments in the future. In this way both the Minister and Parliament will receive the information necessary to form the basis of future regulation.

2. To Formulate Guidelines for Practice and Research and to Liaise with Other Advisory Bodies

4.7 The next task of the Council should be to formulate guidelines for practice and research in IVF. Compliance with these guidelines should be made a condition of the issue of a licence. As part of this function the Council would liaise with and help coordinate the work of other State and federal organizations performing similar functions in Australia. The Council would be obliged to keep the guidelines under constant review and to review them thoroughly at least once every three years.

C. New South Wales Biomedical Council and the Licensing System

4.8 The New South Wales Biomedical Council should become the central feature in a general licensing system, the structure of which is illustrated in the chart which appears in Appendix D. All institutions and individuals engaging in IVF practice and research should be licensed. We recommend that some of the conditions of the licences should be contained in legislation at the outset, but others may be formulated by the Biomedical Council and added to the legislation in the future. The matters to be contained in legislation at the outset appear in Chapter 5 as Recommendation 6. The Council would also develop guidelines into a Code of Ethical Practice, compliance with which will be one of the statutorily imposed conditions of each licence.

4.9 The licences should be divided into two categories. There would be licences to practise IVF and licences to conduct research. The practice licences should be issued by the Department of Health. The Health Department would also have power to revoke and review the practice licences. The research licences should be granted by the Council itself. All institutions and individuals wishing to engage in IVF research should be required to obtain a licence. The conditions of the research licences would also be enforced by the Council. Breach of a condition of either a practice or a research licence could lead to revocation of the licence, and the revocation procedure should be backed by criminal sanctions imposed for practising without a licence.

D. Strict Controls on Research

4.10 Although licensed, a research institution or individual should still be required to seek the approval of an institutional ethics committee before beginning any research. This is standard practice in most institutions already.³ In addition, however, the researcher and institution should be required to obtain approval from the New South Wales Biomedical Council for every research project. In this way the Commission envisages that the Council will be able to maintain strict controls over all research in New South Wales. As compliance with the Code of Ethical Practice is to be one of the conditions of the licence, breach of the Code would allow revocation of the licence by the Council. Subsequently engaging in research work without a licence would be an offence. It is important to stress that all institutions and individuals considering IVF practice or research would be required to have a licence. Each IVF clinic should be responsible for ensuring compliance with the conditions of its licence by all doctors and scientists in its employment. Revocation of an individual's licence could therefore lead to revocation of the licence of an institution.

III. NEW SOUTH WALES BIOMEDICAL COUNCIL

A. The Three Functions of the Council

4.11 The New South Wales Biomedical Council is central to our recommendations for reform, and the Commission envisages its duties as covering three major areas:

1. *An advisory role:* Advising the Minister for Health on issues arising in reproductive technology and biomedicine and promoting research and informed debate on these topics.
2. *A legislative or policy role:* Developing the licensing system from the compulsory conditions provided by legislation and by formulating the terms of the Code of Ethical Practice. There will need to be

constant review of the statutory conditions and the Code by the Biomedical Council as circumstances and community attitudes change.

3. *A regulatory role:* Issuing research licences and policing them to ensure compliance. This would include giving approval for each research project undertaken by a licensed research institution or individual.

B. Membership

4.12 The Council should be a small organization, with no more than 11 members and a small support staff attached to the Department for Health. The Commission recommends that members of the Council should be drawn from a wide variety of disciplines and other areas of interest, and that there should be, as far as is practicable, equal representation of men and women. Appointments to the Council should be made, from the statutory list of disciplines and areas of interest, by the Governor. The Governor should also nominate the person who is to chair the proceedings of the Council. It is the Commission's view that the public importance of the Council and the representative nature of its membership require that the appointments be made by the Governor. While the Commission recommends that one member of the Council should represent the Department of Health, we do not think that this person should be eligible for appointment as chairperson.

IV. PRACTICE LICENCES

4.13 All clinics offering IVF procedures would be required to obtain a licence from the Department of Health. In recommending the issue of licences in this manner, the Commission believes the system of regulation should be able to take advantage of existing resources and thus keep the administrative functions of the New South Wales Biomedical Council to a minimum.

4.14 As already outlined all practice licences would contain a number of conditions imposed by the legislation. These would not be subject to alteration, except by Parliament. To supplement these compulsory conditions the Council should be given power to formulate extra conditions and to advise the Minister for Health on their inclusion in the legislation. In its recommendations the Commission has deliberately kept the number of statutory conditions to a minimum, to ensure flexibility, allowing the Council to develop further conditions as the technology and understanding of its implications, develop. Breach of any licence condition should be a ground for revocation of the practice licence. Failure to operate with a licence would be an offence under the legislation.

4.15 The compulsory licence conditions should include a requirement that all IVF clinics and researchers comply with a Code of Ethical Practice. The Commission envisages that this Code would contain the governing principles for all aspects of IVF practice. Their formulation and review should be one of the major tasks of the Council. Our recommendations list several matters to be included in the Code by statute (see recommendation 6). For example, the prohibition placed on the development of an embryo beyond the time at which implantation would normally occur would become part of the Code. As compliance with the Code is a condition of a licence, any breach of the Code would be a ground for its revocation.

V. RESEARCH LICENCES

4.16 The structure of the system of research licences would be much the same as that for practice licences. All institutions and individuals who wish to engage in research would be required to obtain a licence, and all would be required to conform to the general Code of Ethical Practice, which would cover research programs as well as practice. The main difference between the two schemes lies in the fact that the research licences would be the direct responsibility of the Council. They would be issued directly by the New South Wales Biomedical Council, rather than by the Department of Health. In addition, all licensed institutions would be required to obtain the approval of the Council for each research project they proposed to conduct. This approval would be required in addition to the current obligation to obtain approval from an institutional ethics committee. Breach of a condition, or a term of the Code of Ethical Practice would provide a ground for revocation of the licence by the Council and responsibility for ensuring compliance by individual licensees would be imposed on the licensed institution.

FOOTNOTES

1. Family Law Council, *Creating Children: A uniform approach to the law and practice of reproduction technology in Australia*. (AGPS, Canberra, 1985) at 88, para 6.8.22; Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters* (Vol II, 1985) at 209; Department of Health and Social Security, *Report of the Committee of Inquiry into Human Fertilization and Embryology* (Warnock Report) (HMSO Cmnd 9314, London, 1984) at v; Committee to consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization (Waller Committee) *Report on the Disposition of Embryos Produced by In Vitro Fertilization* (Vic Govt Printer, August 1984) at para 3.2, and see also the minority view of Professor Priscilla Kincaid-Sniith and Professor Roger Pepperell at Appendix C, at p35, paragraph c2.5.
2. Denmark has established a 17 member ethics council which will be required to assess future and current directions in IVF; Biomedical and Ethical Issues in France are dealt with via the Comite Consultatif National d'Ethique, a consultative, body with no regulatory powers; In 1981 the Swedish Government formed a committee which continues to investigate issues of Artificial Conception.
3. National Health and Medical Research Council. *Ethics in Medical Research* at 11. (AGPS, Canberra, 1983).

5. Recommendations

I. THE NEW SOUTH WALES BIOMEDICAL COUNCIL

A. Membership and Functions

Recommendation 1:

Legislation should establish a Council to be called the New South Wales Biomedical Council, with membership and functions as follows:

1. Membership

- (i) There shall be no more than 11 members of the Council.
- (ii) Members shall be selected to represent one or more of the following disciplines or fields of interest:

The community

Infertility support groups

Health care planning

Medicine including reproductive medicine

Biomedical research including research related to human reproduction

Law

Representative of the Department of Health

Moral theology

Philosophy and ethics

Women's health

Social science

- (iii) There should be as far as possible, an equal representation of men and women.

5.1 The composition and number of members for the Biomedical Council have been modelled on the broad representative approach of the National Bioethics Consultative Committee (NBCC).

2. Functions

- (i) To advise the Minister on any question or issue arising in relation to biomedicine.
- (ii) To promote (by the dissemination of information and in other ways) informed public debate on ethical, social and scientific issues that arise from reproductive technology and biomedicine generally.
- (iii) To formulate, and keep under review, a code of ethical practice to govern the use of artificial fertilization procedures and research on the human embryo.
- (iv) To advise the Minister on the conditions to be included in practice and research licences.
- (v) To promote research into the causes of human infertility.

- (vi) To advise the Minister on questions arising out of or in relation to reproductive technology.
- (vii) To collaborate with other bodies carrying out similar functions in Australia.
- (viii) To provide for compulsory review of the storage of embryos by IVF clinics (Recommendation 22) and as part of this function, to make decisions as to the transfer or discontinuance of storage of records (Recommendation 29).
- (ix) To review the 10 year limit on the storage of embryos (Recommendation 22).
- (x) To set out in a code of ethical practice the nature of information required to be recorded by IVF clinics (Recommendation 28).
- (xi) To make decisions as to access to non-identifying information when there is no agreement between the record-keeper and the person seeking access to that information (Recommendation 30).
- (xii) To consider and approve or disapprove all research projects proposed by holders of research licences (Recommendation 19) and as part of this function, to consider and approve or disapprove any proposal in such a project to allow the transfer to a woman of an embryo that has been the subject of research (Recommendation 16).
- (xiii) To monitor developments in relation to access to identifying information, with a view to making recommendations to the Minister if circumstances alter (Recommendation 32).
- (xiv) Such other functions as the Minister may specify from time to time.

5.2 The functions of the Council derive from the recommendations in this Report, proposals outlined by the Federal Minister for Health for the National Bioethics Consultative Committee and powers given the South Australian Council on Reproductive Technology under the Reproductive Technologies Act, 1987. Their purposes are explained in Chapter 4.

B. Code of Ethical Practice

Recommendation 2:

A code of ethical practice should be formulated and kept under review by the Biomedical Council. The Code should be reviewed regularly by the Council but the following matters should be included in the Code by legislation at the outset:

- (i) An embryo may only be stored for 10 years, after which it may not be kept alive. (Recommendation 22).**
- (ii) An embryo may not be used, dealt with or disposed of unless the couple for whom the ovum was fertilized agree. Where one of the couple dies, the survivor retains the power of use, dealing and disposition. Where both die, such power vests in the clinic or storage facility. (Recommendations 24, 25 and 26).**
- (iii) No embryo should be allowed to develop in vitro, beyond the point at which implantation would normally occur, and should therefore not be kept alive longer than 14 days (excluding any period in storage.) (Recommendation 15).**

The Code of Ethical Practice is discussed in relation to Recommendation 6 at 5.12-5.14.

II. PRACTICE OF IVF

A. Regulation Not Prohibition

Recommendation 3:

- (i) There should be no prohibition of the practice of IVF or GIFT by legislation or other official action.
- (ii) Regulatory measures should be applied to the practice and procedures of IVF and GIFT in accordance with the succeeding recommendations.

5.3 Our recommendations on regulation of the practice and procedures of IVF apply to the procedure known as GIFT, as well as to IVF itself. Although GIFT does not involve fertilization of ova outside the body of a woman, the technologies used are so similar to those used in the IVF process that they should be subjected to the same regulation as applies to the IVF process.

5.4 Until recently the debate surrounding the prohibition of IVF has centered on the subject of embryo experimentation rather than the practice of IVF *per se*. Issues such as the effect of superovulatory drugs,¹ the financial cost to the community,² multiple pregnancies,³ the commercialization of IVF⁴ and its links with controversial surrogacy cases⁵ have heightened public concern over IVF practice and procedure. The mass media, often a good barometer of popular sentiment, is now approaching the subject with a more circumspect eye, in contrast to the rather romanticized image conveyed in the past.⁶

5.5 With the increasing community disquiet over IVF, the Commission has thought it necessary to make recommendations on its practice and procedures. A neat calculus of the benefits and harms of IVF is not easy to state.⁷ In the Commission's opinion, because it assists infertile couples to have children, thereby fostering and encouraging stable family units as well as alleviating the emotional stress of childlessness, the procedure is worthy of support. The benefits outweigh the arguments for prohibition which we identified in Chapter 4 of the discussion paper.

5.6 In making this recommendation the Commission notes that nowhere in the Western world has legislation been enacted to prohibit the practice of IVF. Although only of persuasive value, the evidence from the public opinion polls reviewed in the discussion paper suggests that the practice of IVF, at least where stable married couples are involved, commands substantial support in the community.⁸ In making the recommendation to permit IVF to continue the Commission recognizes that there is still public concern over certain aspects of the procedure and acknowledges a need for real and effective regulation. The primary aim of the regulations proposed is the protection of the public, whether the consumer, the child or the community at large.

B. A Licensing System Controlled by the Department of Health

Recommendation 4:

Legislation should be enacted to establish a licensing system whereby the practice and procedures of IVF may be both carried out and controlled under conditions consistent with the public interest. The conditions of the licences should be determined by the New South Wales Biomedical Council and the system should be administered by the Department of Health.

5.7 The practice of IVF has two aspects: a medical and a social dimension. Although IVF is a treatment for infertility employing predominantly medical skills and techniques, the motivation and many of the ramifications for the patient are social. Solutions to the moral, ethical and social questions raised by IVF are often beyond the competence of individual IVF practitioners and hospital ethics committees. As Justice Kirby has pointed out:

The individual practitioner may be as uncertain as the next man in society about rules that should govern his conduct. He too may not have the time to reflect upon the issues of state and many of them will be uncertain in any case. An ethics committee generally meets in private. It is not obliged to give reasons there is too much secrecy, too little frank dialogue with the whole community which is affected.⁹

5.8 The type of regulation required is one that ensures a properly controlled and monitored system without unduly restricting personal choice or scientific freedom. The licensing system provided in the South Australian Reproductive Technologies Act 1987 provides a model for the Commission. Its chief virtue is that it allows flexibility in operation which is not possible when all the details of the scheme are contained in legislation. Safeguards may be needed to ensure that the system remains responsive and accountable to public demand.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

These should be provided by ensuring public representation on the Biomedical Council and by giving the Council a public voice in its reports to Parliament through the Minister for Health.

5.9 The principal ingredients of the South Australian Act are :

(i) The issue and supervision of licences to practise IVF is the responsibility of the South Australian Health Commission, a Government department.¹⁰

We recommend that the Department of Health undertakes these responsibilities, but that the Biomedical Council should be the body responsible for formulating and advising the Minister for Health on the conditions to be contained in the licences.

(ii) The South Australian legislation imposes a number of compulsory conditions upon the grant of a licence, some negative and some positive. The negative conditions forbid the Commission from issuing a licence unless it is satisfied that there is "a genuine and substantial social need that cannot be adequately met by existing licensees", and that the applicant for the licence has appropriate staff and facilities to carry out artificial fertilization procedures. A number of positive conditions are to be inserted in every licence including requirements for the keeping of records, for compliance with a published code of ethical practice and for infertile married couples to be the only eligible patients. In this context the term "married couple" extends to couples living in stable de facto relationships.¹¹

We recommend in Recommendation 6 that a licence be subject to conditions which (a) define the kinds of artificial fertilization procedure authorised; (b) require the licensee to ensure that the New South Wales Biomedical Council's Code of Ethical Practice is observed; and (c) require that IVF be practised only by or under the direction of a medical practitioner. The Commission's recommendations on the other matters addressed in the South Australian Act appear in Recommendation 7.

(iii) The South Australian Act also prescribes the circumstances under which licences may be varied and revoked and makes provision for appeals to the Supreme Court.¹²

We recommend that in this State existing procedures under the Medical Practitioners Act 1938 be utilized to enforce compliance with IVF licences, with the one reservation that it should always be open to the New South Wales Biomedical Council to initiate proceedings for breach of a condition in a research licence. We envisage that proceedings for breach of a practice licence would be commenced by the New South Wales Medical Board, in the same way as complaints are dealt with under s28 of the Medical Practitioners Act. The complaint could also be settled in the same way as the Board may settle s28 complaints. The means of disposing of these complaints are provided in s31 of the Act. They may be referred to the Medical Tribunal, or the Board can decide to direct the practitioner concerned to accept counselling. These procedures should also be available to sanction breaches of research licences. However, because the Commission is concerned that the Biomedical Council should not lose the initiative in the superintendence of IVF research in the State, we recommend that provision be made for it to refer matters to the Medical Tribunal when not satisfied with the response of the Medical Board. The Council would then have responsibility for prosecuting the proceedings for breach before the Tribunal, and if not satisfied with the outcome, could take an appeal to the Supreme Court on questions of law, under s32U(1)(a) of the Medical Practitioners Act. The Commission does not recommend that any further provision be made for appeal to the Supreme Court. We are satisfied that the merits of the case can be satisfactorily dealt with in the Medical Tribunal and that any questions of procedural irregularity can go before the Supreme Court by use of the procedures currently available for judicial review of administrative decisions.

(iv) Behind the Health Commission in South Australia stands a newly-created Council on Reproductive Technology whose functions include the formulation of a compulsory code of ethical practice, the delivery of advice to the Commission and the fostering of uniform procedures with other States. The Council also has general powers to regulate research into human infertility. Further conditions, beyond those contained in the Act, can be added by the Council and Commission in co-operation.¹³

We recommend that the New South Wales Biomedical Council have similar powers to regulate research, including the power to initiate proceeding for breach of the licence before the medical Tribunal. It is the view of this Commission that the approval and regulation of research projects should be controlled only by the Council

because it is a representative body and because it is to be endowed with the powers and resources to conduct investigations and to keep abreast of contemporary literature and research practices.

C. Medical Practitioners Only

Recommendation 5:

IVF should only be practised or performed by, or under the direction of, a medical practitioner.

5.10 The complexity of the IVF procedure and the high degree of medical and scientific skill necessary for its performance require that it be classified as the practice of medicine, which is itself already regulated by statute. Further regulations, specific to IVF, are set out in Recommendation 6.

5.11 Both the patients and the general public will receive a measure of protection from classifying IVF as the practice of medicine. In addition to common law duties imposed upon the medical practitioner, there are well established statutory controls applying to medical practice under the Medical Practitioners Act 1938. Professional standards applying to the practice of medicine are also set down by bodies such as the Australian Medical Association, the Fertility Society of Australia and the royal medical colleges.

D. Clinics to be Licensed

Recommendation 6:

Legislation should provide that all IVF clinics are required to obtain a practice licence which should include the following conditions:

- (i) A condition defining the kinds of artificial fertilization procedures authorized by the licence.**
- (ii) A condition requiring the licensee to ensure that the Council's Code of Ethical Practice is observed.**
- (iii) A condition requiring that IVF will be practised only by or under the direction of a medical practitioner (Recommendation 5).**
- (iv) A condition requiring that adequate counselling facilities be available and be formally offered to prospective patients (Recommendation 10).**
- (v) Such other conditions as the Minister may determine.**

5.12 The Commission believes that some matters should be fixed by legislation and not left for determination by the Biomedical Council. These matters are set out here. Other matters are amenable to decision by the Council and, the Commission believes, should be the subject of a Code of Ethical Practice to be drawn up by the Council. Some additional matters, referred to in Recommendation 2, should be included in the Code by legislation.

5.13 As explained in Chapter 4, the Commission believes that the flexibility of policy and decision-making which it requires can only be achieved by establishing a representative body to evaluate the community's needs as the potential of the technology is revealed. The means by which the New South Wales Biomedical Council will make its decisions known are threefold:

by advice to the Minister;

by the tabling of its reports in Parliament; and

by the formulation and review of the Code of Ethical Practice.

5.14 Some matters are regarded as so fundamental that they should be included as part of the original legislative framework. Amongst them are our recommendations that IVF be practised by medical practitioners only and that the licence contain a description of the type of practice it permits. If the Council comes to the conclusion that more matters are of a similarly fundamental nature, it may advise the Minister and have the legislation amended to reflect its views. In general, however, we see the flexibility we require as being achieved as the Council develops and reviews its Code of Ethical Practice. As this will be a document of which the Council has control it may alter it at will to accord with the demands of the time. The Commission would expect that some forms of the Code will become fixed to form the basis of the conditions of practice and research. Others will need to change as new information is received and *old* techniques are superseded. In the Code of Ethical Practice the Council will have the means available to keep abreast of the technology. The Code of Ethical Practice should be kept under constant review by the Council. To ensure that it does not become dated, the Council should be obliged to undertake a formal review of its terms at regular intervals of not less than three years.

E. Admission to IVF Program

Recommendation 7:

Legislation should be enacted to provide that before commencing or authorizing the commencement of a procedure of IVF and ET in relation to a woman, a medical practitioner should give due consideration to the following matters:

- (i) Whether the woman is a member of a couple who are infertile, or whose children are likely to be affected by a genetic abnormality or disease;**
- (ii) The welfare and interests of any child born as a result of the IVF procedure;**
- (iii) THE home environment and stability of the household in which the child would live;**
- (iv) Whether or not counselling is desirable;**
- (v) The prospective parent's physical and mental health, age and emotional reaction to IVF and ET.**

This recommendation is discussed with Recommendation 9 at 5.16-5.18

F. Consent to Treatment

Recommendation 8:

No legislation imposing compulsory requirements for consent should be enacted. This matter should be left to the general common law principles that govern consent to medical treatment.

5.15 As the Commission has recommended (in Recommendation 5) that practice and research in IVF should be regarded as part of the practice of medicine, we do not think it necessary to make special provision for the giving of consent to treatment. Practitioners who treat patients without obtaining their consent render themselves liable to civil or criminal actions in trespass. In its circulars the Department of Health recommends that consent be obtained before any surgical operation, procedure or medical treatment is undertaken. The Department also provides examples of the forms of consent it recommends be used. Under these circumstances we regard the addition of a special statutory requirement of consent for the IVF procedure as unnecessary duplication. The principles of common law, supported by the practices of the Department of Health, provide sufficient guarantee that the IVF procedure will not be embarked upon without consent.

G. Medical Misconduct

Recommendation 9:

Breach of the duty imposed by Recommendation 7 should be capable of being found to be "Misconduct in a professional respect" either within section 27(2) of the Medical Practitioners Act 1938, or by a comparable provision.

5.16 Eligibility to be considered for treatment for infertility should not be restricted but should be regarded in the same way as eligibility for any other medical treatment. Thus, a person who is not affected by infertility of a type that can reasonably be treated by IVF, should not be able to compel the provision of IVF any more than a healthy person could compel a doctor to perform a pointless operation.

5.17 A person who suffers from infertility should be entitled to be considered for treatment. If the IVF practitioner declines to treat, the reasons for refusal should be made available to the person concerned. The Commission envisages that the decision to accept a patient on the IVF program will not be made in isolation by the medical practitioner but after consultation with the counselling unit linked to the IVF clinic (see Recommendation 10). The final authorization, however, should remain with the practitioner. These recommendations appear in the Commission Report on Artificial Insemination. A full explanation of our reasons for their inclusion appears in Chapter 6 of that Report.

5.18 The Commission also suggests that a provision similar to section 9 of the draft Artificial Conception (Amendment) Bill, contained in Appendix A of the Commission's Report on Human Artificial Insemination be enacted to give effect to Recommendations 7 and 9. This suggestion is made for the purposes of legislative drafting.

H. Counselling of Patients

Recommendation 10:

Counselling should not be made compulsory for every IVF patient; however it should be a compulsory condition of practice licences that adequate counselling facilities be available and be formally offered to prospective IVF patients in every IVF clinic.

5.19 Because of the complicated medical procedures involved, and the emotional and physical stresses often endured during the treatments, counselling becomes a very important part of IVF treatment. It is important that patients are made aware of what is happening, and counselling is one way of ensuring this. Many submissions made to the Commission argued that counselling should be made a compulsory prerequisite for admission to a program. Other submissions, particularly those from individual patients and patient groups, were opposed to any sort of compulsory counselling which was imposed by statute or regulation.

5.20 The Commission has recommended that all clinics should, as a compulsory condition of their practice licence, offer counselling facilities. Failure to do so will mean breach of the licence, possibly leading to its revocation. This does not mean that all patients will be obliged to use the service; merely that it must be offered, and we envisage that it should be readily available and given adequate resources. It should not be regarded as a formality.

5.21 The Commission envisages that the New South Wales Biomedical Council will formulate the standards required for adequate counselling and that in doing so, the Council will consult patients and medical practitioners, and particularly social workers already working in the infertility area.

I. No Special Legal Liability

Recommendation 11:

No legislation should be enacted to impose any specific legal liability upon medical practitioners or parents of IVF children to pay compensation for damage or injury resulting from IVF. This matter should be left to the courts for judicial determination.

5.22 Although there are no principles of common law which deal specifically with the IVF procedure, general legal duties relevant to medical and professional practice exist which are applicable to the parties to IVF. For instance, once a medical practitioner accepts a person as an IVF patient and commences treatment, the practitioner owes

the patient a duty of care. The standard of care required is the general professional standard to which a reasonably careful, skilled and informed practitioner should conform.¹⁴

5.23 In the Human Artificial Insemination Report the Commission recommended that no action should be taken to enact legislation imposing specific legal liability upon medical personnel or parents to pay compensation for damages or injury resulting from AI.¹⁵ The Commission felt that the law in this area are best left to the courts for determination. This is also our conclusion here.

III. RESEARCH ON HUMAN EMBRYO

Recommendation 12:

No general prohibition of research on the human embryo should be enacted (by majority).

5.24 By a majority the Commission recommends that there be no general prohibition on the practice of IVF and no prohibition on research being carried out on the IVF embryo for a period of 14 days after fertilization of the ovum. Again by a majority, we recommend that there be no prohibition on the creation of embryos solely for the purpose of research nor on the transfer to a woman of an embryo that has been the subject of research. The research is to be conducted under the umbrella of a licensing system supervised by the New South Wales Biomedical Council. It is envisaged that the Council will license institutions and personnel undertaking research, and that each new project will be submitted to the Council for approval before research is commenced. The licensee will then be required to comply with a Code of Ethical Practice and any further conditions formulated by the Council. Details of our proposals are given in Chapter 4 and in the commentary on Recommendations 14-16 below. The views of the two Commissioners who dissented from Recommendations 12 and 14 appear in the Minority Opinion in Appendix A to this report.

Recommendation 13:

The Commission recommends the two procedures known as cloning and trans-species fertilization should be prohibited.

5.25 The process known as cloning is said to occur when “viable or potentially viable offspring that are multiple and genetically identical” are created from human tissues.¹⁶ This process is considered ethically unacceptable by the NHMRC and has been prohibited in Victoria.¹⁷ Although not falling within its terms of reference, the Senate Select Committee also condemned the procedure.¹⁸ While it was not convinced that there was cause to fear use of the procedure in the future, the Warnock Committee recommended that it be kept under review.¹⁹ In recommending the prohibition on cloning the Commission does not intend to prohibit the process of embryonic biopsy. In this process cells are removed from the embryo at a stage when their removal does not interrupt its development. If pursued, the technique of embryonic biopsy has potential for use in the early diagnosis of foetal abnormality. The Commission prefers to leave the question of the acceptability of this procedure to the New South Wales Biomedical Council for decision when more is known about the technique.

5.26 The process of trans-species fertilization has also been condemned elsewhere. The process occurs when the gametes of a man or woman are fertilized by the gametes of an animal. The Victorian Infertility (Medical Procedures) Act 1984 prohibits it²⁰ and the Warnock Committee recommended that, except when used in close association with “a recognized program for alleviating infertility”, it should be treated as a criminal offence.²¹ The Senate Select Committee also suggested that the practice be prohibited.²² This Commission regards these two practices as so abhorrent that they should not be left to be regulated by ethical guidelines. We therefore recommend that both procedures be prohibited by statute. Mr Russell Scott was no longer a member of the Commission when this Recommendation was settled.

Recommendation 14:

No general legislative prohibition should be enacted to prohibit the creation of embryos solely for the purpose of research (by majority).

This recommendation is discussed below Recommendation 16.

Recommendation 15:

Accepting the principle that an embryo should not be allowed to develop beyond the time at which implantation would normally take place, the Commission recommends that no embryo be kept alive longer than 14 days (excluding any time kept in storage).

This recommendation is discussed below Recommendation 16.

Recommendation 16:

No general legislative prohibition should be enacted on the transfer to a woman of an embryo that has been the subject of research (by majority). Conversely, such transfer should not be made compulsory. The New South Wales Biomedical Council should be given the duty and power of considering and permitting the transfer of such embryos as part of its function of considering each research protocol (see Recommendation 19).

5.27 The recommendations of this Commission are similar to those made by most other major inquiries into IVF. None has recommended that research on the human embryo be prohibited, but most have been divided on the question of whether conditions should be imposed on its conduct. There have also been divisions of opinion in this Commission on these recommendations. These are detailed below. The other inquiries have each recommended that IVF technology be supervised by an advisory council.²³ This Commission concurs in the view that there is a need for a council to advise the Minister for Health on developments in IVF technology. Such a council should also scrutinise all proposals made for research and regulate their conduct.

5.28 The recommendations of the Commission are in essence, that research into IVF should be allowed to proceed under the supervision of an advisory council to be called the New South Wales Biomedical Council which reports and is answerable to Parliament through the Minister for Health. The majority of the Commission believes that it should be open to the Council to approve proposals for research which involve the use of embryos for purposes which may not be beneficial to them. This type of research is referred to as non-therapeutic experimentation by the Senate Select committee in its Report.²⁴ Two members of the Commission have dissented from this recommendation. They would place a legislative prohibition on what they call destructive non-therapeutic experimentation. A statement of their reasons appears in Appendix A.

5.29 The Commission also recommends that the Council should have power to approve a research project which involves the creation of embryos for the purposes of research. Those members of the Commission who dissented on the question of non-therapeutic research also dissented from this recommendation. Their views appear in the minority opinion in Appendix A.

5.30 A majority of the Commission recommends that it should be open to the Council to approve research which involves the transfer to a woman of embryos which have been the subject of research. Mr Russell Scott dissented from this recommendation.

5.31 It is expected that these recommendations will be met by strong opposition from some members of the community. Our reasons for not accepting some of the views that have been put to us are set out below.

The public good

5.32 The main reason behind most of the Commission's recommendations on research relates to the novelty of the technology. It is the Commission's firm belief that research and practice in IVF are in a very early stage of development, and that significant and unknown advances in technique and knowledge are still to be made. The task before the Commission. was to design a system to regulate research and practice at a time when much of what is to be known of IVF technology has yet to be discovered. In view of this, it is unacceptable to the Commission to prohibit research completely. We prefer to establish a council with expertise and authority to examine and approve or reject individual proposals for research.

5.33 Two members of the Commission are not prepared to permit the Biomedical Council to approve research not beneficial to the embryo, but the majority would confer this power on the Council. The reasons given by the

minority appear in Appendix A, and those of the majority view are presented here. It should be made clear at the outset that the recommendation made by the majority does not contemplate that research on the embryo will be conducted without preliminary research on other subjects in accordance with normal scientific practice. The recommendation is made in the expectation that the Council will view all applications for approval for research on the human embryo as exceptional and requiring the most convincing evidence to support them. There is an assumption in our recommendation that the protocols for medical research as prescribed in the Declaration of Helsinki and as adopted by the NHMRC have been complied with. This means, for instance, that where practicable thorough research will have been carried out on animal subjects first and an estimation made of the likely benefits and rates of success of further research on human subjects.²⁵ It should be made clear at this point that the Commission does not intend its comments on research and experimentation to extend to non-invasive procedures which involve only observation of the embryo.

5.34 It is the Commission's view that the need to comply with existing research protocols first will meet the most serious objections the Senate Select Committee had to experimentation on human embryos. That Committee defined experimentation as involving "the testing of an hypothesis with no certainty as to result, though with a degree of expectation that a particular outcome is probable depending on the aim and type of experiment".²⁶ Such experimentation could be therapeutic or non-therapeutic. Based at least in part on the belief that at present all non-therapeutic experimentation on embryos was "intrusive and destructive",²⁷ the majority of the Senate Select Committee decided not to permit non-therapeutic experimentation. It did acknowledge, however, that "in the future, non-destructive, non-therapeutic procedures may be developed".²⁸

5.35 A majority of this Commission is prepared to leave the decision whether research or experimentation is carried out on human embryo to the New South Wales Biomedical Council which it proposes should be established. The decision will then be made on the basis of scientific knowledge established at the time of the request for approval of the research and in the context of the particular circumstances surrounding each request. The Council will at that time be better equipped than this Commission, or any other contemporary inquiry, to make a decision which is fully informed both as to scientific fact and community acceptance. The decision the Council will have to make will be less hypothetical than the general question of principle we are asked to settle. Therefore, we would expect it to be a better decision than any we can make at present.

The need for research

5.36 The majority of this Commission has also been influenced by the strongly expressed opinion of the NHMRC that "research with sperm, ova and fertilized ova has been and remains inseparable from the development of safe and effective IVF and ET".²⁹ The NHMRC guideline stated further that, "as part of this research other important scientific information concerning human reproductive biology may emerge".³⁰ Scientists working in the field are also convinced that the technology is still at a very early stage of development and that its success rates can only be improved through further research and experimentation.³¹ Both the Waller Committee and the Ontario Law Reform Commission recognized the need for further scientific research to allow development of the techniques used in IVF and an improvement in the success rates.³² The Ontario Commission also acknowledged "it seems to be widely recognized that embryonic research is necessary for human welfare, not simply for the development and refinement of the IVF procedure itself".³³

5.37 Given the uncertainty surrounding the potential of the technology the Commission is not prepared to recommend a legislative halt to what may be important scientific development. The Commission believes that the establishment of the Council will provide the safeguard necessary to prevent unacceptable research projects.

Therapeutic research only

5.38 The majority of the Commission is not persuaded that research on the embryo must be restricted to therapeutic, non-destructive research. The views of the two members who would so restrict the research are given in Appendix A. The demand to restrict research in this way arises from the debate on the status of the embryo. Put in its strongest form this view concludes that because no distinction can be made between the human embryo and a fully formed person, the embryo should be accorded the same respect as is due to any person. This approach requires research which is not beneficial to the individual embryo to be proscribed because it regards the Declaration of Helsinki, adopted by the World Medical Assembly in 1964, as being

applicable to embryos. The Declaration dictates: "in research on man, the interests of science and society should never take precedence over considerations related to the wellbeing of the subject".³⁴

5.39 The majority of the Commission is not persuaded by the argument that the Declaration of Helsinki should be applied automatically to the human embryo in vitro. We are in agreement with the findings of many other inquiries on this point and in this regard accept the general view expressed by the Ethics Board of the United States Department of Health, Education and Welfare in its report of 1979 that:

... the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal moral rights attributed to persons.³⁵

The Warnock Committee in England and the minority of the Senate Select Committee arrived at a similar view of the status of the human embryo.³⁶ By contrast, the majority of the Senate Committee was of the view that the embryo should be "regarded as genetically new human life organized as a distinct entity", and that its "known and social future" compelled respect.³⁷ That Committee's conclusion was "prudence dictates that, until the contrary is demonstrated 'beyond reasonable doubt'... the embryo of the human species should be regarded as if it were a human subject for the purpose of biomedical ethics".³⁸ Basing its views on the work of a medical ethics committee appointed by the French Government in 1983, the Family Law Council also reached the conclusion that the respect due to the human embryo meant that it should not be subjected to research.³⁹ However, the Council withdrew from this position somewhat when in its next recommendation it proposed the establishment of a national council of reproductive technology which would "consider, as a priority, and keep under review the question of research/experimentation on human embryos".⁴⁰

5.40 The majority of the Commission can agree with the view, expressed in other inquiries and by many individuals, that the determination of the status of the human embryo is not a matter of simple biology.⁴¹ It is a moral, ethical and ultimately a legal question upon which there is currently no consensus.⁴² The unanimous opinion of this Commission is that the human embryo should not be accorded the same status as a human person, however, there is a division of opinion as to how much respect is due to the embryo. The minority would give far greater respect to the embryo than the majority in that they would apply the Helsinki Declaration to research on the embryo by a legislative prohibition on destructive, non-therapeutic research. In view of the continuing debate, the majority of this Commission does not recommend that the Council's power to examine and approve research proposals should be restricted by a legislative prohibition on non-therapeutic research. We agree with the Family Law Council that, "whether research should be permitted, and if so under what constraints and limits - is a social, moral and ethical [question], and as such must be... dealt with by a body as representative of community views, and as free from bias, as is possible".⁴³ The Family Law Council recommended a national advisory council. We recommend that the New South Wales Biomedical Council we propose should be regarded as fulfilling this role for New South Wales.

Creation solely for the purposes of research

5.41 As indicated above (para 5.29) a majority of the Commission recommends that the New South Wales Biomedical Council should have power to approve projects which contemplate the creation of embryos solely for the purpose of research. Again, our view has been reached in the belief that the powers of the Council should not be circumscribed by legislative prohibitions which may turn out to be founded on misconceptions or misinformation. It is not envisaged that the Council will readily approve a project which involves the creation of embryos solely for research purposes, even if the research can be regarded as therapeutic and non-destructive. However, we do not wish to prevent consideration of such proposals.

Use of Spare Embryos

5.42 The Commission also finds the arguments which would limit research to so-called spare embryos unconvincing.⁴⁴ They are neither sufficient to answer the arguments based on status⁴⁵ nor persuasive in the context of the realities of scientific research.⁴⁶ The Commission is not persuaded that the intention with which an embryo is created should be a crucial factor in whether it can be used as a subject for research. Although a prohibition on the creation of embryos solely for the purposes of research would restrict the numbers of embryos which could be used for the purpose, it would not satisfy those who have moral objections based on the status of

the embryo. Nor does the identification of an embryo as spare and therefore available for research purposes, satisfy this Commission's requirement, stated in paragraph

5.39 above, that the embryo is entitled to profound respect. We believe that respect is better accorded to the embryo under the scheme we recommend in which each proposal for each research project is evaluated by the Biomedical Council in order to establish that the intrusion on the integrity of the embryo is justified by reference both to the rigour of the experimentation which has preceded it and to the benefits which are likely to ensue. The Commission also has difficulty in accepting the scientific basis of the spare embryo theory. Most scientific experiments require some guarantee that the sample on which the tests are to be made is of a sufficient size and that it has been randomly selected. The results of any experiment conducted under less than optimum conditions are not likely to be trusted. It seems important that if research on the human embryo is to be permitted, each project should be conducted under the most ideal conditions attainable. In this way, and not by use of the spare embryo theory, the numbers of embryos used for the purpose should be kept to a minimum. In this way also, there will be some guarantee that those embryos used for research purposes will not be wasted in the process.

Use of Embryo After Research

5.43 The majority of the Commission adopted a pragmatic view of the powers of the New South Wales Biomedical Council in making the recommendation that there should be no legislative prohibition on the use of an embryo for reproductive purposes after it has been subjected to research. One member of the Commission dissented. Mr Russell Scott considered that legislation should be enacted to prohibit the transfer to a woman of an embryo on which research had been conducted. The purpose of the majority recommendation is to ensure that we do not create an anomalous position in which therapeutic research carried out on an embryo would be frustrated by a prohibition on its transfer to a woman. We would not expect the Council to approve projects involving transfer of the embryo to a woman in which no guarantee could be given of the embryo's potential for normal growth. The Commission does not envisage that on most occasions transfer to a woman will be part of the experimental process. The expectation is that the research will have been completed prior to the transfer and that no attempt will be made to transfer an imperfect or incomplete embryo.

5.44 There should be no compulsion to transfer an embryo which has been the subject of therapeutic research to a woman. It is the Commission's view that the woman's personal liberty demands that she be given the choice to refuse to accept the embryo. Where the woman does not wish to receive the embryo, she and her partner should have the right to decide how to dispose of it. As stated in their minority opinion (para 19), two members of the Commission would place limits on the types of research for which the embryo may be used. The rights of the parties for whom the embryo was created would be restricted accordingly. The majority's recommendations on this question are discussed above.

Recommendation 17:

Legislation should be enacted to establish a licensing system whereby research on the human embryo may be both carried out and controlled under conditions consistent with the public interest. This system should be administered by the New South Wales Biomedical Council.

This recommendation is discussed in Chapter 4 and below Recommendations 12-14.

Recommendation 18:

Legislation should provide that any person or institution intending to carry out research on the IVF embryo, should be required to obtain a research licence, which should include the following conditions:

- (i) Defining the kinds of research authorised by the licence.**
- (ii) Requiring the licensee to observe a code of ethical practice formulated by the Council in relation to such research.**
- (iii) Requiring the licensee to maintain adequate records.**

(iv) Such other conditions as the Council may determine.

This recommendation is discussed in Chapter 4 and below Recommendation 12.

Recommendation 19:

Every research project proposed by a licensee shall, in addition to the usual process of approval through institutional ethics committees, be submitted to the New South Wales Biomedical Council for consideration and approval.

This recommendation is discussed in Chapter 4 and below Recommendation 12.

Recommendation 20:

The New South Wales Biomedical Council should supervise and review each institution's research records.

5.45 It is important that the New South Wales Biomedical Council has access to all the facilities and records of all research projects. It is only through visiting the research institutions that the Council will be able to ensure that it is properly informed of contemporary scientific development and of the level of compliance with the licences it issues. It is expected that the Council will work co-operatively with the institutions and their research workers, but in cases of friction or misunderstanding it is essential that it has the authority to enforce its visiting and investigative powers.

IV. STORAGE AND DISPOSAL OF EMBRYO

A. Ethical Code to Regulate

Recommendation 21:

Subject to the other recommendations made in this report, legislation should be enacted to provide that the IVF embryo may not be stored or dealt with except in accordance with the Code of Ethical Practice. The Code should regulate all dealings with the IVF human embryo.

The Code of Ethical Practice is discussed below Recommendation 6 at 5.12-5.14.

B. Ten Year Limit on Storage

Recommendation 22:

There should be an overall time limit placed on the storage of embryos. The Commission recommends an initial limit of 10 years, after which the embryo may not be kept alive. Power should be vested in the New South Wales Biomedical Council to vary that limit and provide for compulsory review of storage by a clinic at prescribed intervals.

5.46 The period of 10 years accords with recommendations made in the United Kingdom and Ontario reports and by the NHMRC.⁴⁷ The recommendation for this limit is prompted by concern for the possible adverse effects of long-term storage and the legal and ethical implications of disposing of embryos whose parents have died, divorced or separated. However, to ensure the regulations are responsive to changes in medical science, we recommend that the New South Wales Biomedical Council be given power to alter the time limit and to provide guidelines for compulsory regular reviews of storage of embryos.

C. Consent to Use and Disposal of Gametes

Recommendation 23:

(i) The power to deal with and dispose of sperm and ova produced for IVF should vest in the respective gamete providers.

(ii) In the case of the unconditional donation of gametes, the power to determine the use, storage and disposal of gametes should vest in the IVF clinic.

5.47 In a typical IVF procedure with the use of “super-ovulation” the woman may produce more ova than is necessary for the treatment cycle and the question of the disposal of the excess ova will arise. The common law recognizes no rights of control over ova or sperm stored as a consequence of IVF procedures.⁴⁸ While the courts may be able to construe an agreement to enforce the wishes of the gamete providers, the situation is uncertain and the Commission believes that legal regulation is required.

5.48 In relation to unconditional donation of gametes, we recommended in the Report on Artificial Insemination that legislation be enacted to give the clinic power to determine use, storage and disposal when semen is donated unconditionally.⁴⁹ The Commission considers that there is no reason to distinguish between an unconditional donation of semen and an unconditional donation of ova. Therefore we recommend that the clinic be given power to dispose of ova which have been donated unconditionally.

5.49 This recommendation will not prevent parties making an agreement setting out the terms on which the donation was made. Where such an agreement has been made to regulate the terms under which the gametes are to be stored, the clinic will be obliged to respect it. If compliance with the terms of the agreement becomes impossible the clinic will be obliged to contact the depositor and to make alternative arrangements. If the depositor has died or cannot be traced, the clinic should have power to dispose of the gametes.

D. Consents to Use and Disposal of Embryos

Recommendation 24:

Within the proposed time limit the stored embryo cannot be used dealt with or disposed of unless the couple for whom the ovum was fertilized agree.

This recommendation is discussed below Recommendation 26.

Recommendation 25:

Where one of the couple for whom the ovum was fertilized dies the power to make decisions as to use or disposal vests in the survivor.

This recommendation is discussed below Recommendation 26.

Recommendation 26:

Where the couple are dead, the power to make decisions as to the use or disposal of the stored embryo vests in the clinic or storage facility.

5.50 The principles we have applied to the storage and disposal of gametes are in general the same as those we would apply to embryos. The model we have used is that of guardianship. We regard those for whom the ovum was fertilized as the people most appropriate to make the decisions on disposal of the embryo. Equally, it is the people for whom the embryo was created who should decide on its use or storage. We would prefer that the decision be made jointly by those for whom the embryo was created. After the death of one of them, we recommend that the decision be taken by the survivor. It is only when both parties have died that the clinic or storage facility should be given power to make decisions on the use or disposal of the embryo. As expressed in their Opinion in Appendix A, at paragraph 19, two members of the Commission would qualify the rights to be given to the guardians by restricting the types of research or experimentation which they could approve.

5.51 This leaves the difficult question of what is to happen if the parties cannot agree on use, storage or destruction. The Commission has not made an express recommendation on this matter because it regards the decision on disposal as of such fundamental importance that it should not be taken out of the hands of the parties concerned. Where they cannot agree therefore, the Commission would expect the status quo to be maintained. If the embryo is in storage when the dispute arises, it will continue there, until the statutory limit of 10 years of

storage is reached and it must be destroyed. Where the dispute arises earlier and before storage has taken place, destruction would occur after the 14 day period recommended in this report, unless the parties agreed to storage pending settlement of their dispute. The Commission would expect that the clinic's counselling facilities would be offered to anyone engaged in such a dispute in the hope that agreement could be reached.

V. RECORD KEEPING AND ACCESS TO INFORMATION

A. Clinics to Keep Records

Recommendation 27:

All IVF records should be created, kept and maintained by the IVF clinics themselves.

5.52 The Commission believes that there is no need for a central register of IVF information to be created. There are many disadvantages in the centralization of information; the primary one being the potential for invasion of privacy. A central register could give the state access to intimate personal information about citizens that is unique. This may infringe a person's desire for privacy and anonymity and have important repercussions on gamete donations. To a lesser extent, the use of such a central register would involve a duplication of records already kept that could be both labour-intensive and expensive to set up and maintain.

5.53 One of the major concerns of leaving the management of records to individual clinics has been the fear of loss of information through poor organization or the closure of a clinic. The Commission believes that the system of licensing proposed in Recommendation 6 overcomes these concerns. All clinics will be licensed and will therefore be required to satisfy the Department of Health of their suitability to practise. In addition the Commission envisages that the Department would be given powers similar to those embodied in section 17 of the South Australian Act, permitting an authorized person to enter and inspect any premises, to ensure compliance with the conditions imposed on the maintenance of records.

B. Code of Ethical Practice

Recommendation 28:

All clinical reports relating to the IVF and ET procedure and to the parties involved in that procedure should be retained. The extent of the records, their content, and the methods used to preserve anonymity are matters for good medical practice. In addition the New South Wales Biomedical Council should be empowered to set out facts which must be recorded in the Code of Ethical Practice.

This recommendation is discussed below Recommendation 27.

Recommendation 29:

No time limit should be fixed on the retention of the records of IVF clinics. Transfer or discontinuance of storage of records should only be allowed on permission of the Biomedical Council.

5.54 According to our information, all IVF clinics in New South Wales retain recorded information indefinitely, although there is no formal requirement for them to do so. In our view, there should be no fixed time limit for retention of records. Recorded information should be kept indefinitely, but a procedure should be provided whereby a record keeper may apply for permission to dispose of records or transfer them to an acceptable custodian. Permission to discontinue or transfer storage could be granted by the New South Wales Biomedical Council.

C. Access to Non-Identifying Information

Recommendation 30:

A statutory entitlement should be created whereby IVF children, gamete donors and any other person, upon showing "good cause" may have access to recorded non-identifying information either by agreement with the record keeper or, failing agreement, upon the decision of the New South Wales Biomedical Council.

5.55 This recommendation is consistent with the Commission's conclusions in the Human Artificial Insemination Report.⁵⁰ Where the anonymity of parties to IVF is not affected, access to information should be available to persons with a sufficient interest or a good cause. For example, access to certain non-identifying information contained in IVF records may be justified for research purposes such as the gathering of statistical information for the National Perinatal Statistics Unit reports on IVF pregnancies in Australia and New Zealand. "Good cause" should be based on the Health and welfare of the parties to IVF.⁵¹

D. Access to Identifying Information

Recommendation 31:

No person should have a legal right of access to information that may identify a party to IVF and no record keeper may divulge such information, unless:

- (i) The person who is the subject of the information formally consents.
- (ii) The disclosure of information is required for the administration or enforcement of provisions of the IVF legislation.
- (iii) The disclosure of information is required in the course of the official duties of persons engaged in the administration of a hospital or other place where IVF procedures are carried out or records relating to IVF or the donation of gametes are kept.
- (iv) The information is required for the purposes of medical research and its release has been approved by the Biomedical Council.
- (v) A judge or magistrate orders disclosure in connection with any legal proceedings or report of those proceedings.

5.56 When donated gametes are used in the conception of an IVF child there may be a conflict of interests between the gamete donor's expressed wish for anonymity and the IVF child's wish to learn his or her genetic origins.

5.57 The Commission accepts that the guiding principle should be that the welfare of the IVF child should be the paramount consideration in any dispute. With respect to access to identifying information, what is in the best interests of the IVF child is a difficult and sensitive question. Current trends in adoption law and practice in jurisdictions such as Victoria, New Zealand and England are towards providing a legal right for an adopted person, upon reaching majority, to have access to identifying information about his or her biological parents.⁵² As the Commission noted in the AI Report, however, the adoption parallel is not strictly in analogous to IVF. IVF children will know the biological identity of at least one of their parents, unless it is the rare case of IVF using both donor sperm and ova.⁵³

5.58 The status of children legislation, on the other hand, deliberately circumvents the truth of biological origins. The Artificial Conception Act 1984 and the Children (Equality of Status) Act 1976 both reject biological paternity, in favour of social paternity. The husband who consents to the use of donated semen for his wife's pregnancy, is conclusively presumed to have caused the pregnancy and to be the father for all legal purposes.⁵⁴ This approach has been criticized by bodies such as the Chalmers Committee and the Family Law Council.⁵⁵ They argue that it distorts the truth of the parent-child relationship as well as having implications for birth registration records.

5.59 For the purposes of consistency with the Artificial Conception Act the Commission recommends that there be no legal right of access to identifying information. However, in recognition of the recent trends in adoption law

and the likelihood that at a future time the perception of the best interests of the child may alter, the Commission further recommends that the New South Wales Biomedical Council be given power to review the legislation. This recommendation appears below as Recommendation 32.

E. Biomedical Council to Review

Recommendation 32:

The Commission acknowledges the concerns expressed in relation to access to identifying information therefore in recognition of the possible claims of IVF children the New South Wales Biomedical Council should be vested with the power to review legislation implementing Recommendation 30 with a view to recommending alterations as changing circumstances dictate.

This recommendation is discussed with Recommendation 31 above.

F. Legislation to be Retrospective

Recommendation 33:

Legislation creating access to non-identifying information should be retrospective in respect of records in existence at the time the legislation takes effect. In relation to identifying information, the Commission makes no recommendations as to retrospectivity.

5.60 If access is only permitted to non-identifying information the Commission has no objection to the legislation applying to existing as well as future records. However, if access is to be permitted to identifying information, difficult questions arise where arrangements and understandings have been made at the time the records were created. The Commission makes no recommendation on this matter.

5.61 Extensive and detailed records of information about the parties to IVF have been created by all IVF clinics in response to directives from the NHMRC and the Fertility Society of Australia. Parliament has power to enact legislation with retrospective effect if it chooses, and modern statutes often contain specific provisions allowing for the prospective and retrospective operation of legislative provisions. Hence, in order to achieve certainty, it is desirable that a legislative statement be made with regard to the operation of laws dealing with access to information whether or not the information is already in evidence.

5.62 Section 17 of the Commission's draft Artificial Conception (Amendment) Bill, contained at Appendix A of the Report on Human Artificial Insemination provides an acceptable model which would carry this recommendation into effect. Section 17 provides:

17. (1) In this section, "non-identifying information" means information relating to artificial insemination, but does not include information whereby the identity of any party to artificial insemination might become publicly known.

(2) A person is entitled to be supplied with non-identifying information in any records relating to artificial insemination if -

(a) the person has good cause to be supplied with the information; and

(b) the information is supplied by agreement with the person having custody of those records or by direction of an authorised officer.

(3) For the purposes of this section, a person has good cause to be supplied with non-identifying information if the person who agrees to supply the information or the authorised officer who directs that the information be supplied is satisfied that the supply of the information is in the interests of the health and welfare of a party to artificial insemination.

(4) In this section -

“authorised officer” means a person for the time being authorised by the Minister for the purposes of this section;

“records” includes records made before the commencement of this section.

G. Confidentiality and the Donor

Recommendation 34:

Subject to the preceding recommendations in relation to access to identifying and non-identifying information, legislation should be enacted to give the gamete donor the same duties of confidentiality and anonymity as a patient, particularly for the purposes of record keeping.

5.63 At common law, there may be no special legal duty owed by the medical practitioner to a gamete donor. Unlike the infertile couple, the donor is not a patient and therefore is not necessarily entitled to the same duties of confidentiality as a patient.

5.64 Because of the circumstances of artificial conception and the sensitive nature of the donation the Commission recommended in the Human Artificial Insemination Report that the law should impose upon practitioner- and clinics the same obligation to observe confidentiality in relation to semen donors as medical practitioners have to patients, and that the donor should be treated as though he is a patient for the purpose of record keeping.⁵⁶ We believe the same principles are applicable to gamete donors in IVF.

H. Non-Disclosure by Donor

Recommendation 35:

A criminal offence should be created in relation to a person who knowingly conceals or misrepresents information about his or her health when offering or agreeing to donate his or her gametes for the purposes of IVF.

5.65 Potential donors should be warned of this sanction when giving their personal particulars. This recommendation follows one made in paragraph 5.18 of the Human Artificial Insemination Report.⁵⁷

5.66 Section 11 of the Commission’s draft Artificial Conception (Amendment) Bill, contained at Appendix A of the Report on Human Artificial Insemination provides an acceptable model to carry this recommendation into effect. It provides:

11. A donor of semen shall not -

(a) knowingly sign a certificate which contains any statement which is false or misleading in a material particular; or

(b) knowingly make any other statement (whether or not in writing) relating to the medical suitability of the donor which is false or misleading in a material particular.

Penalty: \$5,000 or imprisonment for 1 year, or both.

I. Release of Health Information

Recommendation 36:

The supply of information suggesting that a person’s health is at risk involves an ethical duty of medical practitioners which operates in all areas of medical practice. The Commission therefore recommends that no statutory obligation should be created to require the supply of such information. This matter should be left to the courts for judicial determination.

5.67 In principle, the Commission believes that information that discloses a risk or danger to the health of a party to IVF should be disclosed to that person. It is not convinced, however, that a statutory obligation to this effect is called for. Medical practitioners are under a general duty to disclose to their patients information that suggests their health is at risk. The nature of the risk and the sensitivity of the information should be taken into account when determining the most appropriate method of dealing with the problem. Just how much information should be disclosed is best left for determination. At present, the common law is moving steadily in the direction of creating positive duties of disclosure.⁵⁸

VI. PARENTAGE OF IVF CHILD

A. Maternity

Recommendation 37:

Where IVF involves the use of donated ova, legislation should be enacted to determine conclusively the issue of maternity by stating that the woman who gives birth to a child will be presumed at law to be its mother.

5.68 Legislation is desirable to resolve any doubts in relation to a child's maternity and paternity,⁵⁹ and it is desirable that the woman who bears the child and intends to raise it, should be conclusively be presumed to be its mother.

5.69 While the Artificial Conception Act 1984, deals conclusively with the issue of paternity, there is no equivalent legislation in relation to donor ova, although the issues and requirements are the same. This recommendation is consistent with the approach taken by the Commission in the Report on Human Artificial Insemination⁶⁰ and would bring New South Wales into line with legislation in most other Australian States.⁶¹

B. Posthumous Conception and Inheritance

Recommendation 38:

Subject to Recommendation 39, no legal regulation or prohibition of IVF is called for in relation to the use of IVF procedures to achieve pregnancy with the stored gametes of a deceased person.

This recommendation is discussed below Recommendation 39.

Recommendation 39:

Where a child is conceived posthumously through the IVF process, that is, where a human ovum is fertilized in vitro af ter the death of one or both of the gamete providers, the Commission makes the following recommendations:

(i) The law should allow, or should not preclude a specific testamentary gift in favour of a posthumously conceived child or a child born from a stored embryo.

5.70 The law should not preclude the creation of a specific gift by will in favour of children conceived posthumously. Anyone who wishes to provide for a child conceived posthumously should be entitled to include an express provision to that effect in their will. This is consistent with the Commission's recommendations on Artificial Insemination⁶² and also with paragraph (ii) below.

(ii) Where an ovum of a widow is fertilized in an IVF procedure, by the posthumous use of her deceased husband's semen and transferred to her by embryo transfer, the resulting child should be recognized as the lawful child of the dead husband except for the purposes of inheritance and succession.

5.71 This recommendation also reflects those made in the report on Artificial Insemination.⁶³ Under current law, the child born to a married woman through the use of donated sperm is presumed to be the child of her

husband.⁶⁴ For these purposes “married woman” includes someone living in a stable de facto relationship.⁶⁵ Problems may arise where a woman wishes to use the AI procedure to become pregnant using her deceased husband’s semen. We argued in Chapter 12 of the report on Artificial Insemination that under the terms of the Artificial Conception Act 1984 the dead husband of such a woman may be excluded from paternity. The Commission considers that the law should be amended to make it clear that the deceased husband should be recorded as the father of the child so long as the woman is his widow at the time of insemination.

5.72 However, the Commission has also concluded that the recognition of paternity should not extend to recognition of the child under the laws of inheritance and succession. Serious practical difficulties would be created if the child were automatically treated as the child of the deceased under the scheme of distribution on intestacy in New South Wales. Similarly, if the child were considered his child in a gift to his “children” mentioned in his will. The executor or administrator of the deceased’s estate could not confidently make a distribution of assets until exhaustive investigations had been undertaken to ensure that there was no possibility of the subsequent birth of persons who may be regarded as children of the deceased. It is only by excluding posthumously conceived IVF children from these benefits that this problem can be overcome.

(iii) The Commission recommends that children conceived posthumously as a result of IVF procedures and children born from stored embryos should be able to make a claim against the estates of their genetic parents under the Family Provisions Act 1982.

5.73 This recommendation also appears in the report on Artificial Insemination and is designed to allow IVF children to take advantage of the benefits to which they are entitled under the Family Provision Act. Benefiting under the Family Provision Act can be distinguished from those including the IVF child amongst the beneficiaries under a will or intestacy. To share in an estate under the terms of this Act the IVF child will have to be able to show a close relationship with the testator and an obligation owed by him or her. Mr Russell Scott had left the Commission before this recommendation was settled.

Recommendation 40:

Where the ovum of a deceased woman is fertilized by IVF, the subsequent transfer of the embryo will necessarily involve another woman. The circumstances therefore cannot be equated with the circumstances referred to in Recommendation 39(ii), and the Commission makes no recommendations. This matter will be considered in our report on surrogate motherhood.

5.74 As the posthumous use of ova would require the use of a surrogate mother, the Commission has decided to consider this matter in detail in the Surrogate Motherhood discussion paper and report.

C. Registration of Birth

Recommendation 41:

There should not be any alteration in the law relating to the registration of births of IVF children where donated reproductive tissues have been used.

5.75 In the Commission’s view the names of the persons presumed by law to be the parents should be the names recorded in the register of births. This recommendation is consistent with the views expressed by the Commission in Chapter 11 in the report on Human Artificial Insemination.⁶⁶ In that report we indicated that the question of the registration of births was to be addressed by the Commission in another reference. Although we thought that existing legislative presumptions of parentage should be respected in the registration legislation we left the matter for decision in our later report on the Registration and Certification of Births, Deaths and Marriages. That report is due for completion soon. We propose to make our final recommendation on the matter in that report.

5.76 However, the Commission recommends that all IVF practitioners be required to record information in relation to the genetic parenthood of children born as a result of an IVF procedure, where donated human reproductive tissue is used. The Biomedical Council should be given power to review the terms of Recommendation 40 and

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

evaluate the needs of IVF children and make further recommendations at the appropriate time. Mr Russell Scott had left the Commission before this recommendation was settled.

FOOTNOTES

1. S Voumand "Fertility drug a cancer suspect: sociologist" *Age* 17 May 1988; S Voumand, "Scientists worried about IVF Drugs" *Age* 8 June 1988; R Klein, "The Exploitation of Infertility: The New Reproductive Technologies and their Impact on Women", paper delivered at ANZAAS Centenary Congress, University of Sydney (Sydney May 1988).
2. P Clark, "Blewett counts cost of the \$40,000 baby" *Sydney Morning Herald* 12 May 1988 at 1; J Allensdar and C McGee, "Cash battle for the baby-makers" *Australian* 13 May 1988 at 9; I Svendsen "Canberra to review IVF program funds" *Age* 12 May 1988 at 1. See also G Batman, *Commonwealth Perspectives on IVF Funding: A Discussion Paper* (Cth Dept of Community Services and Health, Canberra 1998).
3. "Fabulous Four: Quads jackpot a GIFT" *Daily Telegraph* 22 June 1988 at 1, 4.
4. D Cameron, "IVF company stated as McDonald's operation" *Sydney Morning Herald* 12 April 1988 at 3; R Koval, "What price the Sale of Reproductive Technology?", paper delivered at *Liberation or Loss?* conference (Canberra May 1986).
5. J Comley and M Pirrie, "Cain willing to change law for IVF baby" *Age* 4 April 1988 at 1; R West, "Victoria's first IVF surrogate mother may also be the last" *Age* 20 April 1988 at 22.
6. See, for example, L Keens, "IVF: Is it worth it?" *Australian Womens Weekly* June 1988 at 91.
7. See discussion of the principles of utilitarianism with respect to scientific research in M Warnock, "Law and the Pursuit of Knowledge" (1986) 175 *Conquest* 1.
8. IVF Discussion Paper, paras 4.4-4.7.
9. M Kirby, "Law for Test-Tube Man?", paper delivered at Queen Victoria Medical Centre (Melbourne September 1981) at 16, 17.
10. Section 13.
11. *Ibid.*
12. Sections 15, 16.
13. Sections 10, 14.
14. *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118; *Furniss v Fitchett* [1958] NZLR 396.
15. AI Report, 414.2-14.9.
16. National Health and Medical research Council, *Ethics in Medical Research* (AGPS Canberra 1983), Supplementary Note 4 at para 8.
17. Infertility (Medical Procedures) Act 1984 (Vic) s6.
18. Senate Select Committee Report, para 4.4.1.
19. Warnock Report, paras 12.11-12.16.
20. Section 6.
21. Warnock Report, paras 12.2-12.3.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

22. Senate Select Committee Report, para 4.41.
23. United Kingdom Report, para 11.18 at 64; Ontario Report, 208-209 Victorian Report Recommendation 6.16; Senate Select Committee Report para 4.4S; Family Law Council Report, Recommendation 2; Reproductive Technology Act, 1987 (SA) s5.
24. Senate Select Committee Report, para 2.29-2.34.
25. NHMRC Statement on Human Experimentation at para 4.
26. Senate Select Committee Report, para 2.22.
27. *Id* para 2.29.
28. *Id* para 2.30.
29. NHMRC, Supplementary Note 4 - In Vitro Fertilisation and Embryo Transfer, para S.
30. *Ibid*.
31. I Johnston & A Lopata - Letter to PL Carron, 13/1/86, 2 (Confidential - Senate Inquiry?).
32. Victorian Report, para 3.25; Ontario Report, 208.
33. Ontario Report, 208.
34. Set out in the Senate Select Committee Report and adopted by that Committee, Appendix 4, 156, see III, 4 of the Declaration.
35. Ethics Advisory Board, Department of Health, Education and Welfare, *HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (4 May 1979) 101, referred to in the Commissioners Discussion Paper on *In Vitro Fertilization* (DP 15, 1987) para 8.13.
36. United Kingdom Report at para 11.17; Senate Select Committee Report at paras D.11 to D.20.
37. Senate Select Committee Report, para 3.5-3.6.
38. *Id* para 3.18.
39. Family Law Council Report, paras 6.8.19-6.8.22.
40. *Id* para 6.8.23.
41. Submission of Fr Brian Lucas to the NSWLRC Public Hearing on IVF, 15 April 1988.
42. Senate Select Committee Report, para 2.40; Family Law Council Report, para 6.8.22.
43. Family Law Council Report, para 6.8.22.
44. Victorian Report, para 3.26.
45. The Family Law Council agrees with us in relation to the status argument, para 6.8.20, as does the Senate Select Committee, para 3.33.
46. JA Robertson, "Extracorporeal Embryos and the Abortion Debate" (1986) 2 *Journal of Contemporary Health Law and Policy* 53, 68-70.

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

47. Warnock Report at para 10.10; Ontario Report at 217; and National Health and Medical Research Council, *Ethics in Medical Research* (AGPS Canberra 1983) Supplementary Note 4 at 26.
48. See generally, R Scott *The Body as Property* (Allen Lane London 1981).
49. AI Report, para 10.13.
50. *Id*, para 13.23.
51. *Ibid*.
52. Adoption Act 1984 (Vic) ; Adult Adoption Information Act 1985 (NZ); Adoption Act 1976 (UK).
53. AI Report, paras 13.4, 13.12 and 13.17.
54. Section S(2).
55. Family Law Council Report at para 6.2; *Chalmers Committee Interim Report* at 53.
56. AI Report, paras 8.13, 14.10.
57. *Id*, paras 5.17-5.18.
58. *Hawkins v Clayton* (Unreported High Court, 8 April 1988).
59. Section 5(2).
60. AI Report, para 11.4.
61. Status of Children (Amendment) Act 1984 (Vic); Family Relationships Act Amendment Act 1984 (SA); Status of Children Amendment Act 1985 (Tas); Artificial Conception Act 1983 (WA). At the time of writing, there was a bill before the Queensland Parliament on status of children legislation.
62. AI Report, paras 12.4, 12.8.
63. *Id*, paras 12.9-12.11.
64. Artificial Conception Act 1984 ss5, 6.
65. *Id*, section 3.
66. AI Report, paras 11.1-11.4.

Appendix A - Minority Opinion on Embryo Research

Research and the IVF Embryo

Note of Dissent by Keith Mason QC and Eva Learner

1. We dissent from the majority recommendations relating to research on the fertilised ovum *in vitro* (hereafter referred to as the embryo) because they do not in our view go far enough to protect the embryo and the values it symbolises. In addition to the specific recommendations on the topic in the report we recommend that:-

1. "*Destructive non-therapeutic experimentation*" on an embryo should be prohibited; and
2. *The creation of an embryo for the purpose of research or experimentation on it should be prohibited.*

2. Each of the two principal recommendations is derived from our belief that the fertilised ovum is biologically a unique living entity with potential to grow into a human person. For that reason it is, we believe, morally entitled to such a degree of respect that protection in the form of the recommended prohibitions is appropriate. Our reasons are given below. As will be apparent from the form of the first of our recommendations we have drawn substantially upon the report of the majority of the Senate Select Committee on the Human Embryo Experimentation Bill 1985 (the Tate Committee) *Human Embryo Experimentation in Australia* (1986) (hereafter called "the Tate Report"). We specifically adopt the following passage from that Report:

"Whilst it may not be possible to achieve agreement, either among scientists or others, on the complete set of attributes of this entity formed from the fusion of sperm and ovum, it may be of assistance to establish those attributes for which there is general agreement; that is, to achieve a minimum description of it. Two universally accepted attributes are that the fertilised ovum has 'life' and that it is genetically human (ie it is composed of genetic material entirely from the species *Homo sapiens*). It is also generally agreed that it is an entity a centrally organised unit which has a purposeful independent function as opposed to an organ or tissues). It also has developmental potential (whether that may progress to little more than cleavage, or to birth and on to subsequent adulthood). The latter attribute is of great significance." (Para 2.6)

See also the evidence of Dr Kerin set out in para 2.17 of that Report.

3. It is our understanding that there is universal support for the proposition that the embryo is entitled to respect that reflects these biological facts. Disagreement centres upon the level of that respect; whether it has any different application before the period in which the embryo is capable of implantation (generally accepted as 14 days from fertilisation); whether decisions about the "fate" of particular embryos are to be made by the donors of the gametes, by ethics committees, or by society generally and universally; and about the means of enforcing such decisions.

4. In our judgment the appropriate level of respect to be afforded to the fertilised ovum requires that it should not be regarded as an object to be created or to be used for research as an end in itself. In one sense this is but to restate the two recommended prohibitions in an alternative form. This method of expressing this principle which we shall seek to support below draws attention to the fact that the embryo has in our view *in this regard* the same attributes as a living person. It attracts these particular attributes and as a result qualifies for recognition of the rights which form part of these attributes. (The nature and level of *legal* recognition of these attributes is a separate issue dealt with later.) The conclusion in this paragraph is a moral judgment not a scientific fact. We seek to defend it on ethical grounds and it may be disputed on ethical (but not exclusively scientific) grounds.

5. We do not assert that the embryo is a person with all of the legal or moral rights of a person. To say that would be to contradict the reasoning of a virtually unbroken tradition of Western moral philosophy, canon law (until changed in the Catholic Church as late as 1869) and English common law that held the termination of fetal life that was not formed (recognisably human) did not constitute homicide (see P Badham, "Christian Belief and the Ethics of In-Vitro Fertilization and Abortion" (1987) 6 *Bioethics News* p7). This same tradition condemned abortion, with varying degrees of opprobrium, depending on the stage of development of the foetus. But it did not, so far as we are aware, ever treat the embryo or "unformed" foetus as an object to be baptised or, if expelled by natural or procured abortion, afforded any form of burial rite.

6. The rights of a living person not to be treated as a mere object for research are stated categorically and authoritatively in the introduction to the "64 Declaration of Helsinki:

"In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research."

Section 3 of that Declaration, dealing with non-therapeutic clinical research, states that "in the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out." Whilst the Helsinki Declaration was obviously intended to deal with biomedical research on living human beings we consider it should be applied to the fertilised ovum for reasons set out below.

7. The starting point in our reasoning why the embryo attracts these attributes is its biological nature summarised in para 2 above. These scientifically ascertainable facts represent a recent confirmation of something that was simply asserted in former times or even denied by the majority of moral philosophers who contended that "quickening" occurred well after fertilisation. In this sense science has created or presented material calling for a moral judgment in the light of new facts. It is also science that has brought us IVF itself, with its capacity to "create" and sustain extra-corporeally a living entity that may grow to a human person after transfer. It is only in the last decade that anyone could examine with a microscope the cells constituting the early embryo and discern and track their development.

8. A further analysis of the debate around the status of the embryo in respect of its "personhood" or the attribute of "life" given it by the Tate Report, is offered by Daine Mary Warnock. ("In Vitro Fertilization: the Ethical Issues (11)", in the *Philosophical Quarterly*, Vol 33 No 132). She believes it may be preferable to identify the principles rather than the "rights" associated with a person, or the characteristics of those on whom they are to be conferred. The suggestion she poses is that the object about which treatment is being considered should be perceived as a "human being" rather than whether or not "it" is a person. "Human" is a biological term and simply distinguishes human from other animals. She suggests that "we being human... there are ways of treating our fellow humans that are right and ways that are wrong." This in itself "is a moral principle, the very principle, in fact upon which the demand/or rights depends". We believe it is Warnock's suggestion that this principle which reflects our humanity directs us to regard fellow members of our species as in a special relation to ourselves. There is an acceptance that there are problems with such a principle. It will not cover, for example the treatment of all embryos; some will be aborted spontaneously, others will live and die without any awareness of their existence. "Nevertheless however far from full humanity a foetus may be, we would do well to remember that it is a human foetus" she writes.

9. Having decided that the embryo is sufficiently, human to warrant protection, Warnock analyses the philosophical positions of Utilitarianism and what she terms strict Utilitarianism. She identifies the position of people who cannot support these approaches because of their moral beliefs and feelings. She places the emphasis on the fact that it may particularly be their feelings or sentiments which can have a central influence on their moral decision making. In discussing a woman's views on what should be done with say her spare embryos, whether this be consent for experimentation or not, "the matter turns not on her reasons, but her feelings". Warnock quotes Hume who has said that morality is "more properly felt than judged of". Finally she goes on to express her strong view that the essence of morality can be the existence of a set of not necessarily coherent or unified principles, which constitute barriers against what is felt to be wrong doing. She suggests that often members of committees and other organizational enquiries find it difficult to believe anything but that a moral judgment should be rational or else based on religious dogma.

10. Most official inquiries (and this report is no exception) recognise those attributes in the recommendation that at the very least non-therapeutic research and experimentation on the embryo *in vitro* should cease after the 14 day period. There are many reasons why it is generally seen as immoral to develop the embryo beyond or significantly beyond the 14 day period in order to produce a medium for research which is intended to be discarded once the research goal has been achieved. Some of these reasons are basic attitudes of personal revulsion which may or may not reflect moral judgments but which are generally seen to be valid nevertheless. Other reasons are given which are more obviously within the realm of moral discourse and cover a range of deontological and teleological stances. These appear to have nothing to do with the sentience of the embryo

because those that hold them seem generally to accept that brain activity does not commence until 10-12 weeks after fertilisation. Some of these attitudes proceed from concern not to harm or abuse the entity itself ; others add that disrespect for this form of life may lead to disrespect for other and more developed forms of human life including living persons. Not everyone holds these views (see Fortin, "Legal Protection for the Unborn Child" (1988) 51 Mod L 54) , but they are so widely accepted that they require no further elaboration or justification in this dissent.

11. These views about the more developed embryo and the foetus are important because they are the starting point from which debate must be joined concerning the attributes of the embryo during its first 14 days of existence. We call this the early embryo, without (we hope) thereby prejudging or slanting the debate. Why then should the respect which society is generally prepared to afford to the embryo after 14 days from fertilisation not be afforded for this earlier period?

12. The main justifications currently advanced for distinguishing the early embryo and (subject to specific approval by an appropriate authority) permitting destructive non-therapeutic research on it appear to be threefold:-

(a) The interests of humanity in the increase of scientific and medical knowledge justifies using the early embryo as a vehicle for non-therapeutic research;

(b) The process of implantation which the 14 day period conventionally represents is biologically a marker event of such significance that it is not possible to project the moral concern to protect the embryo back earlier than that event;

(c) The IVF embryo does not have the capacity to develop into a living human being because it requires implantation into a uterus and this in turn necessitates the willing consent of the recipient woman.

13. We do not consider any of these propositions to be sound as a justification for drawing the line of protection at the 14 day old embryo.

14.(a) The needs of humanity. It is an historical fact that IVF would not have developed so rapidly to its present stage had such research been prohibited as we would now seek to do. It may be conceded that the prohibition will impede some (but not all) further research into the causes and treatment of infertility and congenital disease as well as the other areas of medicine for which society screams for a cure. As Professor Robertson has put it, "restrictions on embryo research thus carry a price-tag in terms of foregone knowledge which could improve the lives of persons in important ways" ("Embryo & Research (1986) 24 U W Ont LR p17). But the same can be said for non-therapeutic research on the embryo after 14 days, on the foetus, on the neonate, on the healthy adult and the aged person who is about to die from a terminal illness. Yet we are not prepared to allow any of these to be laboratories for destructive non-therapeutic experimentation. The reason is simply stated in the maxim that "the end does not justify the means". We see no reason why the early embryo should be treated any differently, although this involves the need to meet other arguments to which we shall turn shortly. The facts that the early embryo *in vitro* has been "created" by "artificial conception" and that it is accessible simply because it is not *in utero* do not appear to create appropriate grounds for being prepared to do something with it that most would refuse to do were it *in utero*. (We do not say that the maxim about the end not justifying the means has no exceptions, but we cannot conceive of any in this area. To those who ask if we would change our minds if science could guarantee that our view was preventing the immediate discovery of the cure for cancer, we can only say that we are unsure what our response would there be. We are however presently satisfied in point of fact that no-one can guarantee that any specific beneficial advance that cannot be procured by alternative means would occur from permitting destructive non-therapeutic experimentation that is so beneficial and so imminent that this can be justified on any form of utilitarian analysis.)

15. In the case of living human beings, a decision to protect from destructive non-therapeutic experimentation affirms an important value about the meaning of their life itself. Although each such person is one out of billions, he or she is unique and entitled to have that uniqueness affirmed by such an appropriate moral and legal right. We would base such a view partly upon moral premises derived from theological grounds. Others would reach an identical ethical position from different moral premises, some of which we would doubtless also share. Dispute centres upon the conclusions one draws from these and other premises and the question of their application to the early embryo.

16.(b) *Implantation as a significant marker event.* As to this ground for distinguishing the early embryo we adopt the Arguments of the majority of the Senate Select Committee in paras 3.8 - 3.24 of the Tate Report. The competing scientific and moral arguments are there summarised and reasons given for the Committee's conclusion that it was not persuaded of the inherent ethical validity of the marker event. We wish to add simply that we find great difficulty in understanding how the existence of the so-called marker event that others perceive to exist at 14 days becomes the basis for their virtually unanimous consensus for drawing the line against destructive research at 14 days. In other words, the capacity to implant which is achieved at about 14 days' development does not itself explain why that point is chosen as the limit of a particular type of research.

17.(c) *The IVF embryo's incapacity to develop without a willing Recipient.* As to this ground for distinguishing the early embryo, we refer to the discussion concerning the "capacity" or "potential" argument in para 8.39 - 8.46 of this Commission's Discussion Paper In Vitro Fertilization (DP 15, 1987). The Commission there tentatively advanced its reasons why it rejected the "capacity" or "potential" argument which was advanced by the majority of the Senate Select Committee, and why it supported what we have termed (in para 12) the third main justification currently advanced for distinguishing the early embryo. This Commission's reasoning was strongly attacked in a number of submissions made in response to the Discussion Paper. On consideration of these submissions we have reached the view that the tentative conclusions in the Discussion Paper in which we participated cannot be supported. There is in our view no essential difference in this regard between the early embryo on the one hand and the more advanced embryo or the new-born child on the other. All are entirely dependent upon external human assistance for both life and development.

18. In any event, while it may be morally permissible for that assistance to be withdrawn in some cases (eg, arguably extraordinary means of life support for seriously incapacitated neonates), it does not follow even there that destructive non-therapeutic experimentation is justified. In all cases involving persons, including the seriously incapacitated neonate, it is generally considered wrong to treat the person as an object for destructive research that has no therapeutic purpose. As far as we are aware the protection which law and morality affords to any of these persons does not depend upon their capacity to feel pain or their ability to survive and develop. It would generally be regarded as quite wrong for a dying acephalous child to be subjected to such experimentation. Equally, most persons would unhesitatingly deny the right to conduct non-therapeutic experimentation upon an accident victim who has suffered irreversible brain-damage and is permanently comatose (often spoken of as "reduced to a vegetable"). If one accepts the description of the early embryo summarised in para 2 above and the conclusion that nothing occurs at about the 14 day period that represents a significant marker event then we see no logical ground for distinguishing the position of the early embryo from the later embryo, the foetus or the living person so far as concerns external dependency as the basis for a moral decision about research. Indeed the early embryo may have greater "potential" than the accident victim referred to above (cf Michael A Jones, "Research on Human Embryo: The Ethics of Pragmatism" (1985) *Professional Negligence* p21).

19. In stating these views we are obviously rejecting the arguments of Senators Crowley and Zakharov of the Senate Select Committee in para D40 of their dissenting report. They reason that since the developmental potential of what we have described as the early embryo is dependent on decisions made about it, ie for a woman to decide to accept the embryo into her uterus, then it follows that the decision-maker can determine for the embryo prior to implantation. Those same Senators also supported this view by arguing, as did the majority of the Tate Committee, that no woman should be compelled to have an embryo transferred to her uterus (see esp paras D31-D35). The difficulty is that a right to consent to destructive non-therapeutic research simply does not follow from these premises. Together with the other members of the New South Wales Law Reform Commission on the Artificial Conception Division (see para 5.44 of report), we accept that no woman can be compelled to have a fertilised ovum implanted in her uterus; and that in consequence the effective decision as to the fate of the embryo can and will be made in the usual case by the woman who provided the ovum. But this is simply to recognise the reality of the woman's position and the practical limitations of legal control (cf *Re F (in utero)* [1988] 2 All ER 193) if not indeed (as many would claim) the moral right to assert her personal liberty regardless of the apparent state of health of the embryo or her prior decision in the matter. If that leaves to those having the custody of the embryo the effective choice of freezing or destroying the embryo, that is the incidental effect of the woman's decision. The law cannot and (most would argue) should not compel the woman or some surrogate to maximise the embryo's chance of development and survival at the expense of the woman's liberty. Be that as it may, it simply does not follow that the woman or any other person involved in the creation of the fertilised ovum has the right to decide what forms of experimentation are appropriate for the early embryo, other than to prevent certain types of experimentation. The question is not "who shall decide", but "who shall decide what?". We come

back to the position that the early embryo is *in this regard* more than just a part or extension of the woman's body.

20. In any event it seems to us that even if the ovum provider and/or the man whose sperm fertilised the ovum may exercise "guardianship" or other types of control over the early embryo, such rights would seem logically to cease at the time when those gamete-providers cease to have any particular interest in the welfare of the embryo as such. To authorise the use of the embryo as an object for destructive non-therapeutic research has clearly passed to this stage. Personal consent, and *a fortiori* the proxy consent of a guardian does not under current law justify maiming without justification (*Attorney General's Reference (No 6 of 1980)* [1981] 1 QB 715); or the transplantation of non-regenerative tissue of a minor (Human Tissue Act 1983, s8).

21. We wish to stress however that we give no support to those who would in the matter of experimentation or research, seek to give to the early embryo a greater level of respect than that which they afford to a living person. Subject to the resolution of issues about the "guardianship" of the embryo *in vitro* for the purpose of giving appropriate consents, there is in our minds no reason why that embryo should not be subject to therapeutic research which may obviously (but incidentally) lead to the advancement of medical science or which carries a risk of harm which happens to eventuate. For this reason we would reject s14(2)(b) of the Reproductive Technology Act 1987 (SA) as an appropriate model. To prohibit, as it does, research "that *may be* detrimental to an embryo" (emphasis added) is to elevate the embryo to a status greater than that afforded to living human beings. All research and life generally involve elements of risk. Medical ethics frequently addresses the issues of what regard should be given to the *possible* risks inherent in a medical procedure or form of medical research and it does so in a comparatively uncontroversial way (eg, NH & MRC Statement on Human Experimentation, supplementary note 2, clause AS). There is indeed widespread support for the ethical validity of non-therapeutic research on children subject to strict limits, including (obviously) minimal risk to the subject (see G Dworkin, "Law and medical experimentation: Of embryos, children and others with limited legal capacity" (1987) 13 Mon ULR 189 esp at pp198, 202, 205). As we shall we hope make plain in our later discussion about the definition of the concept of destructive non-therapeutic experimentation we are concerned only to prevent experimentation which has no purpose of conferring any benefit on the embryo concerned. We note that the 1987 *Instruction* of the Catholic Church which some would oppose for its "conservative" view in other respects supports this approach (see below para 29).

22. We have, we trust, made plain that our recommendations thus far are based on a judgment which stems from a scientific fact but is essentially an ethical one. The question then arises as to how we justify the recommendation that the two prohibitions should be universal rules. Many highly respected persons and groups argue that decisions as to the type of experiments to which the early embryo may be subjected are matters for individual judgment. Included amongst them are the NH & MRC and the majority of this Commission with whose views on this point we regretfully dissent. They argue that there are many people in the community who do not have a moral objection to what we have termed destructive non-therapeutic experimentation provided that there are appropriate safeguards. These safeguards are said to include the consent of the gamete-providers, the prior approval of an institutional ethics committee and the approval of some established body such as the New South Wales Biomedical Council proposed in Recommendation 1 of this report. Those who hold this view argue (correctly) that the onus rests upon people like ourselves who would seek to deny the liberty of those in control of the early embryo to do with it that which they believe to be morally just and which has the consent of the appropriate persons or bodies whom the law currently deems authorised to give such consent. It is obvious that one is immediately thrown into the area of controversy as to the respective roles of law and morality. The famous Hart-Devlin debate discussed these issues and they recur repeatedly in modern pluralist societies.

23. Those who say that their view of morality should be backed up by legal sanctions and those that deny this in a particular or general context are in turn debating moral propositions on which minds will legitimately differ. While the latter group stress the importance of freedom, that premise and the conclusions drawn from it are matters of moral judgment. Of course the mere fact that something is widely or even universally seen to be wrong does not in itself justify legal regulation. Professor Charlesworth has reminded us that, "we must... not expect the law to be the agency by which a common morality should be enforced in the community. Equally, we must resist the idea that if the law is silent on a particular issue, that it is condoning a line of action or conniving in it". ("New Ways of Life & Death" (1984) 61 *Current Affairs Bulletin* 4 at p20.) To the extent that opinions differ as to the correctness of the conduct, the law should be increasingly hesitant to intrude.

24. Nevertheless the law can and does daily intrude into what may be said to be matters of morality although they are usually described these days as political or social decisions. A clear example is the use of the law to protect the environment, something that was virtually unheard of until this century but now has wide but not universal acceptance at least in matters of detail. Issues of protection of the early embryo and the values it represents cannot be swept into a separate compartment marked "private morality - no regulation" *simply* because this is an area of difficulty and present controversy.

25. It is, we suggest, reasonable to take as a starting point that the law should not be used as a mechanism to control conduct which some regard to be proper and others improper unless at the very least:-

1. those seeking to convert their moral judgment into legal prohibition have a clear and ethically reasonable conviction that the conduct sought to be proscribed is harmful and wrong;
2. the conduct to be proscribed is capable of clear description;
3. prohibition would not be counterproductive, eg because the law would be brought into disrepute when judges and jurors effectively declined to enforce a particular criminal law; and
4. there is some likelihood that the conduct to be proscribed would take place in the absence of the proscription.

26. We stress that the four criteria mentioned in the previous paragraph are but prerequisites to possible legal intervention. They are we believe satisfied in the present case. The threshold is crossed, certainly with respect to specific non-criminal sanctions for breach (see below, para 29). It is, furthermore, appropriate that the law should seek to prevent the two types of conduct to which we have referred. Compendiously but briefly our reasons for these conclusions are:-

(a) There is widespread concern that medical science should be regulated to some degree in this field. To our understanding Most scientists themselves seek to have some limits prescribed if only to ensure they may work within those limits without undue criticism.

(b) Making due allowance for the beneficial work of experimental scientists and the possibilities which research offers in this field, the level of sensitivity which many people in society have about this particular issue suggests a need for caution.

(c) The biological evidence now available in relation to the early embryo means that we have the advantage which former generations lacked of knowing as a scientific fact that it is a genetically unique living entity. We have already dwelt upon its other attributes which relevantly call for this level of protection in our view.

(d) In the absence of restraint there is a clear indication that some, and perhaps an increasing volume of, destructive non-therapeutic experimentation on the early embryo will take place. It has occurred, and scientists in this country wish to engage in such types of research under certain conditions.

(e) Many of those who argue for absence of general control (eg, the dissenting senators in the Senate Select Committee) do so for what in our view is an unsound reason. They assert in effect that the justification for their view flows from the decision of persons who *in this regard* (ie consent to destructive non-therapeutic research) we consider to lack any special interest that would sustain such a decision (see paras 19-20 above). We wish to make plain that we accept that the gamete-providers have an intimate and real concern that sets them apart from the public generally. In this regard their moral opinions are entitled to very special weight. What we are however saying is that their moral judgments must be assessed by the arguments advanced to support them: they do not draw their justification from the simple fact that the judgments are advanced by gamete-providers. Particularly when it is *in vitro* and about to be subjected to destructive experimentation, the embryo is more than a part or projection of their bodies.

(f) We deal. below (paras 29-35) with the question of definition of the proscribed conduct and the proposed sanctions for its breach.

27. Before we turn to the question of the form of legal sanction which is proposed, we recommend that *whatever form of legal underpinning is given to the recommendations made in para 1 there should be a five-year sunset clause*. This will ensure that the arguments which would prevail if our recommendations were accepted have to be advanced again after the five-year period if the legal restraints are to be prolonged. Some will construe this as a lack of conviction on our part about the correctness of the recommendations which we make. We, on the other hand, would see it as a recognition of the fact that this is an area of great difficulty and one in which extensive public debate is just beginning. As scientific knowledge develops, so may the arguments for or against change (cf para 7 above). Because as we have already said the onus should be on those who seek to restrict the liberty of others to do that which they may believe to be morally correct there should be no restraint placed in the way of the matter being debated afresh after a reasonable interval. A five-year period would allow the impact of the restraints to be monitored in terms of developments in this State and elsewhere and it would mean that those whose views differ from mine would bear no impediment or stigma for seeking to re-agitate discussion on the topic.

28. On the topic of sanctions the choice is essentially between a criminal prohibition where a penalty flows, and a licensing condition where the consequence of breach is (after an appropriate finding) the loss of licence. It is of course possible to impose both forms of sanction concurrently (cf Reproductive Technology Act 1987 (SA), ss14(4) and is).

29. We recommend that the *sanction for breach of the prohibitions referred to in para 1 should not be criminal but should be loss of licence for any participant knowingly involved and for the research establishment itself if the prohibition was breached in circumstances other than on where the management had a reasonable excuse for failing to prevent it. In addition breach should constitute professional misconduct for any person who is in a profession having such a concept*. Our reasons for declining to recommend a criminal sanction in lieu or in addition are essentially pragmatic. A criminal sanction would encourage a literal or restrictive as distinct from generous and purposive interpretation of the legislated form of prohibition. It would also inevitably encourage attempts to justify prohibited conduct by an appeal to the moral judgment of the individual jury who would doubtless be given "scientific" evidence about the intended benefit of the proscribed actions. If these things occurred the substantive recommendations we have already made, including that directed at relatively dispassionate review after a decent interval, would risk being undermined at the altar of an individual researcher's possible martyrdom. We note that this non-criminal form of sanction was proposed by several of those who made submissions to the Commission advocating a level of protection for the early embryo equal to or stronger than that embodied in our proposals.

30. If our recommendations are adopted there will be no need to define a period after fertilisation at which any legal restraint is to be lifted, whereas this will be necessary (but not difficult) if the majority recommendations are simply adopted. However, our first major recommendation (see para 1) requires the use of the concept "destructive non-therapeutic experimentation". We believe this term to have sufficient clarity of application that it is appropriate for use as part of a non-criminal prohibition of conduct, although it may be expanded in an appropriate definitional clause.

31. The distinction between therapeutic and non-therapeutic research is well recognised in the field of medical ethics. The clearest illustration of this is in the use of the concept in the Declaration of Helsinki (para 6 above). The National Health & medical Research Council. has formally recognised this Declaration in its published *Statement on Human Experimentation and Supplementary Notes*. Supplementary Note 2 deals with "Research on Children, the Mentally Ill and those in Dependent Relationships or Comparable Situations" and, in dealing with the ethics of research on children stressed the need to determine the acceptability of the risk/benefit relationship of any research study (cl A(3)(ii)). Clause A(S) states:

"Risks of research may be considered in terms of:

- (i) therapeutic research (where the procedure may be of some benefit to the child).

In determining whether there is an acceptable relationship between potential benefit and the risk involved, it is essential to weigh the risk of the proposed research against customary therapeutic measures and the natural hazards of the disease or condition.

(ii) non-therapeutic research (where the procedure is of no direct benefit to the child).

The risk to the child should be so minimal as to be little more than the risks run in everyday life.

Risks of research in this context include the risk of causing physical disturbance, discomfort, anxiety, pain or psychological disturbance of the child or the parents rather than the risk of serious harm, which would be unacceptable."

The same distinction is reflected in the 1987 *Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation* issued on behalf of the Catholic Church by the Sacred Congregation for the Doctrine of the Faith. That stated (in p24):

"One must uphold as licit procedures carried out on the human embryo which respect the life and integrity of the embryo and do not involve disproportionate risks for it but are directed towards its healing, the improvement of its condition of health, or its individual survival."

32. This distinction is also generally recognised by the law: see eg *Re D* [1976] Fam 185 at 196; *Re Eve* (1986) 31 DLR (4th) 1 at 34. Recently members of the House of Lords were critical of the usefulness of the distinction in relation to the exercise of the parental jurisdiction of the court to authorise the sterilisation of a severely mentally handicapped ward (*Re B* [1987] 2 All FR 206 at 213C, 214C, 219C). They stressed, nevertheless, that approval to a medical procedure for a minor or mentally incompetent person would only be given when it was for the benefit of that person. In this field the interests of society generally and of the person's near relations were quite irrelevant (*Re B* at 214C, 219D; see also *Re Eve* at 29, 31). "The discretion is to be exercised for the benefit of that person, not for that of others" (*Re Eve* at 29 per La Forest J).

33. The well known therapeutic/non-therapeutic distinction addresses the question of the overriding intention of the person performing the relevant procedure. It asks whether that was directed to the benefit of the person (or embryo) or at the benefit of others. The fact that healthy development does not occur is not critical (cf the child suffering terminal cancer whose parents consent to some radical treatment with little or no proven chance of success). Nor does a procedure become non-therapeutic simply because it is observed and the results recorded for the benefit of medical science generally.

34. To reduce further the possibility of difficulty in application we propose that "destructive" be added to the prohibited form of procedure. This is intended to add a cumulative requirement in order to underscore that only certain types of non-therapeutic research are to be precluded absolutely (cf para 21). We would expect that this concept of "destructive" might be further defined by Parliamentary counsel who could draw on statements such as those discussed in para 31.

35. One additional drafting matter is prompted by a comment of the dissenting Senators Crowley and Zakharov ("Tate Report" para D98). This is the desirability of indicating whose intent is relevant in relation to the non-therapeutic destructive procedure. In our view the relevant person is the researcher involved.

36. Finally on matters of definition we record, in relation to our second principal recommendation (para 1 above), that we do not see any real difficulty in creating a civil prohibition of an act done for a particular "purpose". There may be difficulties of proof, but the fact that a person may contemplate a number of possible consequences of an action does not mean that each is necessarily part of his or her "purpose". Where there is a plurality of purposes present, the ulterior purposes will only vitiate the act "if the ulterior purpose is a substantial purpose in the sense that no attempt would have been made to do (the act) if it had not been desired to achieve the unauthorised purpose" (*Samrein Pty Ltd v MWSDB* (1982) 56 ALJR 679 at 679).

37. Before ending this note of dissent we wish to address briefly what we perceive to be some likely objections that may be raised to our proposals on the matter of research. Without, we hope, falling prey to pretentiousness, may we do it in the form of a short "socratic" dialogue with someone we shall call X:

X: Your proposals would Stop IVF in this State.

KM/EL: No, there are already clinics here and elsewhere which practice IVF without doing *any* research. Besides, many forms of research would be permitted under my proposals (subject to the other controls recommended in the majority report). A significant one is embryo biopsy which involves the removal and culture of one or two cells from an embryo still *in vitro* which need not affect the subsequent development of the embryo.

X: Well at least it would be tougher in this State than elsewhere. Don't forget that some scientists believe it is morally wrong to implant IVF embryos unless particular procedures have been adequately tested and sometimes this means that some embryos have to be used for such testing even if it means that they are thereby destroyed. Your proposals will either force our scientists to do their research in a less restrictive jurisdiction; or (worse still) cash in on the research of others elsewhere. You are just pushing the moral issue outside this State.

KM/EL: If that is the consequence of our legislators adopting our proposals so be it. But what you are really saying amounts no more than to recognise that we are proposing a universal norm for this State which we both know will not please those who wish to disregard it even for the highest motives. Like individuals, no society can abdicate its own moral or legal responsibility because others see things differently or are not prepared to give effect to the views they in fact hold. The point about the morality of using the research data of others overseas who are not subject to similar constraints is a difficult one. It has surfaced recently in the United States involving proposals to use apparently significant scientific data recorded in the course of inhuman experiments by Nazis upon human subjects.

X: All this talk about "morals". I just want to allow those scientists or couples who see nothing inherently wrong with any type of research to do what they wish to do. You are trying to stop the development of knowledge by making moral judgments.

KM/EL: But can't you see we are all making ethical or moral judgments. The protection which we choose to give or withhold from the early embryo necessarily involves the making of moral judgments. We may argue about our premises and about the conclusions we draw from them for that is the nature of ethical discourse. Those who assert the liberty of the gamete-donors or the scientists to decide what they think is right and themselves making judgments. It is often they who appear unwilling to argue the reasons why the premises lead to permitting all forms of research (subject to individual restraints). Similarly, the pluralism of Australian society cautions one to be restrained but it does not paralyse action. We happen to believe that we don't solve an immense ethical problem by passing it to others to decide.

X: It worries me that you want to give such a level of protection to what you term the early embryo, but what are really clusters of up to a few dozen undifferentiated cells. The Economist summarised what we are talking about as follows (15 November 1986): "There is no distinguishing between cells which might much later become part of a foetus - or two foetuses - and those which may become a placenta, an umbilical cord or other extra-embryonic matter. Indeed, the cells may become a cancerous mole which could kill a mother if it was in her womb. But the likeliest fate for such a cluster of cells if it is in its natural environment, a womb - is destruction. Most early embryos (at least 60%) fail to implant themselves in the wall of the womb and are lost before anybody knew they were there".

KM/EL: We don't dispute those facts, but to us they miss the point. Don't forget that we are only against destructive non-therapeutic research and the creation of embryos for the purpose of research. If you accept the proposition that the embryo is human life which (given ideal circumstances) can develop into a living human person we draw the Line (for reasons already given) at using that embryo for ends which have nothing to do with its own individual welfare.

X: Well society will look rather silly if it legally condones the therapeutic abortion of the fully developed foetus (eg at 8 weeks) and the destruction of the *in vitro* embryo after 14 days but balks at using your early embryo for research which may lead to significant advances.

KM/EL: Those who take an absolutist or near-absolutist view on the abortion debate would agree. But again, we say we are dealing with different things. Whatever be the moral rights and wrongs about a decision to abort therapeutically where there is no real risk to the mother (however defined) the fact is that there are significant legal difficulties in the enforcement of any abortion prohibition. The evidentiary problems and the unwillingness of juries to convict coupled with the risks to health of mothers if they are driven by law to disreputable and unqualified abortionists are factors which are totally removed from the present issue. The law cannot effectively require any woman to become an unwilling life support system for an ovum fertilised *in vitro*, even if it were morally right to contemplate doing so in any circumstances. For these reasons the embryo's and the foetus's viability and potentiality can in fact be frustrated by circumstances external to it. But this does not address what we perceive to be the issue, which is the appropriateness of using that entity for research purposes that have nothing to do with its own welfare and which are necessarily destructive of it. If the debate really were about abortion we would be finding people willing to contemplate destructive or even non-therapeutic research well beyond the 14 day limit which is widely acknowledged today. We know that there are many who seem to take a strong stance for or against destructive non-therapeutic research depending on their attitudes to the abortion issue, but we don't. The dangers of confusing the two are fully discussed by Professor Robertson in his article "Extracorporeal Embryos and the Abortion Debate" (1986) 2 *Journal of Contemporary Health Law & Policy* 53.

Appendix B - Schedule of Organisations and Persons Who Made Submissions

- I. Written Submissions to this Commission.
- II. Oral Submissions to this Commission at Public Hearing.

Schedule of Organisations and Persons who made Submissions

I. WRITTEN SUBMISSIONS TO THIS COMMISSION

Albury, Ms R M (SB2)

Albury, Ms R and Dietrich, Ms H (SB3S)

Australian Catholic Social Welfare Commission (SB29)

Bartels, Dr D (SB33)

Board for Social Responsibility, Uniting Church in Australia (SB6)

Christian Centre for Bioethics, Sydney Adventist Hospital (SB28)

Concern NSW, WISH, IF Group and HOPE (Infertility Support Groups) (SB17)

The Council of Churches in NSW (SB18)

Cosgrove, Mrs J (SB41)

Daly, Rev Fr T V (per St Vincents Bioethics Centre newsletter, 26 November 1987) (SB26)

Dept of Fertility and Reproductive Endocrinology, Royal Hospital for Women (SB37)

Dooley, Rev M (SB24)

Fertility Society of Australia (SB42)

Ford, Rev Dr N M (SB10)

Foundation Genusis (SB31)

General Legal. Committee, Law Society of NSW (SB39)

Hepburn, Ms L (SB44)

IVF Patient (Name Withheld By Request) (SB43)

Jefferson, Mrs A L (SB46)

Kannegiesser, Mr H (SB7)

Kasimba, Mr P (SB13)

Knights of the Southern Cross (SB3)

Maher, Mr B (SB20)

Marke, Mr R (SBIS)

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

McCullagh, Dr P (SB34)

Miller, Dr L (SB36)

New South Wales Council for Civil Liberties (SB4S)

NSW Humanist Society (SBIL)

NSW Infertility Social Workers' Group (SB22)

NSW Women's Advisory Council (SB4)

Potempa, Mrs V (SB21)

Presbyterian Women's Association (SB16)

Pope, Mr J (SBIZ)

Right to Life Association (NSW) (SB25)

Right to Life Australia (SB5)

Royal Hospital for Women Fertility Group (SB38)

Salvation Army (SB32)

Singer, Professor P and Dawson, Dr K (SB27)

Social Issues Committee, Anglican Church (Diocese of Sydney) (SB40)

St Thomas More Society (SB19)

Steigrad, Dr S (SB8)

Sullivan, Ms L (SB23)

Women's Legal Resources Centre (SB1)

Women's Legal Resources Centre (per "On the Record" newsletter, December 1987) (SB30)

Woods, Mr L and Mrs M (SB14)

Yovich, Dr J L (SB9)

II. ORAL SUBMISSIONS TO THIS COMMISSION AT PUBLIC HEARING

Albury, Ms R and Dietrich, Ms H (PH18)

Bannon, Mr C J (St Thomas More Society) (PH5)

Bartels, Dr D (PH4)

Brown, Ms M and Sadlier, Ms L (Women's Legal Resources Centre) (PH14)

Burton, Dr B (Maternity Alliance) (PH2)

Coombs, Miss J (PH9)

NSW Law Reform Commission: REPORT 58 (1988) - ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION

Deagen, Ms J (PH8)

Dill, Mrs S (IF Group) (PH15)

Emmett, Mrs L (PH10)

Fisher, Mr A and Harrigan, Mrs K (Right to Life Association (NSW)) (PH19)

Garner, Ms F (Infertility Social Workers Group of NSW) (PH17)

Hale, Mrs J (PH22)

Lucas, Fr B (Catholic Church, Archdiocese of Sydney) (PH16)

McCullagh, Dr P (PH1)

McKean, Mr A (PH21)

O'Donovan, Mr B J (PH7)

Potempa, Mrs V (PH11)

Smith, Mr G (PH20)

Smith, Mrs M (PH13)

Sperling, Ms K (NSW Council for Civil Liberties) (PH12)

Tighe, Mrs M (Right to Life Australia) (PH3)

Tonti-Filippini, Mr N (PH6)

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