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A STUDY OF THE ISSUES INVOLVED IN THE LEGAL REGULATION OF HUMAN EMBRYO RESEARCH AND RELATED PRACTICES.

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ABSTRACT

The development of artificially assisted reproduction has challenged some of the fundamental values which underlie the legal systems of the Western world. This thesis attempts first to put in context the continuing debate over the use of early human embryos in scientific research by considering the nature of the medical technology involved. In the second section, several aspects of the controversy over embryo research are then examined. Attempts to classify the human embryo and endow it with a particular moral or legal status are considered with a view to recommending an approach which legislators could adopt in regulating research on embryonic life. Thirdly the nature and scope of some of the attempts to regulate embryo research which have already been made are examined to test the approach suggested in the second section.

This thesis covers material up to and including September 1993. No account has been taken of any developments in policy or legislation which have occurred since then.

RESUME

Le développment de la reproduction assistée par des moyens artificiels a remis en cause certaines des valeurs fondamentales qui sont à la base des systèmes juridiques du monde occidental. Cette thèse essaie tout d'abord de replacer dans son contexte le débat qui se poursuit sur l'utilisation d'embryons humains précoces dan la recherche scientifique en considérant la nature de la technologie médicale mise en jeu. Dans la deuxième section, on examine plusieurs aspects de la controverse qui règne sur la recherche portant sur les embryons. On considère les tentatives qui ont été faites pour classifier l'embryon humain et le doter d'un statut moral ou juridique particulier. En troisième lieu, on examine la nature et la portée de certaines des tentatives de réglementation de la recherche sur les embryons auxquelles on a déjà assisté afin de tester l'approche suggérée dans la deuxième section.

Cette thèse repose sur des matériaux allant jusqu'a septembre 1993 inclus. Elle ne tient pas compte des développements qui sont intervenus depuis dans le domaine politique ou législatif.

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Morag B Wise
November 1994

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INTRODUCTION

Louise Joy Brown,[1] heralded as the world's first "test-tube baby",[2] is fast approaching adulthood. The success of her birth marked the culmination of countless years of scientific research, involving both animal and human embryo experimentation and clinical trials using human embryos conceived in vitro to attempt pregnancy by embryo transfer.[3] Why, then, so long after the original fruits of that labour were yielded, does a seemingly irreconcilable debate rage on over the ethics and legality of the scientific research which necessarily preceded the clinical application of IVF and on which, some argue, its continued practice depends?

It has become increasingly evident that of all the issues raised by artificially assisted conception, those concerning storage and disposition of, and research on human embryos are the most bitterly challenged. Few other topics within the entire "reproductive technology" debate have sparked such controversy, creating deeply diverse positions both among the public at large and within the many Committees appointed to deal with problems raised by the new reproductive methods. It seems appropriate, therefore, to focus on the question of the ethics and legality of embryo research as one of the most pressing unresolved issues in the continuing conflict between scientists of the new biology and those seeking their control. It will be argued that the attempts to legislate about the matter thus far have done little, if anything, to answer the central questions.

1 Born on July 25 1978 in Oldham, England

2 The expression is a media distortion of the term in vitro (literally, "in glass") fertilisation.

3 The British team who achieved the first birth after in vitro fertilisation recorded each stage of success. See; Edwards, Banister & Steptoe, Early Stages of Fertilisation In Vitro of Human Oocytes Matured In Vitro, Nature 1969;632: Steptoe & Edwards, Laparoscopic Recovery of Preovulatory Human Oocytes after Priming of Ovaries with Gonadoptrophins Lancet 1970 ; ii : 683; Steptoe, Edwards & Purdy, Human Blastocysts Grown in Culture, Nature 1971 ; 132 Steptoe & Edwards, Reimplantation of a Human Embryo with Subsequent Tubal Pregnancy Lancet 1976 ; ii : 880; Steptoe & Edwards, Birth after the Reimplantation of a Human Embryo Lancet 1978 ; i : 366.

The embryo experimentation discussion will be shown to have been of fundamental importance within the wider context of artificial reproduction generally. It has influenced much of the regulatory action in that field.

This thesis will attempt first to set the scene for debate by outlining some of the events in reproductive technology which have together resulted in what may be described as "the burgeoning embryo crisis".

The central theme of the unresolved debate regarding embryos will then be tackled; defining the issues, their examination by the various Committees formed for such discussion and critical analysis of the various standpoints taken. Several matters will be isolated for consideration, namely the embryo's place in the human developmental process, its status in law, the motives behind its creation, uses of concepti in vitro, and time limits on such use.

Attempts which have been made to resolve the embryo debate by regulation will then be addressed in the third section. Various forms of regulation have now been introduced, and there has been activity at all levels, including the sphere of International Law. The approaches will be considered both as illustrative of the diversity of possible solutions to the embryo debate and with a view to examining whether any universal solution can ultimately be adopted.

The embryo debate has caught media as well as academic attention worldwide. it was the subject of numerous Committee discussions and recommendations for years before any regulation was introduced. This thesis cannot hope to serve as an exhaustive review of those materials, which encompass everything from government publications, reports of various religious bodies and political pressure groups to scientific evidence from some of the physicians and researchers involved. The author's intention is rather to examine in detail only the major proposals pertaining to each particular topic within the debate. For this purpose the concentration is mainly on some of the Reports and legislation emanating from the Commonwealth countries of Canada, Australia and the United Kingdom, but reference is also made to materials from the United States and from Europe, where appropriate.

Experimentation on human embryos was described some years ago as a "continuous and intractable" debate.[4] It is the aim of this paper to analyse critically the various standpoints which have contributed to this supposed intractability and compare some of the methods now adopted to manage resolution of the dilemmas posed.

The conclusion attempts to summarise whether or not the regulation discussed in Part C has begun to answer any of the fundamental questions about the status of the human embryo tackled in Parts A & B.

This thesis presents an in-depth comparative study of the background against which various jurisdictions have approached the legal regulation of embryo research. As already indicated, it is not intended to represent an exhaustive scrutiny of the available Reports and legislative provisions. In particular, there is no mention in the text of the thesis of the Report of the Canadian Royal Commission on New Reproductive Technologies which became available on 15 November 1993. The present writer had completed all of the research in the area covered by this thesis, and written the text, prior to the release of that Report. Due to its extensiveness, the Royal Commission's Report would merit a separate detailed study. In any event, the aim of this thesis, which is to examine the background to the issues involved in human embryos' moral and legal status and methods to control their use, can be achieved independently of that Report.

4 R Scott, "Experimenting and the New Biology: A Consummation Devoutly to be Wished" in Proceedings, American Society of Law & Medicine, 1st International Conference on Health Law & Ethics (Sydney '86) (1986) 14 Law Medicine & Health Care 123.

PART A

THE MEDICAL TECHNOLOGY: CHALLENGING FUNDAMENTAL VALUES

There has not yet emerged, in any of the countries presently utilising artificial reproduction techniques, a clear public policy framework within which the various forms of assisted conception can be evaluated.[1]

It may be useful, then, to look at some of the major techniques of assisted conception in order to assess their relation to each other and their place, if any, in the embryo research debate. Policy decisions regarding the use and fate of early embryos are unlikely to stand or fall alone; they will continue to have a profound influence on changing societal reactions toward related practices.

CHAPTER I

AIH AND AID

Artificial insemination (AI) represents the first medical procedure developed which separate conception from sexual activity. It has been recognised and used in a veterinary context for centuries, and was first applied to a woman at the end of the eighteenth century.[2] The technique is strikingly simple; semen is obtained from the male by masturbation and is inserted through a syringe in or near the cervix of a woman's uterus. Timing is crucial to the success of AI, as the period of maximal fertility in a woman coincides with ovulation. A rate of 70-75% pregnancies within three or four months of the start of treatment was achieved some years ago.[3]

1 The distinction here is between piecemeal legislation, which has been passed, and a coherent socio-legal policy which balances effectively the competing claims and interests of those it affects. Assessment of such a policy could take many years after its inception.

2 A McLearen, 'Biological aspects of AID' in Law and Ethics of AID and Embryo Transfer, Ciba Foundation and Symposium 17 (New Series) (Associated Scientific Publishers: Amsterdam (1973)) at 3.

3 See S J Behrman, 'Techniques of artificial insemination', in Progress in Infertility, Behrman, S J & Kistner, R W, eds., (Churchill, London, 1968).

The semen used for insemination may be provided by the husband (AIH) or by a donor (AID). AIH may be resorted to in cases of unexplained infertility, where the husband has oligospermia,[4] or where he is unable to achieve intercourse due to severe physical disability. In the simple case where the semen is fresh [5] and the husband has consented to the procedure, AIH appears to raise few legal or ethical problems. Only those committed to the notion that any deliberate separation of the sexual act and procreation is 'unnatural' and therefore unacceptable have objected to its use.[6] Such views, while usually representing the powerful voice of the Catholic Church, necessarily include condemnation also of most contraceptive methods and the practice of masturbation for obtaining semen. They can be regarded then as the most extreme points on a sliding scale of attitudes toward intervention with the reproductive process in general, and are unlikely ever to be the primary influence on policy decisions relating to these matters. In fact the major Committees discussions regarding artificial insemination concluded that AIH needs little, if any, formal regulation.[7]

Conversely, the now widespread practice of AID has raised several ethical and legal issues, and many still regard them as unresolved. Since the courts settled the matter that AID did not constitute adultery some

4 Defined as "a subnormal concentration of spermatozoa in the penile ejaculate". Stedmans Medical Dictionary, Fifth Unabridged Lawyers' Edition. (Anderson Publishing Co, Cincinnati 1982). Commonly referred to as 'low sperm count'.

5 For a brief discussion of the issues raised by the use of stored gametes in reproduction see post, p. 32-35.

6 A short statement of this position can be found in M Rapinet "The Religious and Moral Dilemmas Posed by Scientific Developments in the Field of Genetics: A Catholic Viewpoint" (1988) 28 Med. Sci. Law 256, at 258.

7 eg see UK, Department of Health & Social Security, "Report of the Committee of Inquiry into Human Fertilisation and Embryology" Cmnd 9314 (July 1984) (Chair: M Warnock) [hereinafter referred to as Warnock Committee Report] at 18; Canada, Ontario Law Reform Commission, "Report on Human Artificial Reproduction and Related Matters", vols 1, 2 (Toronto: Ministry of the Attorney General, 1985) (Chair: J R Breithaupt) [hereinafter referred to as Ontario Commission Report] at 143-144, 151.

time ago,[8] later discussions focused primarily on the status of a child born as a result of the technique. Applying traditional legal concepts such a child was presumed to be a child of both parents, in accordance with the maxim pater est quam nuptiae demonstrant, but the evidence to rebut that presumption was readily available. However, as most couples tended to register the child as their own, without reference to the part played by the anonymous sperm donor, falsified records belied the true state of affairs.[9] The result, after protracted argument, was that numerous Committee recommendations on the subject reached a consensus that any child born through AID to a married couple should be deemed to be a child of that marriage provided that the husband has consented to the procedure.[10] Several jurisdictions have now enacted legislation to

8 The Scottish Court of Session held that even in a situation of AID without the husband's consent it could not amount to adultery - MacLennan v MacLennan (1958), S.L.T 12. This decision has long been accepted as good law in England also. In People v Sorrenson (1968) 60 cal. Rptr. 495, 437 p.2d 495, a Californian Court held that, where a child has been born by AID to which the husband had given his written consent, the husband was criminally liable for failure to support the child, of which he was the father within the meaning of the criminal code. Thus the child was not regarded as the product of an adulterous union.

9 O M Stone, 'English law in relation to AID and embryo transfer' in Law and Ethics of IAD and embryo transfer, op. cit.supra n.2, at 71.

10 See eg Warnock Committee Report at 23-24; Ontario Commission Report at 176. The Commission extended this recommendation to unmarried couples of a stable union seeking AID; Australia, Queensland, "Report of the Special Committee Appointed By the Queensland Government to Enquire into the Laws Relating to Artificial Insemination, In Vitro Fertilisation and Other Related Matters" (1984) (chair: Mr Justice A G Demack) [hereinafter referred to as Queensland Committee Report] at 56; South Australia, "Report of the Working Party on In Vitro Fertilisation and Artificial Insemination by Donor" (1984) (chair: Dr Aileen Connon) [hereinafter referred to as South Australia Report] at 4, British Columbia, Royal Commission on Family and Children's Law, Ninth Report of the Royal Commission on Family and Children's Law: Artificial Insemination (1975) at 5-6 [hereinafter referred to as British Columbia Commission Report].

this effect.[11] As will be seen, problems of status have also arisen in situations of in vitro fertilisation using donor gametes and in surrogate motherhood agreements.

Another matter linking AID with more recent advances in reproductive technology is the issue of donor selection and payment. Human gametes are now in great demand for use in medical scientific experiments and for clinical practices such as AID. Whereas one American study found that payment for sperm was given almost without exception,[12] there have on the other hand been strong views expressed against any measure of commercialisation with regard to human reproductive material.[13] The most practicable suggestions with regard to unfertilised gametes have, in the writer's view, been those seeking to permit minimal payment such as

11 In the United States, at least fifteen states have enacted in whole or in part the Uniform Parentage Act, (adopted by the National Conference of Commissioners on Uniform State Laws in 1973). See Uniform Laws Annotated, Vol 9A section 5 of which legitimates AID children of married couples where the husband's consent was obtained. Legislation in Australian States includes Status of Children (Amendment) Act 1984 (Victoria) and Artificial Conception Act 1985 (Western Australia). Canadian jurisdictions having similar legislation include Article 586 of the Civil Code of Quebec (enacted by 'An Act to establish a new Civil Code and to reform family law', SQ 1980, c.39 s1) and Children's Act, SYT 1984 c.2 s14 (adopting the relevant part of the Uniform Child Status Act, Appendix F, 'Uniform Law Conference of Canada, Proceedings of the Sixty-Fourth Annual Meeting (1982)'). S.27 of the English Family Law Reform Act (UK) 1987, c.42 legitimated such a child if born (not 'conceived') in England and Wales. The child of a married woman who conceives by A.I.D. was still illegitimate if born in Scotland or Northern Ireland. This distinction has now been addressed and resolved by Section 28 of the Human Fertilisation and Embryology Act (UK) 1990 C.37. [Hereinafter referred to as "The UK Embryology Act"]. See Sections 27-30 of that Act for the full provisions now governing status of children concerned through artificial methods in the UK.

12 See M Curie-Cohen, L Luttrel & S Shapiro, 'Current Practice of Artificial Insemination by Donor in the United States' (1979) 300 New Eng.J.Med.585, at 587.

13 Gena Corea, in a strident critique of new reproductive technology, uses the term "sperm vendor" for those who receive any compensation for doing so, to distinguish them from those who truly 'donate'. G Corea "The Mother Machine" rev'd ed. (London: The Women's Press Ltd 1988) at 20.

reimbursement of expenses.[14] As far as selection of donors is concerned, it is well known that in the early years at least, an overwhelming majority of those used were medical students or other university graduates. While this was generally accepted as the most convenient source for physicians, especially those practising in teaching hospitals, the eugenic consequences of such selection should not be ignored. One commentator noted that, whereas physicians may be convinced that society needs more individuals with the attributes of physicians, it is unlikely that society as a whole would concur with this view.[15] Such selection, he pointed out, as opposed to one matching the donor's characteristics with those of the husband, "seems to be primarily in the best interests of the physician rather than the child, and can probably not be justified".[16]

Whether sperm donated is to be used for AID or other clinical or even experimental purposes the socio-biological result of having pooled the genetic material of a specific minority of the community at least in the early years of assisted reproductive practices should perhaps have been considered in more depth by the appropriate authorities.

Positive eugenic consequences of such selection should of course be distinguished from the negative eugenic approach which must be applied to donor screening. Doctors practising AID undoubtedly have a moral responsibility to help prevent the transmission of genetic disease by rejecting donations from those likely to pass on conditions such as Tay-Sachs, haemophilia, cystic fibrosis and even the HIV virus. Given that work in this field still involves the specialised skill and can be

14 see eg Australia, Victoria, Committee to consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation, Report on Donor Gametes in IVF (1983) (chair: Prof L Waller) [hereinafter referred to as Waller Committee Donor Gametes Report] at 18, where it recommended that "it (should) be unlawful to buy or to sell, or to agree to buy or to sell, any gametes" although donors should be reimbursed"for any costs, including medical expenses they incur, in making the donation". The Warnock Committee Report, at 79, took a similar standpoint, as did the Ontario Commission Report at 168-169.

15 G J Annas, 'Fathers Anonymous: Beyond the Best Interests of the Sperm Donor' (1980-81) 14 Fam.Law Quarterly 1 at 7.

16 Id.

categorised as an unorthodox area of medicine [17] it seems likely that the applicable standard of reasonable care would be exactingly applied, although to the writer's knowledge this has not yet been tested. Donor screening aside, the incorporation of positive eugenic principles into the AID procedure may have had some influence on public attitudes toward other biomedical advances. There have been reports for example of sperm banks breeding offspring of Nobel prize winners which many find disturbing.[18]

If a relatively simple technique such as AID can be used to manipulate the genetic make-up of future generations, then it could be argued that the line of acceptance should always be drawn well short of more complex methods, such as extra-corporeal growth of human beings, which represent the most extreme type of human interference with reproductive biology. It is of course the potential impact on society and future generations which causes concern and it is the simpler techniques such as AID which have quickly become readily available and the consequences of which are accordingly more pressing issues.

In summary, then, it seems that while the trend is toward legislating for AID as a separate matter,[19] there are undoubtedly 'common threads' linking artificial insemination with the debate over the other developments and research involving all human genetic material. These links will continue to have an impact on the type of policy now being formulated with regard to artificial conception in general.

17 B M Dickens, 'The Ectogenic Human Being: A Problem Child of Our Time', (1979-80) 8 Univ.West.Ontario.L.R. 241 at 267. For a more recent discussion of the medical profession's concerns in this area, see C L R Barratt and I D Cooke "Risks of Donor Insemination" (1989) 299 Brit. Med J 1178.

18 O Friedrich, "A Legal, Moral, Social Nightmare" TIME, (10 September 1984) 52 at 54. Also see the recent expression of fears about eugenics in the context of reproductive technology in Robyn Rowland, "Living Laboratories. Woman and Reproductive Technology". (Cedar: 1993) at pp 113-117.

19 See supra n.11.

CHAPTER II

IN VITRO FERTILISATION (IVF): CREATION OF HUMAN EMBRYOS IN THE LABORATORY

In contrast to AID, which provides a solution to male infertility, in vitro fertilisation with embryo transfer can enable women previously unable to conceive to bear children. The most common cause of infertility in women seeking such a remedy is apparently diseased or damaged Fallopian tubes resulting from infection, endometriosis, or previous therapeutic or elective surgery.[20] The technique of in vitro fertilisation effectively simulates in the laboratory the natural process of fertilisation and development within the fallopian tube. There are several accepted stages in this process of 'test-tube' conception, pioneered by Drs. Steptoe and Edwards [21] and emulated and improved on worldwide.[22]

First, in many cases the development of multiple eggs is stimulated through use of hormones, namely clomiphene citrate and human menopausal gonadotropin.[23]

The availability of several eggs per cycle increases the chances of producing a high quality embryo for implanting. Even if all eggs fertilised are suitable for implantation, the possibility of at least a

20 Prof Carl Wood's team in Melbourne, Australia, reported a primary diagnosis in 1533 cycles in 831 patients as: tubal disease 36.7%, uncertain 31.2%, male factor 14.3%, endometriosis 3.5%, and miscellaneous 14.3%. See C Wood, R McMaster, G Rennie, A Trounson & J Leeton, 'Factors Influencing Pregnancy Rates Following In Vitro Fertilisation and Embryo Transfer' (1985) 43 Fertility and Sterility 245-250.

21 The British pair recorded the story of their success in R Edwards and P Steptoe, 'A Matter of Life: The Story of a Medical Breakthrough' (William Morrow and Company Inc., New York 1980).

22 A great deal of early success with IVF and related techniques was achieved in Australia. The work of Professor Carl Wood's team in Melbourne is documented and compared in P Singer & D Wells, "The Reproductive Revolution" (Oxford University Press: Oxford 1984).

23 R P Dickey, "The Medical Status of the Embryo" (1986) 32 Loyola Law Review 317, at 318.

single pregnancy is enhanced.[24] Some objections to IVF and its related procedures relate to this first stage of superovulation due to the inevitable consequence that a certain amount of 'human life' will not, or cannot, be allowed to develop.

Secondly, the ova are retrieved from the ovary, either by way of laparoscopy or by ultrasound. The former requires general anaesthesia and the insertion of an instrument through the navel to visualise the eggs. Additional instruments are then used to stabilise the ovary and withdraw the fluid containing the eggs from the ovaries. The more simple technique of ultrasound is now more commonly used, involving a needle guided by ultrasound being passed through the abdominal wall and the bladder in order to withdraw the fluid from the ovary. Egg recovery using ultrasound identification involves only a local anaesthetic, and has been developed with considerable success,[25] being a less discomforting and invasive method of egg collection.

Thirdly, the retrieved ova are placed in a culture medium and left for up to 12 hours in an incubator to complete maturation. At the same time, a sample of the husband's semen is washed in a solution to induce capacitation (the shredding of the outer coat of the sperm head). A sample containing approximately 50,000 sperm is then added to each ovum, to allow fertilisation to take place within the culture medium. The fertilisation process itself takes several hours to complete.

Fourthly, the fertilised ova are then cultured for another 24 to 48 hours in a growth medium where they develop by division until they reach a stage between two and eight cells. This cluster of cells is not yet visible to the naked eye.

24 Apparently the possibility that a clinical pregnancy will occur following implantation of the embryo is directly proportional to the number of good quality embryos that are transferred, but does not increase and may in fact decrease after transfer of three good quality embryos. See statistics in J L Yovich, Embryo Quality and Pregnancy Rates in In Vitro Fertilisation, (1985) i Lancet 283.

25 See A F Riddle, V Shorma, B A Mason, N T Ford, J Pampigliane, J P Parsons and S Campbell, "Two years experience of ultrasound directed oocyte retrieval" (1987) Fertility and Sterility, 454.

Lastly, the embryos are removed from the medium and introduced into the uterus of the mother through a catheter threaded through the cervix, using local anaesthetic. From the time the embryo is so introduced, the pregnancy continues in identical manner to one following natural conception.

In Vitro fertilisation is not always carried out using the gametes of the couple who will raise the resulting child. Donated sperm may be used, for example, where in addition to the wife's problem of tubal disease the husband is infertile. Donated ova may be resorted to in a situation where the woman is able to carry a fetus to term but cannot produce healthy eggs of her own. In the latter case, if the husband is also infertile, an embryo may be created through fertilisation of donated ova and sperm. This has resulted in what seems to be ever increasing permutations of genetic parenthood being possible.[26]

The success rate of the IVF procedure has been and continues to be surrounded by controversy, and is crucial, as we shall see, to both sides of the debate regarding research on live human embryos. While pregnancy rates per laparoscopy reached 20 per cent, some years ago[27] the number of live births per egg collection was significantly lower, with many programmes taking years to achieve a single complete success.[28] Those who have advocated scientific experimentation on embryos created by IVF pointed to these statistics as figures which could be greatly improved by such work. Indeed, recent reports suggest that the success rate has now

26 For a comprehensive table of possible genetic permutations using AID, IVF, Embryo transfer and Surrogacy see B Dickens, "Surrogate Motherhood Legal and Legislative Issues", in Genetics and the Law III, A Milunsky and G Annas (eds) Plenum Press, New York (1985).

27 C Grobstein et. al., "External Human Fertilisation: An Evaluation of Policy", Science 1983; 222: 127 especially Table 1, at 128.

28 In a survey conducted in March 1985, of 108 clinics in the United States, only twenty-six clinics reported having had a live birth by in vitro fertilisation. See "IVF: A Game for Losers at Half of US Clinics", Medical Tribune, (3 July 1985) at 1, col 2.

stabilised at a slightly higher rate.[29] A dispute remains, however, about whether that has been achieved through clinical practice or as a result of additional embryo experimentation. Opponents of IVF and related procedures have suggested that the success rates should be relabelled "failure rates" and that such experiments should not be used to promote a method of procreation which seems to have been "singularly unsuccessful".[30] Acceptance of IVF as a legitimate medical technique may be regarded, in the writer's view, as prerequisite to contemplation of the more sensitive issue of embryo research.

With regard to the risks associated with IVF, studies carried out thus far have tended to indicate that the risks to the woman are minimal and that there is no proven increase in congenital abnormalities among IVF children.[31] There has some evidence, however, that in vitro conception produces a "higher rate of early embryonic death"[32] than natural conception, although it has also become evident that the natural wastage rate is far higher than previously believed.[33]

29 See the Table of Mean Pregnancy and Live Birth Rates for 1989 in The Sixth Report of the Interim Licensing Authority for Human In Vitro Fertilisation and Embryology (Medical Research Council 1991) (hereinafter referred to as Sixth VLA Report) at 21.

30 The expression "failure rates" as synonymous with "success rates" for IVF is used by Robyn Rowland, who analyses what she described as misleading information by clinics publishing "success rates" in terms of clinical pregnancies rather than live births. See Robyn Rowland, op. cit., supra n.18.

31 See P C Steptoe, R G Edwards and D E Walters, "Observations on 767 clinical pregnancies and 500 live births after human in vitro fertilisation" (1986) 1 Human Reproduction, 89-94. But contrary experiences have also been documented. P A Lancaster "Congenital Malformations After In Vitro Fertilisation" Lancet 1987 ; ii : 1392

32 See Grobstein, supra n.28 at 128-129.

33 See Dickey, supra n.23 at 322.

Clinical IVF, when its sole purpose is the creation of a child for an infertile "married"[34] couple, is now widely accepted and its prohibition has not been recommended by any of the major Reports looking into the matter.

In contrast to AID the process of in vitro conception is highly sophisticated and requires both laboratory and hospital type facilities. Thus the areas of its control inevitably relate as much to regulating who is permitted to perform IVF and under what circumstances than to the ethics of the technique itself, at least in the "simple case" where the couple participating will be the genetic parents of the resulting child. Where donor gametes are used, legislative changes are required to cover the status of children born through IVF, registration of birth, disclosure of information about parentage and so on, and here the solutions must be identical to those contemplated for AID children.[35] Questions of control and ownership donors might have over their genetic material should be distinguished here from legal matters concerning resulting issue; only the former problem refers to the status of and control over unfertilised and fertilised human gametes, and will be addressed in Part B of this thesis.

In Vitro Fertilisation, more than any other method of artificial reproduction, has forced us to examine whether or not we regard infertility as a recognised illness or a disease for which a cure should be readily available. Classification of infertility as a disease may have far reaching consequences in countries where medicine is largely state-controlled. The cost to the public purse of granting access to IVF to all those who might benefit from it would be considerable, bearing in

34 Some Committees thought that couples living in a stable de facto relationship should also be admitted to IVF programmes. See e.g. Warnock Committee Report, 10, Ontario Commission Report 158. This latter report went so far as to recommend extending artificial conception services to "stable single women".

35 See supra n.10 and 11. Most Reports recommended that egg donors should be regarded in the same way as sperm donors as far as resulting children are concerned. See e.g. Warnock Committee Report 36-37, Ontario Commission Report 176. For a subsequent legislative enactment, see again the Embryology Act 1990 supra n.11.

mind the expense of each individual procedure[36] and the rising number of potential 'patients'.[37] Nevertheless, the trend is toward securing access to artificial conception services for all infertile couples, and seeking to change the medical profession's present practice of selecting only "suitable" candidates for IVF.[38]

This liberal approach is consistent with contemporary claims of a "positive right" to reproduce, which view such a right as including assistance in exercising the right where the subject of it is not capable of doing so unaided. The important distinction between IVF and AID/AIH

36 Estimated to be approximately $US 5,000-8,000 in the USA, £1,100-1,800 in Britain and DM 3,000-5,000 in West Germany. See S Downie "Baby Making - The Technology and Ethics" (The Bodley Head Ltd; London 1988), at pp 244-248.

37 A detailed study undertaken in Bristol, England, in 1985 found that as many as one in six couples seeks medical help to conceive. See M G R Hull et al, "Population Study of Causes, Treatment and Outcome of Infertility", (1985) 291 Brit. Med. J. 1693-7. The Warnock Committee, taking expert advice, estimated that approximately 5% of infertile couples could benefit from the IVF procedure. See Warnock Committee Report, at 29.

38 The Ontario Commission Report, 152 recommended that legislation should provide the IVF and other artificial conception procedures constitute the "practice of medicine" under the Health Disciplines Act R.S.O. 1980 C.196. That Report also discusses at length (153-160) the question of eligibility for participation in IVF and other programmes, including a look at what resources may be available to those refused access on unlawfully discriminatory grounds. The Warnock Committee Report, at 31, recommended that "IVF should continue to be available within the NHS" (National Health Service) and therefore available to all, although see supra n.33 on restriction of the service to 'couples'. It would appear, however, that unless individual hospital committees adopt wholly unreasonable selection procedures, they will continue to have an unchallengeable discretion - see the English decision of R v Ethical Committee of St Mary's Hospital, ex P Harriott [1988] FRL 512

in this context is that the former requires such assistance on a higher level.[39]

Conversely, many regard the infertile woman's longing to bear children as more of a wish, an expressed desire than a physical or psychiatric need giving rise to a legal right to treatment. As one commentator has argued,

> "If pregnancy and child rearing serve emotional rather than physical or strictly psychiatric needs, in achieving a sense of fulfilment, self-esteem, and enhancement of human experience, they may appear cosmetic rather than therapeutic"[40]

The debate over the nature of the right to reproduce, if one exists, will undoubtedly develop both within and without the field of artificial reproduction.[41]

39 For a discussion of whether a 'right to reproduce' may include the 'positive right' of assistance in reproduction, see M A Somerville, 'Birth Technology, Parenting and "Deviance"' (1982) 5 Int. J of Law and Psychiatry 123.

40 B Dickens, 'Reproduction Law and Medical Consent,' (1985) 35 Univ Toronto L. J. 255, at 284.

41 The arguments for and against a legal right to reproduce have considerable application to the whole artificial reproduction debate, but it would be impossible to include any adequate analysis of them in this thesis. Some of the most interesting commentaries on the matter include S McLean, 'The Right to Reproduce in T Campbell, D Goldber, S McLean and T Mullen (eds.,) Human Rights - From Rhetoric to Reality (Oxford & New York: Basil Blackwell 1986), B Knoppers, 'Modern Birth Technology and Human Rights' (1985) 33 Am. J. Comp. Law' 1, and the discussion in the context of non-consensual sterilisation on J K Mason, "Medico-Legal Aspects of Reproduction and Parenthood" (Dartmouth Publishing Company Limited, England 1990) at 73-75.

In addition to determining access to IVF and other reproductive technologies, classification is important in applying standards of disclosure of risks when consent to a procedure is obtained and in assessing what standard of care ought to apply in actions of negligence arising from the practice of IVF. With regard to consent, the important distinction is between 'therapeutic' and 'non-therapeutic' treatment, the latter category demanding a higher standard of disclosure of risks.[42]

While the issue of consent of IVF falls well within the ambit of existing law relating to consent to medical procedures, the nature of the procedure tends to make it preferable to draw up express guidelines of consent. In Victoria, Australia, which was the first Commonwealth jurisdiction to pass legislation on IVF, rules of consent are specifically enacted in legislative form.[43] As with all kinds of medicine, innovative or otherwise, IVF may give rise to medical negligence litigation where the physician or staff who undertook the procedure breached the duty of care owed in all medical situations.[44]

42 Again, the issue of consent in the field of reproductive technology cannot be examined here, for reasons of space. See Dickens supra n.40 for a good survey of the relevant problems. For a discussion of the categories and standards employed in the law of consent to medical treatment in general, see M A Somerville, Structuring the Issues in Informed Consent (1981) 26 McGill L. J. 740.

43 The Infertility (Medical Procedures) Act 1984 (Victoria, Australia) No. 10163 provides that consent must be in writing [ss.10(3)(b), 11(3)(b)]. Before IVF is undertaken, the couple must be examined and treated by a doctor other than the one who will carry it out. He must be satisfied that the woman would not become pregnant except by artificial means and, where donor gametes are used, that conception with the couple's own gametes would probably result in an undesirable hereditary disorder being transmitted to the resulting child. [ss.10(3)(d), 11(3)(d), 12(3)(d)]. The IVF physician must be satisfied that the couple have undergone counselling by an approved counsellor (as defined in s.9) and that post IVF counselling will be available [ss.11(5), 12(5), 13(6)]. In the UK the Embryology Act, Section 12 and Schedule 3 now impose similar obligations on those conducting IVF procedures.

44 See J K Mason & R A McCall Smith, 'Law and Medical Ethics', 3rd ed. (London: Butterworths 1991) Chapter 9 on Medical Negligence especially pages 207-211.

For example, there may have been a mishandling of the couple's gametes, negligence in implanting the embryo may have caused injury to the woman, or perhaps insufficient care taken in screening potential donors, where donor gametes were used.[45] As a general rule, it would seem that the existing legal principles of liability for medical negligence apply to the IVF process as to any other surgical or medical procedure, and some Committee Reports supported this view.[46]

The cases which may be brought before the courts in future years can adequately be solved by reference to legal concepts already developed, rendering separate discussion of the possible scenarios resulting in liability after IVF procedures largely unnecessary.[47]

45 A 'defective' child born as a result of such negligence may have a claim for 'wrongful life' or 'wrongful birth'. See Ontario Commission Report at 194-197. For a survey of court decisions concerning, inter alia, preconceptual injury see Knoppers supra n.41.

46 See eg Ontario Commission Report 194-197, UK, Council for Science and Society. 'Human Procreation - Ethical Aspects of the New Techniques', (Oxford University Press: Oxford 1984) at 73 [hereinafter referred to as Council for Science and Society Report].

47 In fact the Ontario Commission Report, at 197, recommended that wrongful life and related claims should be the subject of a separate study (ie separate from a study of Artificial Reproduction) so that more general principles of tort law could apply. It should be noted, however, that in the UK Section 44 of the Embryology Act 1990 now specifically brings infertility treatment within the ambit of Section 1 of the Congenital Disabilities (Civil Liability) Act (U.K.) 1976. Disabilities resulting from negligence during IVF, GIFT or AID procedures can therefore give rise to actions in tort or delict. See Mason & McCall Smith, supra n.44 at pp59-60.

In summary, it can be said that while the development of *in vitro* fertilisation with embryo transfer followed by live birth has been a truly admirable achievement in medical science, its clinical practice at first sight raises a few novel or irresolvable legal problems. A closer look at the process soon reveals, however, that at every stage of the way, techniques which are invasive of human life at its very earliest stages of development take place. Superovulation by administration of drugs, for example, brings into existence human gametes not intended by 'nature' to be present, which may eventually be those fertilised and implanted to produce a healthy child. The practice of fertilising all ova retrieved necessarily results in more embryos being produced than it would be advisable to implant. Creation of embryos later found to be genetically deficient draws further attention to the idea that 'man' may be intervening so much in the natural reproductive process that its failures are compounded instead of reduced. All this points to what emerged during the last decade as the most ethically difficult and politically controversial aspect of artificial conception: what exactly *is* that group of cells, commonly termed an embryo, and what ethical and legal status should be afforded to it? Only satisfactory answers to that question can break the deadlock in what is here termed "the unresolved debate" on experimentation with human embryos. While that debate may seem to have arisen from the practice of IVF as a means of alleviating infertility, it will become clear that it is largely due to the uses of embryos by scientists which have nothing whatsoever to do with clinical IVF that such widespread concern of its consequences has ensued. The embryo debate has overtaken both in time and in stature the miracle of a child born after conception in a test-tube. It has become the most tenacious of all dilemmas involving questions of 'life and death'; it may yet force us to redefine certain positions we hold on contraception, abortion, the process of fertilisation and parenthood; above all it may represent the ultimate test of whether law and society control science or vice-versa. The problems raised in Part B of this thesis, which will be devoted to examining the fundamental positions taken on all sides of the embryo debate, and Part C, which will analyse some of legislation thus far adopted for its solution, can thus be regarded as 'fallout' from the original achievement, outlined above, paradoxically causing more havoc and leaving a greater state of ethical disarray than the original achievers could ever have contemplated.

CHAPTER III

SURROGATE MOTHERHOOD

A "surrogate" can be defined as a person or a thing that acts for, or takes the place of, another: a substitute.[48] Thus a 'surrogate mother' is one who acts for another woman, taking her place as mother for a certain time, namely during conception and pregnancy. The first accounts of such surrogacy are to be found in the First Book of the Old Testament, in which Abraham had a son through the handmaiden of his barren wife Sarah, and in which the maid of Rachel bore her husband Jacob's child.[49] Unlike those first 'surrogacy arrangements', where insemination took place during a necessary, but nevertheless adulterous sexual union, the development of artificial insemination techniques has paved the way for highly sophisticated contractual agreements between a couple and a woman who will bear a child for them. If properly organised, arrangements can be such that the parties to the contract need never meet, and may even live on separate continents.[50] The practice of modern surrogacy then, has forced legal commentators, courts and legislators alike to address questions of the legality of surrogacy contracts, custody of the resulting infant should there be a dispute between the "gestational mother" and the "social parent",[51] and again the status of a child born through surrogacy who in the most complex situation may have five people who may each regard themselves as "parent".[52]

48 The Oxford English Dictionary (Oxford Press: Claredon 1961)

49 Genesis 16:3 and Genesis 30:1-6 respectively.

50 This was the situation for example much publicised in the 'Baby Cotton' case, where an American couple commissioned a British woman to have a child for them. See Re C. [1985] F.L.R. 846.

51 The gestational mother is she who carries the fetus to term, and the social parents are the couple who will rear the child, whether or not they have any genetic relation to it.

52 See Dickens, supra, n.26 for a comprehensive table of possible genetic permutations using AI, IVF, Embryo transfer and Surrogacy.

So far as advancements in medical technology are concerned, surrogacy has not represented a new scientific development. It merely utilises the technologies of AID and /or IVF in such a way as to create a new social rather than medical, phenomenon. The change involves the previously unchallenged assumption in law that a mother is the woman who bears and gives birth to a child, such presumption being expressed in the maxim mater est quam gestatio demonstrant.[53] Surrogacy has produced situations where it is arguably far from certain that this principle holds true, and has thrown into confusion traditional beliefs about motherhood. In the words of one legal writer,

> ".... under the impact of reproductive technology, motherhood may be a collaborative enterprise involving genetic, uterine, and social functions, which may be discharged by different women".[54]

In contrast to the embryo research debate, then, the concept of surrogacy has questioned some fundamental and deeply entrenched social notions about motherhood and the family, without adding anything to the arguments over the beginnings of life and the value of human genetic material. It is concerned primarily with fully grown adults and the relations between them and little with early human embryos and how to protect them. The various Committee Reports tended, as a result, to treat surrogacy as an issue somewhat disconnected from reproductive technology, despite the fact that in most instances it represents practical application of the new techniques. For example, the Warnock Committee Report, while taking a liberal stance on all other aspects of reproductive technology, including the commercialisation of certain practices, condemned surrogacy outright, recommending, inter alia, criminal liability for those involved in organising surrogacy agreements.[55] The Committee's main objection to

53 J K Mason and R A McCall Smith supra n.44 at 77-78. The U.K. Embryology Act 1990 effectively gives legislative clout to this presumption, if sections 27(1) and 30 are read together.

54 B Dickens supra n.26 at 185.

55 Warnock Committee Report, 47

surrogate motherhood seemed to be what it regarded as inevitable exploitation of the women involved, thus being contrary to the Kantian notion that people must never treat others as a means to their own ends.[56] Certainly surrogacy in its truest sense, where a woman bears a child from another woman's ovum is only possible where artificial reproduction techniques are employed. Although it has been argued most vociferously that most aspects of reproductive technology will lead to exploitative conduct and consequences, it was surrogacy which was earmarked for the first piece of UK legislation following Warnock. Almost precisely one year after the Warnock Committee published its Report the Surrogacy Arrangements Act 1985 [57] was enacted, having passed swiftly through Parliament unamended.[58] The Act was generally perceived as a "stop-gap" measure,[59] designed to quell the moral panic generated following the birth of 'Baby Cotton', the product of Britain's first publicised commercial surrogacy contract.[60] While it has been strongly criticised as vague, ineffective and ambiguous,[61] the 1985 Act clearly represents one attempt at reconciling the inapplicability of outmoded legal concepts and categories to these innovative uses of conception techniques. Many problems were left untackled however, such as who should be regarded as the mother where a whole embryo has been transferred to the surrogate, and not simply the father's sperm. The U.K. Human Fertilisation and Embryology Act 1990 now makes clear that in all situations the woman who gives birth to a child is its mother.[62]

56 Ibid, 46.

57 (UK) 1985 C.49.

58 See U.K. HL Parliamentary Debates Vol 465 cols 925, 931 per Earl of Caithness; col 934, per Baroness Warnock. See also Kenneth Clarke MP, HC, Vol 77, col 56, and Lord Denning HL, Vol 465 col 942.

59 M D A Freeman, 'After Warnock-Whither the Law'? (1986) 39 Current Legal Problems 33, at 38. See the discussion also in K T Condie, "Surrogacy as a Treatment for Infertility (1986) 31 J.L.S.S. 469.

60 The case of 'Baby Cotton', who was taken into the care of the local authority which sought a place of safety order to protect the child from being 'handed over' on completion of the contract, is reported as Re A Baby in (1985) 135 NLJ 106; and in (1985) F.L.R. 846 as Re C. (ante).

61 For some sound criticism of the Act see Freeman supra n.59 at 38-41.

62 In the situation where the surrogate merely rents her womb and has no genetic tie to the resulting infant, the problem of choosing between the blood tie and the gestational tie is most acute. See D W McKenzie, "Who are a Child's Parents?" 1986 Scots Law Times 303, where it is suggested that the tie of birth should given such cases.

This question of whether the genetic relationship or the gestational tie should govern forms parts of the larger issue of redefining parenthood in the wake of the new biology, and some considered it would best be dealt with in comprehensive legislation covering the family law aspects of AID, ova sperm and embryo donation, and surrogate motherhood.[63]

But even if the status and welfare of the children born through surrogacy arrangements can be dealt with in family law legislation, the legality of the contracts themselves and regulation of the agencies which organise them must be approached with consistent and practicable policy methods. The interm measures adopted by the UK Parliament have followed no such coherent pattern, and therefore should not, it is submitted, be adopted elsewhere.

By contrast, the Ontario Law Reform Commission Report in Canada meticulously reviewed the various options available in regulating both artificial conception in general and surrogacy in particular.[64] In the context of surrogate motherhood contracts, three main regulatory models have been identified,[65] and it is on these that the Commissioners in Ontario based their discussion.

The first of these, the "Static" model, is said to envisage,

> "an understanding of biological and social life which is hostile to surrogacy and which therefore responds with legal mechanisms which, among other things, prohibit or frustrate surrogacy contracts"[66].

63 See H Krause, Artificial Conception: Legislative Approaches (1985) 19 Fam L.Q. 185.

64 Ontario Commission Report 'Alternative Approaches to Reform, 105-130' and 'Proposals Relating to Surrogate Motherhood, 218-273'.

65 See Dickens supra n.26 at 19-26, where he adopts the taxonomy suggested by Walter Wadlington, "Artificial Conception: The Challenge for Family Law" (1983) 69 Va.L.Rev. 465.

66 D Morgan, "Who to be or not to be: the surrogacy story" (1986) 49 Modern Law Review 358, at 359.

Secondly, the "Private Ordering" model, the most extreme libertarian approach, would approve the recognition of surrogacy contracts and allow for commercialism. Limited supervision and sanction would be carried out through some non-legal institution.[67]

The third option, and the one propounded by Dickens as more likely to be taken than a "laissez faire" attitude, is the "State Regulation" approach. This Model may take on one two forms, the "punitive" or the "inducement" approach. Under the former, surrogacy would be prohibited outright as a commercial enterprise, and perhaps even where not for profit, with criminal and/or civil penalties and sanction to enforce the ban and act as deterrents. Some aspects of the legislation passed in Victoria, Australia, fit neatly into this paradigm. The Infertility (Medical Procedures) Act 1984 provides for a fine of up to 50 penalty units[68] or imprisonment of up to two years for an advertiser, commissioning parent or surrogate mother, where payment or reward is anticipated or actual. Following the recommendation of the Waller Committee Report,[69] the statute also renders void a contract or agreement, drafted before or after the Act's commencement, under which a woman agrees to act as a surrogate mother.[70] Conversely, the "inducement" type of State Regulation is based on the assumption that prohibition of surrogacy would merely drive it 'underground', promoting the very exploitative arrangements it would be designed to avoid, to the detriment of both the women who would continue to "rent" their wombs for cash,[71] and the welfare of the resulting children. The Law Reform

67 Ibid. at 360.

68 s.30(2).

69 Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation, Report on the Disposition of Embryos Produced by In Vitro Fertilisation, Victoria, Australia 1984. (Chair; Prof L Waller) [hereinafter referred to as Waller Committee Report] Surrogate motherhood is discussed at pp 49-54.

70 Infertility (Medical Procedures) Act 1984 s.30(3).

71 Paradoxically, the 'crusade' against surrogacy on grounds that it exploits women brings together unlikely bedfellows; members of the right wing 'moral majority' and radical feminist commentators. For examples of the former see the rantings of MP's in the UK Parliament, Hansard Reports, HC (1985) Vol 77 col. 23; (1985) Vol 79 cols. 115-122. Some of the most interesting feminist writings are included in G Corea et al; (ed) Man-Made Women, (Hutchinson, London 1985).

Commission of Ontario drafted an elaborate scheme along the lines of this "inducement" approach,[72] which would involve, inter alia, court approval of any surrogacy contract and make provision to ensure that children born by this method entered into a caring, stable environment free of uncertainty or controversy.[73] Commercial agreements would thus be acceptable but controlled, rather than outlawed and therefore left to irreputable back-street agencies, rather like the illegal abortionists prior to the liberalisation of abortion laws.[74] The underlying rationale of the balanced approach taken by the Ontario Commission is that any attempt to make surrogacy illegal would be dysfunctional and even damaging. It might be appropriate to accept that surrogacy, while perhaps not an ideal way to beget a child, is merely another alternative method of reproduction which increases procreative choices for any infertile couple. Conversely, those opposed to the methods of AID and IVF are hardly likely to condone the additional layer of surrogacy to the reproductive technology network.

Questions of whether surrogacy is to be condoned morally, socially and legally, cannot be answered here.[75] But the various approaches to its

72 The scheme gained majority approval only, with a dissenting report by Commissioner A Leal, at 287-291.

73 See Ontario Commission Report, 236-272 which lays out the proposed scheme in detail.

74 See R Cook and B Dickens, 'Emerging Issues in Commonwealth Abortion Laws, 1982' (Commonwealth Secretariat, 1983) 5-19, which surveys the evolution of abortion law in Commonwealth countries.

75 There now exists a vast amount of legal literature discussing surrogacy, its past and present legal position, and alternative forms of regulating its practice. From amongst the many insightful commentaries see E A Erickson, "Contracts to Bear a Child", (1978) 66 Calif. L.R. 611, D J Cusine, "Some Legal Implications of Embryo Transfer" (1979) 129 New L.J. 627, C Sappideen, "The Surrogate Mother - A Growing Problem", (1983) 6 UNSW Law Journal 79, Dickens, op. cit. supra n.26 and Morgan, op. cit. supra n.66, J Robertson, "Surrogate Mothers: No so Novel After All", (1983) 13 Hastings Centre Report 28, Singer & Wells, op. cit. supa n.22, D J Brahams 'The Future of Surrogacy in Great Britain', (1985) 53 Med-Leg J.3, O'Brien, "Commercial Conception: A Breeding Ground for Surrogacy" (1986) 65 N.C.L. Rev. 127. For an up to date overview see Mason & McCall Smith op. cit. supra n.44, at 66-78.

regulation outlined above may serve as useful analogies in tackling the embryo debate. The nature and form of the present regulation of embryo research will be seen to be similar to that used for regulation of contracts to bear children.[75a]

75a For a recent critique of the way in which the UK legislature has approached the regulation of surrogacy, see E Blyth, "Section 30 - The Acceptable Face of Surrogacy"? 1993 4 Journal of Social Welfare & Family Law 248.

CHAPTER IV

RELATED TECHNIQUES

(a) In Vivo Fertilisation Followed by Lavage

Despite being no more complex scientifically than IVF, in vivo fertilisation followed by lavage is a later development in the work of reproductive technology. A woman, perhaps wishing to donate an ovum, is inseminated with sperm, probably that of the husband or partner of an infertile woman. Three or four days later, prior to the start of the implantation process, the donor's uterus is "washed out" and any embryo retrieved is subsequently transferred to the uterus of the infertile woman. The "washing out" process, termed "lavage", involves the insertion of a catheter through the cervix and the gradual introduction of certain fluid onto the uterine walls. The developing fertilised ovum, not yet attached to the walls of the uterus, is carried by the fluid into the catheter. After examination under a microscope, the early embryo is delivered through the cervix, again by catheter, to the uterus of the recipient woman who, if the procedure is successful, will become pregnant and eventually give birth.[76]

The Warnock Committee, reporting in July 1984, recommended that "the technique of embryo donation by lavage should not be used at the present time".[77] Reservations had been expressed due to a perceived risk to the egg donor, and the Committee felt obliged to side with caution on the matter. Notwithstanding reports of successful births following perfection of the technique[78] the Victorian legislation[79] precludes by omission the use of in vivo fertilisation and lavage

76 Ontario Commission Report at 27028.

77 Warnock Committee Report, 40.

78 The world's first "lavage babies" were born in Los Angeles in January 1984. See Downie op. cit. supra n.36 at 192-193.

79 Infertility (Medical Procedures) Act 1984 op cit., supra n.43.

as an acceptable form of infertility treatment.[80]

Attitudes toward the procedure changed, however. The Law Reform Commission in Ontario, for example, listed the procedure as a novel method of ovum donation,[81] pointing out that its practice raises few legal issues that are not shared with either AID or IVF.[82] Most importantly, as with IVF, there exists a fertilised ovum outside the body, raising the dilemmas over its status and fate that the embryo debate has been concerned with. Originally, unlike programmes involving IVF, the sole intention behind in vitro fertilisation and lavage was to achieve a pregnancy in the recipient woman. It would of course be possible for the gamete donors to agree to produce an embryo using in vivo fertilisation and lavage specifically for scientific research purposes. It might seem highly unlikely that they would want to do so, given the simplicity of the egg removal procedure in comparison to the "flushing out" technique of lavage, which may even be accompanied by psychological difficulties where the donating woman has second thoughts about the removal of an egg already fertilised. Again, however, the research lobby has developed a non-clinical use for the procedure, arguing that its continued use is necessary to the study of pre-implantation diagnosis. In the UK this application of the technique has been challenged by those condemning embryo research, most of whom have favoured prohibition of the practice of lavage itself. The pro-research lobby has, however, resisted attempts to criminalise it.[83] Issues relating to intention behind fertilisation will be

80 S.5 of the Act prohibits all "fertilisation procedures" except "relevant procedures" performed in accordance with the statute, and the use of in vivo fertilisation and lavage is not articulated as a "relevant procedure". See Ontario Commission Report, 385, n.642.

81 Ontario Commission Report, 27.

82 Ibid., 28. For example, as with AID, the procedure involves gamete donation, and this raises questions of donor selection and screening processes.

83 U.K. House of Lords, (Official Report 6 February 1990), col.805; Lord Walton).

considered in the context of the debate over in vitro embryos in Part B, but it is sufficient to note here that, as with IVF, it is the non-clinical aspects of lavage procedure which have been developed in a climate of controversy.

There is one possible consequence of in vivo fertilisation and lavage, peculiar to this procedure, pointed out by the Ontario Law Reform Commission,[84] which adds to its apparently controversial nature. In a situation where the lavage procedure failed to "flush out" the embryo, the intending donor may risk pregnancy, and thus be faced with a new set of choices. It could hardly be denied that the pregnant woman would have all the rights of any prospective mother to abortion, carrying the fetus to term before giving it up, or raising any child born as her own.[85] If she agreed to surrender the child to the couple to whom she had intended to donate the ovum, the pregnant woman would effectively be making a surrogacy contract. Thus the Ontario Law Reform Commission, after approving the scheme mentioned above for recognition and regulation of surrogacy agreements, recommended that where in vivo fertilisation and lavage failed, leaving the woman pregnant, "she and the intended social parents should be able to apply to the court for approval of a surrogate motherhood arrangement ...".[86]

It may be considered inconsistent, then, to condone surrogate motherhood but outlaw in vivo fertilisation and lavage, and vice-versa. The procedure, although not widely used,[86a] thus serves as another example of the inextricable linking of some of the new reproduction methods. In the writer's view, fine lines have to be drawn if distinctions are to be made between acceptable and unacceptable forms of assisted conception in producing guidelines for their regulation.

84 Id. Ontario Commission Report, 28.

85 Where the woman who unintentionally become pregnant decides to keep the child, the couple who intended to raise it after embryo donation would appear to have no legal recourse. If the man is not the sperm donor, this is certainly true. Where the man's sperm fertilised the donor's ovum, if he can prove paternity, he could presumably claim custody or access. See Ontario Commission Report, 263 n.404.

86 Ibid., 264.

86a For a discussion of the contraversial aspects of this procedure and the attempts to prohibit its use, see Rowland, op . cit . supra n.18 at pp. 35-40.

(b) Gamete Intrafallopian Transfer (GIFT)

In an attempt to mimic even more closely the early physiological processes that lead to gestation in humans, GIFT involves direct transfer of pre-ovulatory oocytes and washed sperm into a woman's fallopian tubes.[87] The gametes, placed at the normal site of fertilisation, are in this way permitted to fuse together as they might after natural sexual intercourse. It is the gamete insertion prior to fertilisation which demonstrates the ethical importance of GIFT. There is no contact in vitro between oocyte and sperm, and no real potential for gamete or embryo manipulation. It may therefor be more acceptable than say, IVF, to those with certain religious or philosophical perspectives, in particular those who focus on the process of fertilisation as the time where a human 'person' comes into existence.

Gamete intrafallopian transfer is used primarily in cases of unexplained infertility or where the cause is a male factor.[88] It would clearly be of no use to women whose fallopian tubes were damaged or destroyed, and is thus more likely to replace AIH and AID than IVF as the most successful form of infertility treatment. Some of the initial statistics compiled indicated that pregnancy rates after GIFT were indeed higher than, for example AIH.[89] Later statistics, however, illustrate that, as

87 R H Asch et. al., 'Preliminary experiences with gamete intrafallopian transfer (GIFT)', (1986) 45 Fertility and Sterility 366.

88 Ibid., 367.

89 See J L Yovich & P L Matson, "Pregnancy Rates After High Intrauterine Insemination of Husband's Sepermatozoa or Gamete Intrafallopian Transfer" (1986) i Lancet, 128, from which the following table is taken:-

PREGNANCY RATES AFTER AIH AND GIFT

	Pregnancy Rate (Pregnancies/cycles) after:-	
Cause of Infertility	AIH	GIFT
Oligospermia	5/66 (8%)	6/21 (29%)
Asthenospermia	0/22	- -
Negative Post-coital Test	20/155 (13%)	18/58 (31%)
Unexplained	15/183 (8%)	7/25 (28%)
TOTAL	40/426 (9%)	31/104 (30%)

with IVF, GIFT is associated with triplet and other higher order births, with attendant problems of increased perinatal and infant mortality rates.[90] It would appear that GIFT and IVF are not regarded as mutually exclusive treatments, and may even be complementary. Where the original intention is to perform GIFT but the physician makes unexpected surgical findings and/or the oocytes recovered are immature, it may be necessary to switch to IVF rather than GIFT. One team instigated a program which attempts GIFT initially, using any extra oocytes retrieved to perform IVF as a back-up procedure where GIFT fails, thus giving the greatest chance of success.[91] It should also be noted that GIFT, like IVF, generates more ova than can be used as a result of superovulatory drugs. It is these 'spare' eggs whose fate must be controlled. While GIFT will undoubtedly continue to be practised as an ethically acceptable alternative reproduction method for couples where the woman's fallopian tubes are functioning normally, it should be remembered that without IVF and its concomitant research activities this option would not have become available. Again one is driven to conclude that no method of assisted conception can be perceived as an isolated achievement, but as part of a body of work dependent on the results of many years of related research. The development of GIFT and other variations of the IVF concept, such as Intra Vaginal Culture, also exemplifies the challenge of regulating an area of science which produces fresh legal and ethical problems with each achievement.[92]

90 See the discussion in Derek Morgan & Robert & G Lee, 'Blackstone's Guide to the Human Fertilisation and Embryology Act 1990, (Blackstone Press Ltd 1991), Chapter 5 at 133-135.

91 See Asch et. al., supra n.87, 370.

92 See the comment in D Morgan and R Lee, supra. n.90 at 124-126 on the way GIFT has been regulated under the UK Embryology Act 1990.

(c) Cryopreservation

The technique of cryopreservation, or "freezing" of gametes and embryos, has been described as "..... placing human life outside the bounds of time".[93] By storing embryos in liquid nitrogen at temperatures as low as -196c, and subsequently thawing and transferring them to women who thereby become pregnant and ultimately give birth, medical scientists have also now divorced procreation from traditional notions about length of human gestation, and genealogy. For example, if an infertile woman undergoes clinical IVF in the course of which several of her ova are removed and fertilised with her husbands sperm, some may be implanted immediately and some may be frozen for use at a later date or dates. If the frozen embryos are used say, two and four years after a successful birth from the initial embryo transfer, the siblings in the family involved will all have been conceived on the same date, but have been born years apart.

Some of the legal and ethical questions arising from the practice of cryopreservation, such as what time limit should be imposed on freezing human reproductive material, are unique to it, but many of the issues surround status of, and control over, early Human life. To that extent, the debate over embryo research is pertinent to regulation of cryopreservation techniques. For example, those who consider it wrong to destroy embryos which have been created as part of an IVF programme may consider it more justifiable to freeze "surplus" embryos for possible future use, than to use them for research.[94]

The legal difficulties which have arisen from the storage of human embryos can best be illustrated by reviewing three of the now celebrated cases on the matter to date. The first, and most highly publicised, controversy arose after an American couple, the "Rios", who had considerable wealth, attended the Queen

93 See J Bercovitch, "Civil Law Regulation of Reproductive Technologies: New Laws for the New Biology"? (1986) Can J. Women & the Law 385 at 385.

94 The position of the 'surplus' embryo generally will be considered post, in Part B Chapter IV (a), in the context of embryo research.

Victoria Medical Centre in Melbourne, Australia, for infertility treatment. The wife had three ova fertilised with sperm from an anonymous donor, but the couple who intended to use the embryos to create their own family were killed in an aeroplane crash before two of the frozen embryos had been thawed and implanted.[95] For some time after their tragic death, the plight of the two frozen embryos, left without legitimate parent was debated in Australia and commented on worldwide. Ultimately, the second Waller Committee Report[96] made various recommendations on acceptable procedures for the creation and subsequent disposition of frozen embryos.[97] One of those recommendations was that, prior to freezing, any couple involved, "..... shall be required to make their decision about the disposition of the embryo which is to be stored".[98] There was also a recommendation that , in a situation where no provision had been made, as with the aforementioned couple, then the embryos, "..... shall be removed from storage"[99], such removal being said to be analogous with the withdrawal of life-support systems from the terminally ill.[100] However, the Victorian legislation which was subsequently enacted provides that where consent regarding disposition has not been given, or where prior consent cannot be reaffirmed, then any such embryos are to be "..... made available

95 There are discrepancies in detail between some of the accounts of the facts of the case. The sources used here include G F Smith, "Australia's Frozen 'Orphan' Embryos. A Medical, Legal and Ethical Dilemma" (1985-86 24 J Fam Law 27 and J J Saltarelli, "Genesis Retold: Legal Issues Raised By The Cryopreservation Of Pre-implantation Human Embryos (1985) 36 Syracuse L. R. 1021.

96 Victoria, Australia, The Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation: Report on the Disposition of Embryos Produced by In Vitro Fertilisation (1984) (chair: Prof. L Waller).

97 Ibid. at pages 24-33.

98 Ibid. at p28,para 2.8.

99 Ibid. at p32, para 2.18.

100 Ibid. at p29, para 2.12.

for use in a relevant procedure carried out in relation to another woman".[101] Despite that provision, it is thought that the del Rio's embryos have never been transferred to a woman.[102]

The second case involved a couple who attended a Clinic in Norfolk, Virginia, U.S.A. for IVF treatment, during the course of which an embryo was cryopreserved for future use.[103] The couple had entered into a contract with the institution involved, the terms of which recognised them as owning the frozen conceptus. After moving to California the couple contacted the clinic, asking them to send the embryo to a centre in Los Angeles for use in a programme there. When the clinic in Virginia refused to acceded to their request, the couple sued for, inter alia, breach of contract and recovery of personal property. Notwithstanding opposition by the clinic, the couple were allowed to proceed with the case on an interpretation of the contract that classified the embryos as the couple's property.[104]

The third case raised the problem of a disagreement between gamete donors as to the disposition of their resulting frozen embryo.[105] They had the embryos stored during marriage but divorced before they could be used. While the judge at first instance refused the father's application that they be destroyed by applying principles of child custody law, the Court of Appeal reversed his decision on the ground that the parents' rights over them must prevail.[106] The

101 Section 14 (1) Infertility (Medical Procedures) Act 1984.

102 See the comments of J K Mason and R A McCall Smith in Law and Medical Ethics op. cit.s, supra, n.44 at 64.

103 York v Jones 717 F. Supp. 421 (1989)

104 Interestingly, one of the factors which influenced the Court's decision to recognise the frozen embryo as property was a clause in the contract which provided that, in the event of a divorce, the legal ownership of the "pre-zygote", "..... must be determined in a property settlement" see 717 F.Supp. 421 at 426.

105 Davis v Davis 15 FLR 2097 (1989)

106 See the discussion of the reasoning in the case by B Dickens in "Reproductive Technology and the 'new' family" in E Sutherland and A McCall Smith (eds) Family Rights, Family Law & Medical Advance, (Edinburgh University Press, Edinburgh 1990).

contrast in the approaches taken by the American Courts in applying property law principles and then family law principles in the second and third cases can be seen to parallel the dispute over categorisation of the in vitro embryo which will be considered in Part B of this thesis.

Some of the legal considerations peculiar to cryopreservation have now been resolved by legislation. For example the U.K. Embryology Act 1990 eliminates any period of storage from the age of an embryo,[107] thus resolving questions of succession of embryos conceived together but implanted at different times, as in the situation mentioned above. Limits on the period for which gametes and embryos can remain frozen prior to use in an infertility programme have also been placed.[108] Where embryos are preserved for potential future use in a research project however, different considerations emerge. The unanswered questions about whether it is ethical, and legal, to submit the early embryo to experimentation apply equally to thawed and fresh embryos and they should be regarded as the same entity for the purposes of that discussion.

107 Section 3(4) U.K. Embryology Act 1990, op cit., supra n.11.

108 See eg sections 14(3) and (4) of the U.K. Embryology Act 1990, section 10 (3) (c) of the Reproductive Technology Act 1988, South Australian Statutes, No 10 of 1988.

PART B

THE INTRACTABLE DEBATE: USING EARLY HUMAN EMBRYOS IN SCIENTIFIC RESEARCH

CHAPTER I

THE EARLY STAGES OF HUMAN DEVELOPMENT

In determining what has set apart the human embryo debate, both in intensity and in importance, from other socio-legal issues arising out of the new reproductive technologies, the parameters of the discussion must first be outlined. The relatively recently acquired ability to create human beings ex utero has thrown into confusion some previously unchallenged assumptions regarding the earliest stages of human development. Those prior assumptions have continued to underlie legislation protecting human life at its incipience, however, and have had considerable impact on framing policy decisions relating to the moral and legal position of the embryo in vitro. As will later be shown, no consensus may ever be reached on the issue of pinpointing a time or event at which "life" can be said to begin, and yet it is essential to formulate a view on when that "life" should be afforded legal protection. To do so we must first examine the nature and extent of pre-existing protections for the unborn child.

(a) Levels of Protection: Conception to Birth

There are several developmental stages in the life of the unborn child which might be appropriate junctures for legal protection. This begs the question of whether such protection should be incremental or be at a consistent level throughout the gestational period. For example, most jurisdictions grant the fetus in utero significant recognition in law by ensuring protection against abortion unless performed within closely prescribed circumstances.[1]

1 See eg Abortion Act (UK) 1967 (as amended) c.87 s1; In Canada, Criminal Code R.S.C. 1970 c. C-34 S251, but see R V Morgentaler [1988] 1 SCR 30. In the United States, the fetus was guaranteed firm protection against termination during the third trimester of pregnancy in the landmark decision of Roe v Wade, 410 US 113 (US Sup. Ct., 1973). That case also laid down conditions within which abortion could be considered acceptable, in the first and second trimesters.

Some jurisdictions also adhere to the notion that the level of protection should increase as the fetus approaches viability and birth.[2] Others, such as the Canadian criminal law, have traditionally refused to recognise any such distinctions between one stage of fetal development and another.[3] This may have had considerable effect on attitudes toward the in vitro embryo and its status. For example, if legal protection of the unborn child is not seen as an incremental process, the two day old blastocyst may have no more and no less right to such protection than the two week old embryo or the fetus of seven months growth. Even where rules are applied uniformly to protect unborn children at all stages, however, legal recognition is not absolute. Thus a child injured in utero cannot generally be compensated for the consequences of those injuries unless subsequently born alive.[4] Likewise, a child en ventre sa mere whose father dies, may usually only claim inheritance benefits from the deceased's estate once born.[5]

2 The Infant Life (Preservation) Act (UK) 1929 c.34 s 1 attaches the offence of "child destruction" to taking the life of a fetus capable of living outside the body of the mother. This concept of "viability" has its most prominent expression in American jurisprudence, namely in Roe v Wade, (op. cit) and is generally accepted as beginning at 20-24 weeks gestation. There can be seen to exist two distinct levels of protection, then, for the fetus during the gestational period. In some jurisdictions, such as Germany, where protection against abortion begins only after the stage of embryo implantation in the uterus, a third distinctive stage may be recognised in law; - # 219d Strafgesetzbuch 1987 [F.R.G.].

3 S.206(1) of the Criminal Code, R.S.C. 1970 c. C-34, provides that a child becomes a human being in law when it has "completely proceeded, in a living state, from the body of its mother..." A reading of S 206(2) indicates that the offence of homicide, which attaches to one causing injury to a child before or during its birth as a result of which the child later dies, would apply no matter at what stage between conception and birth the injury was caused. In addition, S 251 of the code does not distinguish between stages of gestation in criminalising abortion, though it should be noted that this was struck down as unconstitutional in R V Morgentaler (op. cit. supra n.1)

4 Congenital Disabilities (Civil Liability) Act (UK) 1976 s.1; s. 206(1) of the Canadian Criminal Code (op cit) makes clear that full protection of the (criminal) law may only be claimed after birth, when injuries sustained during gestation affect post-natal existence. See also the case of Medhurst v Medhurst (1984) 46 OR (2d) 263.

5 See the judgement of May LJ. in the English case of Re F (in utero) [1988] 2 All ER 193 at 196, where he reiterates the established law on this point.

Whatever the degree of protection granted to the fetus in utero, no jurisdiction appears to attach a separate legal identity to the child before it is born. In the English High Court decision of Paton v Trustees of the British Pregnancy Advisory Service,[6]

Sir George Baker P, affirmed this position , stating;

"The fetus cannot, in English law, in my view, have a right of its own at least until it is born and has a separate existence from its mother. That permeates the whole of the civil law of this country ..... and is, indeed, the basis of the decisions in those countries where law is founded on the common law, that is to say, in America, Canada, Australia .....".[7]

Consequently, any legal rights pertaining to the fetus en ventre sa mere are incomplete until the time of birth, and bestow no particular status upon the unborn child. This is exemplified by the fetus' inability to have standing in civil litigation, a capacity held only by legal "persons".

In the interesting English case of C V S,[8] where a father failed in his attempt to prevent the mother of his unborn child from terminating the pregnancy, Heilbron J. restated the position already

6 (1978) 2 All E.R. 987 (QB).

7 Ibid., at 989.

8 [1987] 2 W.L.R. 1108 (CA).

established in Commonwealth jurisdictions.[9]

> "The authorities, it seems to me, show that a child, after it has been born, and only then, in certain circumstances, based on he or she having a legal right, may be a party to an action brought with regard to such matters as the right to take on a will or intestacy, or for damages for injuries suffered before birth. In other words, the claim crystallises upon the birth, at which date, but not before, the child attains the status of a legal persona, and thereupon can then exercise that legal right".[10]

Instruments of International Law, while not attempting to define a starting point for "life" within the gestational period, also seem to deny that the fetus possesses legal personality. Thus, declarations claiming that every human being has an inherent right to life and that such right must be protected by law [11] have been interpreted as excluding the unborn child from their ambit.[12] In

9 In Canada, the fetus was declared to lack legal personality in an unequivocal statement by Mr Justice Robins of the Ontario High Court in Dehler v Ottawa Civil Hospital et al., (1979), 25 O.R. (2d) 248 (HCJ); aff'd (1980) O.R. (2d) 677 (CA); leave to appeal refused (1981) 1 S.C.R. viii. Again the time of birth was set as "the line of demarcation at which personhood is realised ....." (1980) OR (2d) 677, at 757. Dehler was applied in Seede et al v Camco Inc. et al. (1985), 50 CPC 78, 50 OR (2d) 218 (HC); appeal dismissed (2 May 1986), 55 OR (2d) 352 (CA); appeal dismissed (23 June 1986), 55 OR (2d) 352 (SCC), a case concerning an unborn child's right to claim compensation under statute. Similar reasoning was applied also in a decision of the Higher Court of New Zealand in Wall v Livingston, (unreported), New Plymouth Registry A. No. 1/82 19 January 1982, when a member of the public was denied standing to challenge, on behalf of an unborn child, a decision to abort under the relevant legislation.

10 See supra n.8, at 1113 (Sir John Donaldson M.R. quoting Heilbron J at first instance). (emphasis added).

11 Article 3, Universal Declaration of Human Rights, UNGA - Res. 217A (III), UN Doc. A/810 (1948); Article 6 (1), International Covenant on Civil and Political Rights, UNGA - Res 2200 (XXI), 21 UN GADR, Supp. (No 16) 52, UN Doc. A/6316 (1966); Article 2 (1), European Convention for the Protection of Human Rights and Fundamental Freedoms, reproduced in Human Rights in International Law, Basic Texts, Council of Europe, Directorate of Human Rights, ed. (Strasbourg 1985) 101.

12 P Sieghart, 'The International Law of Human Rights' (Oxford: Clarendon Press 1983), at 132. The Canadian Charter of Rights and Freedoms, it has been held, does not extend to the fetus. See Borowski V A-G of Canada (1987) 39 DLR (4th) 731 (Sask, CA).

the case of Paton v United Kingdom [13] the European Court of Human Rights was of the opinion that a fetus does not have an absolute right to life. To recognise such a right, it was thought, would place higher value upon unborn life than on the life of the pregnant woman, effectively limiting her own right to life, contrary to the intent of the original drafters of the convention in question.[14]

It can be seen then, that whatever the value placed on the fetus in utero, and at whatever stage of development it may be afforded some legal recognition, its status is primarily governed by the fact that it is (at least until capable of being born alive) inseparable from the body of its mother, whose rights and interests clearly take precedence.[15] On that ground alone, discussions of the status of the embryo in vitro may be able to be distinguished from those concerning fetuses in utero. It is true that technological advances in medicine will continue to have considerable influence on the point at which, for example, fetuses are deemed to have reached the point of deserving protection. Reproductive technology which creates an embryo outwith the womb of the mother, however, raises issues which may, in theory at least, be resolved without condemning the positions taken by the anti-abortion lobby. As one commentator has pointed out, the differences in location and stage of development between the fetus and the embryo make it logically possible to favour embryo destruction where necessary, but deem abortion a wrongful act due to the physiological demands already made on the mother by a fetus which has already embedded in her uterus.[16]

13 (1980) 3 E.H.R.R. 408.

14 Ibid., at 412.

15 Indeed, abortion legislation is frequently worded in terms of preserving the life and health of the pregnant woman. See supra n.1.

16 J A Robertson, "Extracorporeal Embryos and the Abortion Debate", (1986) 2 The Journal of Contemp. Health Law & Policy 53, at 56. The parallel with abortion is discussed again in Chapter III (post.).

Whatever status is adopted for the early embryo in vitro, the author would submit that questions of its protection in law must be consistent with, but not influenced too greatly by, existing law relating to the fetus in utero. Even if the fetus were to be granted uniform status in law from the moment of conception to birth, there might be seen to be a case for excepting the case of an artificially created embryo made and destroyed in a laboratory and capable of surviving a matter of days rather than months in that environment. The conditions under which an embryo develops affect not only its chances of survival but also the way it is regarded by parents and physicians alike. For example, few would deny that a woman's interest in controlling the destiny of the fetus within her can be separated from a discussion of rights she may or may not possess over the embryo outside her body. In addressing the uses and fate of beings which have been described as everything from unborn children to "mere laboratory artefacts" [17] later in this paper, then, we will have to find new points of reference and terminology - to equate the destruction of a blastocyst [18] with abortion would be unimaginative at best and singularly unhelpful in any event. The categorisation of pre-natal life must be reconsidered; existing definitions have proved to be insufficient where 'life' is initiated in the laboratory. With this in mind, the question of the particular moral status of the human embryo may now be addressed.

(b) The Embryo's Moral Status as a Distinct Human Entity : Science, Biology, Religion and Ethics

In the Canadian decision of Dehler v Ottawa Civil Hospital et al [19]

17 This latter description was coined in a discussion of the Warnock Committee Report by the Council of the Law Society of Scotland. See Council Memorandum: the submission by the Council on the Government inquiry into human fertilisation and embryology (1984) J.L.S.S. 29 91. Also see Mason & McCall Smith op. cit. supra Part A, n.44 at 61.

18 A blastocyst is defined as "... the modified blastula stage of mammalian embryos, which consist of the inner cell mass and a thin traphoblast layer enclosing the blastocele". Stedman's Medical Dictionary op. cit. supra Part A n.4. Here used generally to denote any preimplantation conceptus.

19 op. cit. supra n.9.

Robins J A referred, albeit in a slightly different context, to an issue which has thus far been the focal point of the embryo debate, namely the description of the embryo as a human being.

"Accepting as fact .... that the fetus is a human being from conception, the legal result obtained remains the same. The fetus is not recognised in law as a person in the full sense ...."[20] he opined. The statement draws attention to the biological facts which have been somewhat obscured by the highly emotive arguments used both to justify and condemn the use and destruction of embryos in vitro. Simply put, the facts are that such embryos are living, human, beings. It is clear that the conceptus is living, as even the spermatozoa and oocytes can be said to be "alive" before the act of fertilisation, being living cells themselves. Further, excepting the case of trans-species fertilisation,[21] the embryos under dispute are human beings, not other mammalian beings such as mouse embryos. The dicta of Robins J A, then, serves to point out that while one is a human being from the moment of conception, one will not be recognised in law as a person until birth, which has the effect of disregarding the "humanity" or otherwise of the embryo in determining its legal status. But what of its moral status, a concept often considered by ethicists and theologians in particular. Does the "human" element per se oblige us morally to grant the embryo special treatment, or is it the individuality of post-conception life which makes an issue of its use and fate? In other words, even if life cannot, in scientific terms, be deemed to begin at conception, does that event mark a point after which the living entity formed deserves a particular status, with concomitant moral rules regarding its treatment? It will become apparent that the philosophical status afforded the embryo serves to determine the nature of its status and protection in law.

20 Ibid, at 761.

21 The Warnock Committee approved a technique of fertilising hamster eggs with human sperm in the context of investigating male subfertility, (Warnock Committee Report, 70-71) but no Committee has thus far recommended the growth of any such hybrid embryo past the two-cell stage, and none of the legislation enacted thus far permits it. (See Part C - post.).

The Ethics Committee of the American Fertility Society, in its report on assisted reproduction,[22] summarised as follows the three major ethical positions commonly articulated in the debate over the status of the human embryo.

"At one extreme is the view of the pre-embryo [23] as a human subject after fertilisation, which requires that it be accorded the rights of a person ....
At the opposite extreme is the view that the pre-embryo has a status no different from that of any other human tissue .....
A third view - one that is most widely held - takes an intermediate position between the other two. It holds that the pre-embryo deserves respect greater than that accorded to human tissue but not the respect accorded to actual persons".[24]

Let us consider the major justifications for each view and their proponents.

(i) The "Personhood" Theory

This position first denies the relevance of definitions presently accepted in determining the embryo's status. As already shown, even a viable fetus in utero will not attain legal persona until birth, and at the other extreme it can be pointed out that existing definitions of a legal person are extensible to inanimate entities such as ships and corporations. Thus legal definitions can be disregarded and only moral considerations can decide the issue. The human embryo, it is then claimed, is de facto a person due to its possession of all the relevant

22 American Fertility Society, Ethical Considerations of the New Reproductive Technologies, Report of the Ethics Committee of the American Fertility Society (Birmingham, September 1986) published as supp. 1 of (1986) 46 Fertility and Sterility [hereinafter referred to as American Fertility Society Report].

23 The term "pre-embryo" was used throughout the American Fertility Society Report to describe a fertilised ovum of up to two weeks growth. See Chapter II post on the use of terminology as an instrument of debate.

24 Supra n.22 at 29 S-30S.

faculties necessary for 'personhood', albeit in a primitive stage of development. All proponents of the 'personhood' theory isolate conception as the event after which moral protections must be granted to all humans, be they fetuses, children or adult persons. This view of all human life being equally protection-worthy after conception may be based on religious, philosophical or so-called 'scientific grounds'. Religious Committees, particularly those representing the Catholic faith have been the most ardent exponents of the position.[25] To be consistent many deem it necessary to condemn also the practice of abortion and post-fertilisation contraceptives such as the IUD and the "morning-after pill".[26] Others may single out the deliberately mechanical type of conception involved in the IVF process as exemplifying an instance in which, control over the procreative event having already been exercised, greater demands for ensuring the survival of the conceptus must be made. Legal consequences of declaring the pre-implantation embryo to be a person will be considered in due course. It should here be noted, however, that major controversy has surrounded the question of whether or not a duty exists to transfer each embryo created to a uterus for the purpose of realising its full human potential. Clearly, a proponent of the "personhood" theory would advocate the enforcement of such a duty, although again there may be differences of opinion within the same camp. Problems

25 See eg The Submission to the Warnock Committee of a joint committee established by the Catholic bishops of the United Kingdom (March 1983), referred to in L Walters, "Ethical Issues in Human In Vitro Fertilisation and Embryo Transfer", in A Milinsky & G Annas (ed.), Genetics and the Law III (Plenum Press, New York, 1985). See also the article by Rapinet, op cit., supra fn. 6.

26 Those who do not distinguish between post-conception life outside and within the uterus and who condemn any substance or act which disrupts the natural developmental process are likely to view destruction of a two-cell embryo in the same light as an abortion. See HC (UK) Official Report (Hansard) (6th ser.) No. 112 Col. 237 et seq. (10 May 1983) for a statement by the then Attorney General of England on the ethics and legality of the 'morning after pill'.

raised by embryos known to be severely defective prior to implantation and the freezing of embryos which have no identifiable "mother" willing to carry them to term seem to make this first position tantamount to a total condemnation of the IVF process.[27] The technique of GIFT has evolved as one acceptable to advocates of the 'personhood' approach, however, as conception takes place in vivo, and no human intervention whatever with the embryo is undertaken.

What then, are the facets of this position which illustrate the type of status it affords the conceptus? Perhaps the most important notion here is that of "potential". The 'personhood' approach denounces the attitude which demands an exercise of faculties or a realisation of potential as a pre-requisite to treatment as a human being. Existence of the potential to sense, to be rational, to function as a person is sufficient, goes the argument, for the post-conception entity to be deemed a human person.

Exercise of that potential, which may or may not follow, should be disregarded as irrelevant to the nature of the embryo and its function. A convincing line of this reasoning runs as follows:-

> "Every human being, at each stage of its development has a size, form and function proper to that stage of development. Exercise of faculties depends on development, which waxes and wanes during life. We cannot expect a 75 year old man to run a four minute mile, nor a 4 year old girl to use algebra, though

27 The Ethics Committees of the National Health and Medical Research Council of Australia went so far as to suggest that without research (involving destruction of embryos) on pre-implantation concepti it might be ethically unacceptable for the practice of IVF to continue. See Commonwealth of Australia, Senate Select Committee on the Human Embryo Experimentation Bill 1985, Official Hansard Report, [hereinafter referred to as Australian Senate Select Committee Hearings], 26 February 1986 at p350.

> each is equally a human being .....The most we can ask of a human embryo is that it function perfectly as a human embryo, not as an older human being. It is in potency to act as a human adult does; it is not in potency to be human".[28] (emphasis added).

Persuasive as this argument may be, however, it is insufficient. The fact that the embryo is human has never been doubted. Its potential to grow into an adult is identical to that of an embryo conceived naturally. What is required in addition are compelling reasons for lack of destructive interference with the development of the IVF conceptus and for preserving its life if at all possible, as with a fully grown adult. We must decide, in other words, whether or not reproductive technology permits us (to continue) to regard conception as the beginning of 'personhood' and therefore also of its inviolability. Do we require to take all steps reasonably open to us to "save the life" of the IVF embryo?

Treating the pre-implantation conceptus as a human subject for medical purposes would arguably necessitate application of the "sanctity-of-life" principle to all humans from conception onwards. It should be noted, however, that challenges to that tenet have long been posed by, for example, discussion of the discontinuance of life-support for permanently comatose patients [29] and the practice of not operating on Down's Syndrome babies with intestinal obstructions,[30] to name but two examples of assessing whether "life"

28 Submission to the Senate Select Committee on the Human Embryo Experimentation Bill 1985 prepared by Foundation Genesis Research Committee; Australian Senate Select Committee Hearings at p.1063.

29 The court in the case of Karen Quinlan in the US, which captured world-wide media attention, permitted the removal of life-support when it was established that there was "..no reasonable possibility of her ever emerging from her present comatose condition to a cognitive, sapient state...". Re Quinlan 70 NJ 10, 335 A 2d 664 (1976).

30 For an interesting and highly controversial discussion of withholding treatment from severly defective newborn children see H Kuhse & P Singer, Should The Baby Live? The problem of Handicapped Infants (Oxford University Press, Oxford 1985). Chapter 6, entitled 'What's wrong with the Sanctity of Life Doctrine?' outlines many of the inconsistencies involved in attempting to defend that principle.

has any qualitative content before deciding its fate. Thus an approach which claims that life in vitro is sacrosanct from the event of fertilisation onwards must also be prepared to justify the retention of the doctrine that all human life has the same sanctity or value.[31] In addition, the concept of 'brain death' at one end of the spectrum, and the realisation, at the other, that conception is marked not by a 'moment' but by a continuous chain of events,[32] have indicated that traditional notions of when life begins and ends are less certain than previously believed. Biological facts have in this instance proved to be as tenuous as religious dogma! Further, the claim that conception marks a time after which a unique individual can be identified has again been shown to be over-simplistic. As a result of its totipotency,[33] the post-conception entity can develop into two human beings by twinning, or into less than one, as when two early embryos are fused. "Developmental individuality in the sense of singleness is not established until an embryonic axis is formed, an event that

31 See H Kuhse, "An Ethical Approach to IVF and ET: What Ethics is all about" in W Walters & P Singer (ed.) Test-Tube Babies: A guide to moral questions, present techniques and future possibilities (Oxford University Press, Melbourne, 1982).

32 For a Scientific description of the complexities of the fertilisation process see M H Johnson and B J Everitt "Essential Reproduction" (Blackwell Scientific Publications, Oxford 1980), Chapter 9.

33 Totipotency is defined as "The ability of a cell to differentiate into any type of cell and thus form a new organism or regenerate any part of an organism; eg a fertilised ovum ..." Stedman's Medical Dictionary op. cit. supra Part A n.4.

roughly corresponds to the time of implantation .....".[34]

It seems clear then, that the view, whether religious or secular, which proposes inclusion of the embryo within the notion of "personhood" amounts more to an intuitive and deeply held belief than to a rational conclusion supported by scientific fact. Can intuitive appeal, potent as it may be, amount to a moral basis on which to build a framework of legal principles governing the status and control of the human conceptus?

(ii) The 'Human Tissue' Approach

This view holds that "the embryo is not a moral agent and cannot possess rights ...".[35] Its proponents favour treating the embryo like any other human tissue used in biomedical research, subject only to regulations protecting those with decision-making authority over the conceptus, such as the gamete donors. The Australian philospher and bio-ethicist Peter Singer emerged as the most forthright expounder of the view that the early human embryos have no moral status as such. His argument, however, first accepts unreservedly that the pre-implantation conceptus can be described as a human being.[36] What is then questioned is the common assumption that membership of the human race automatically entitles one to the "right to life". According to Singer, our assertion that human beings have a right to life

34 American Fertility Society Report at 27 S.

35 J A Robertson, "Embryo Research" (1986) 24 Univ. West. Ont. Law Rev. 15, at 23.

36 Submission to the Australian Senate Select Committee, "The Moral Status of the Embryo" by Peter Singer. Australian Senate Select Committee Hearings at p.479.

depends on the fact that humans generally possess mental qualities - self-awareness, rationality - which other living beings lack.

He points outs that,

> "The embryo, especially the early embryo, is obviously not a being with the mental qualities which generally distinguish members of our species from members of other species. The early embryo has no brain, no nervous system. It is reasonable to assume that, so far as its mental life goes , it has no more awareness than a lettuce".[37]

From this it is deduced that if we afford a right to life only to those who exhibit some sort of mental activity, then the pre-implantation embryo cannot be deemed to possess this right. Singer further contests the premise that it is membership of the species homo sapiens which should govern our moral inclinations toward embryos. If neither race nor species can of itself provide justification for distinguishing between the wrongness of killing some as opposed to others, then there must be another criterion by which to judge the permissibility of certain actions we take with regard to other living beings. Singer proposes sentience, the capacity to feel pain or pleasure, as being the minimal characteristic which must be present before an embryo could claim rights such as freedom from interference and destruction. Consistency would of course demand that if a human embryo can claim due consideration on attaining a sentient state, then so can all other living beings who have reached a similar level; in fact this accords with the philosopher's early work regarding non-human animals.[38] Such a stance thus attacks the justification behind the

37 Ibid at 482.

38 See eg P Singer, Animal Liberation, (Avon Books, New York, 1977), where the author denounces anything less than equal consideration of a right to life for animals as "speciesism".

widely accepted principle that embryos should only be used in research where animal studies have been exhausted or are inappropriate.[39]

If the early human embryo possesses no moral status as such, the question of when it can be regarded as achieving sentience (and concomitant 'status')becomes the most acutely relevant issue. Singer suggests that the stage when an embryo develops a capacity to feel "cannot possibly be earlier than six weeks, and ... may well be as late as eighteen or twenty weeks".[40]

Although he advocates erring on the side of caution, Singer's conclusion is therefore that embryonic life should be available for research purposes for the first six weeks of its development, a time limit far in excess of all major committee recommendations.[41]

What the present author terms "the human tissue approach" includes several variations on the Singer type of exposition, but all arguments under this heading have a common denominator. Basically, whatever reasons purport to justify a lack of status for the embryo, the consequences of adopting this position would necessarily amount to the approval of the use and disposition of embryos in scientific experimentation, regardless of the provenance of the concepti used and the nature and purpose of any given research project. Indeed, it is these considerations which have led the vast majority of those

39 In other words, if a mouse embryo deserves the same amount of consideration as the human embryo, and the sentient viable mouse fetus the same regard as the human fetus, then all arguments which rely on a hierarchy of value based on species would be rendered redundant.

40 Supra n.36 at 491.

41 The Warnock Committee recommended a limit of 14 days for the culture of human embryos in vitro for whatever purposes, and this has been regarded as near to an acceptable upper limit by Scientists themselves. See post, Chapter IV, part (b) for a discussion of the imposition of a temporal limit on embryo research.

concerned with this debate to grant the embryo some sort of status, albeit a far more limited one than the 'personhood' approach would offer.

The views of one philosopher aside, the 'human tissue' approach has been favoured primarily by scientists working in the field of IVF and related research. Scientific fact is used to play down the importance of the incipient stages of post-conception life. According to one such researcher,

> "The preimplantation embryo consists of undifferentiated cells of which the majority develop into placental tissue. It is only after implantation at about day 14 after fertilisation that the actual embryonic cells can be identified".[42]

Clearly, the insinuation is that no identifiable and unique entity exists prior to the stage of implantation. This begs the question of how a status can be bestowed on an unformed mass, the formulation of which immediately betrays the ethical position behind it. Medical scientists have felt entitled to disregard any notion of status for the embryo based on its humanity or potential.[43] As many point out, a vast amount of

42 Dr A Trounson, letter to Dr P L Carron, Secretary, Australian Senate Select Committee dated 24 January 1986, Australian Senate Select Committee Hearings at p.9.

43 Singer, supra n.36 at 485 notes that there exists no general rule that "a potential X has the rights of an X". Thus, although many research scientists may regard the embryo as a unique entity, a potential human being, few may believe that this entails bestowing any status upon it, and have hitherto interpreted related legislation (eg abortion statutes) as upholding their view.

research and clinical trials using human embryos carried out in the 1960's and early 1970's was undertaken without thought of what status the embryo might have which would preclude its use in such experiments.[44] Whether or not the ends have retrospectively justified the means in that situation remains hotly disputed. What is certain is that no longer can scientists avoid the demand to justify uses of pre-implantation embryos both professionally and in the public sphere, something the original pioneers of the techniques in question did not apparently consider.[45]

44 Professor M C MacNaughton, a leading British Obstetrician involved in assisted reproduction who carried out many research projects using human embryos prior to the practice of IVF, has consistently stated that acceptance of IVF includes an implicit acceptance of the research which preceded it. See M C MacNaughton, "Ethical problems of in vitro fertlisation" (1985), 78 Journal of Royal Society of Medicine, 799, at 800.

45 Early reports of attempts to fertilise ova in vitro were concerned only with scientific methods and prospects of success. The need for discussion about potential ethical and legal problems came much later. For example compare R G Edwards, R P Donative, T A Baramki and H W Jones, "Preliminary attempts to fertilise Human Oocytes Matured In Vitro" (1966) 96 American Journal of Obstetrics and Gynaecology 192, with R G Edwards "The Current Clinical and Ethical Situation of Human Conception In Vitro: The Galton Lecture 1982" in C O Carter (ed), Developments in Human Reproduction (Academic Press, London 1983).

(iii) The "Special Status" Approach

The most commonly held view has always been that some sort of compromise must be reached on the status of the human embryo. This approach would deny that the pre-implantation conceptus possesses the characteristics of a person, but would guard against treating it as mere disposable human material. Its focus is on respect: its advocates have referred to the embryo as a "powerful symbol of human regeneration".[46]

What distinguishes the "special status" approach from the stance which denies any status for the embryo is that here a measure of respect commensurate with the humanity of the conceptus is deemed appropriate. Many different solutions to the moral and legal lacuna regarding embryos have been suggested which all shelter under the umbrella that forms this approach; its spectrum is wide. The general attitude exemplified by those proposing "special status" for the embryo has been described as follows:-

> "The embryo may ..... be accorded respect on grounds other than what it is owed by virtue of its present biological status. Although neither a person nor an entity possessing interests, it may be the subject of duties created to demonstrate a commitment to human life and persons generally. Justice may not require that we grant the embryo rights, but we may choose to treat the embryo differently than other human tissue as a sign of respect for human life generally".[47]

46 G J Annas, "Redefining parenthood and protecting embryos: Why we need new laws", (1984) The Hastings Center Report 50, at 51.

47 J A Robertson, "Embryos, Families and Procreative Liberty: The Legal Structure of the New Reproduction". (1985-86) 59 South Calif. L.R. 939 at 974.

The nature of, and elements comprising, this special status are not so easily summarised, however.

One matter which this writer believes has confused the issue somewhat, is the distinction between bestowing a moral and/or legal status on a particular individual or entity and simply granting it legal protection. To take an example, many jurisdictions have in recent years passed legislation assimilating the position of legitimate and illegitimate children in areas of inheritance and family law.[48] This has not, however, abolished the status of illegitimacy which will persist even in the absence of any discriminatory legal distinctions, until such time as the status itself is declared obsolete.[49]

Similarly, the recent trend of certain courts to protect partners and children of de facto stable relationships by granting financial settlements on their breakdown similar to those awarded on divorce [50] in no way amounts to the

48 For example see England, Legitimacy Act (UK) 1976 c.31, and Family Law Reform Act (UK) 1987 c.42; Scotland, Law Reform (Parent and Child) (Scotland) Act (UK) 1986 c.9; Ontario, Canada, Children's Law Reform Act, R.S.O. 1980, c.68 as am by S.O. 1982, c.20, and Succession Law Reform Act, R.S.O. 1980, c.488.

49 The Law Commission of England and Wales, in a report on the issue, (UK) (The Law Commission, Family Law, Illegitimacy (Second Report)) (Law. Com. No. 157) (Cmnd. 9913) (London: HMSO 1986), para 2.1, implies that this is so. In the absence of any distinctions worth mentioning after the implementation of their recommendations, the Commission noted that an academic discussion on whether it would remain justifiable to refer to a legal status of illegitimacy could begin. The 1987 Act (Supra) thus affects only the consequences of illegitimacy - the legal status itself remains. The important point is that legal protections, no matter how comprehensive, are simply a precurser to the final issue of status, although at the end of the day they may render that issue theoretical.

50 For example see the English decisions of Cooks v Head [1972] 2 All ER 38; Richards v Dove [1974] 1 All ER 888; Eves v Eves [1975] 1 WLR 1338; Bernard v Josephs [1982] 3 All ER 162; Midland Bank v Dobson & Dobson [1986] 1 FLR 171; and Grant v Edwards [1986] 2 All ER 426. In the United States, the landmark decision of Marvin v Marvin 577 P.2d 106 (1976) established the concept of 'palimony' for the separated partners of a cohabitation arrangement. The judgement of the High Court of Australia in Calverley v Green [1984] 155 C.L.R. 242 also recognised a de facto relationship in settling a property matter on its breakdown.

existence of a marital status for such relationships.[51] One must guard against the notion that the enactment of legislation protecting the pre-implantation embryo from abuse will solve the ethical dilemma surrounding its status. With respect, it appears that the approach of the Warnock Committee was to evade the issue of status for embryonic life ex utero. After noting that, under the legal systems of the United Kingdom, human embryos were at that time provided with some measures of protection but no definite status,[52] the Report of that committee stated,

> "The status of the embryo is a matter of fundamental principle which should be enshrined in legislation".[53]

The recommendation following this announcement, however, provided only that "the embryo of the human species should be afforded some protection in law".[54] Was the Committee suggesting that the legal protections envisaged would be tantamount to bestowing on the embryo a particular moral status, or did its members simply wish to avoid the even greater controversy which might have been stimulated by recommending a particularly "lowly" status for the conceptus,[55] a result many would have condemned as a

51 The courts involved in the cases cited supra n.50, mostly relied on the doctrine of resulting trust based on direct or indirect contribution of a party, thus avoiding statements on the status of unmarried vis. a vis. married couples. Even where legislatures have made express enactments regulating cohabitation arrangements, however, the relationship cannot be "conceptualised" as marriage. See discussion J Eeekelaar, Family Law and Social Policy 2nd ed., (London; Weidenfeld and Nicolson; 1984) at 144-151.

52 Warnock Committee Report, 62-63.

53 Ibid. 63. The later failure of the legislature to deal with the point will be considered in Part C (post).

54 Id. (Recommendation 41).

55 Any pronouncement on the moral status of the embryo by the Committee would necessarily have been provocative in its low regard for the conceptus in vitro, given that a majority recommended that such embryos could be created and used in research for periods of up to 14 days after fertilisation - Warnock Committee Report at 69.

degradation of its 'humanity'?

Interestingly, a post-Warnock publication by the British Government on the subject, entitled "Legislation on Human Infertility Services and Embryo Research" [56] referred only to the two polar extremes regarding the embryo's status. Those who support embryo research do not accept "full human status" for pre-implantation concepti, it was claimed, and those opposing any such research, "argue that embryos from the point of conception have the same human status as that of a child or an adult".[57] The various standpoints articulated under what the present writer has termed the "Special Status" approach were then referred to as "other views",[58] under which restrictions on research for the protection of embryos were outlined. The question of status, human or otherwise, for the embryo in vitro was not mentioned at all in that context. Indeed it may be a feature of the publications tending toward a more permissive stance on embryo research that they evaded assigning a particular status to the conceptus. The Ontario Law Reform Commission Report lacked any discussion of the matter, despite being a most detailed and comprehensive report in all other respects.[59]

56 A consultation Document of the Department of Health and Social Security (Cm 46) [London; HMSO 1986] [hereinafter referred to as "DHSS Document on Embryo Research 1986"].

57 Ibid. at 12 (paragraphs 51-53).

58 Id. (paragraph 55).

59 After noting that "vital questions arise concerning ..... the status and control of a fertilised ovum outside the body", the Commissioners seemed to discuss only the various options as to control, not status. The question of embryonic research was then tackled with a view to imposing limits, without consideration of whether the moral status of the 'research material' used might preclude it altogether. See Ontario Commission Report, 198-214.

It is submitted that the absence of detailed argument as to the moral status of the embryo by those adopting this middle position has illustrated a weakness in it. What is required is more than merely a statement of compromise between the 'embryo as person' and 'embryo as mere human tissue' attitudes. The author would therefore support the following reasoning outlined by one legal commentator;

> "It has been argued that where the law seeks to regulate a fundamental moral issue, that moral issue must be adequately addressed before legislation intervenes. Only once the status of the embryo is analysed can the question of how it is right to treat the embryo be addressed".[60]

Further, the present writer is of the opinion that as a matter of good policy, a statement declaring any consensus reached on the moral nature of embryonic life should be enshrined in any legislation enacted. Attempts to frame legislation have thus far dealt only with treatment of, and protection for, the embryo, without first stating the principles from which such protections are derived.[61] If a statute was to guarantee certain protections for the embryo,for example, without wishing to afford it full "personhood" status, the pre-implantation embryo in vitro could be deemed to possess the legal standing of a "partially protected species" or equivalent status. Such a declaration might help to allay the fears of those who believe scientists, left unregulated, will display callous disregard for embryonic life, while no pretence regarding the amount of legal respect to be shown to human life at such an early stage of development would be made.

60 H Barnett, "Biotechnology - Can The Law Cope"? (1986) 15 The Anglo-American Law Review 149, at 154-155.

61 For example see the Victorian Infertility (Medical Procedures) Act 1984 (as am) (op. cit. Part A n.43) and the Embryology Act 1990 (UK) (op. cit. Part n.11). Even the failed Australian attempt to prohibit all experiments involving the use of in vitro embryos - The Human Embryo Experimentation Bill 1985, [presented to Parliament 23 April 1985] (hereinafter referred to as the "Harradine Bill") did not seek to articulate the embryo's status in legislation.

It was suggested earlier that symbolic respect, based on the embryo's capacity to develop into a fully grown human being, was the focal point of the "special status" approach. In determining the range of permissible activities using in vitro embryos, however, proponents of this standpoint refrain from depending on the notion of potentiality as a basis for proposing limited protections for humanity at its earliest stages. Rather, they recognise that potentiality increases along with the greater gestational stage of the embryo. A particular time or event after which the conceptus is deemed "fully protectable" [62] is then designated, in accordance with the level of potentiality reached. Hence the Warnock Committee Report concentrated on the formation of the "primitive streak" [63] at around the fifteenth day after conception as marking the beginning of individual development of the embryo and thus as an appropriate point after which the developing embryo should be afforded certain protections. Several other Reports concurred in this view that the implantation stage or shortly thereafter marks a time after which the embryo cannot be used as a means to an end, [64] however

62 A remarkable feature of the proposals recommending time-limits of approximately 14 days is that, without exception, they failed to discuss what the status and legal position of the conceptus should be between the 15th day and the time when other laws necessarily grant protection to it. Again inconsistencies between treatment of embryos in vitro and those in utero can occur, and abortion policies of certain jurisdictions may create further paradoxes.

63 The Committee felt that the appearance of "recognisable features" of the embryo marked the most distinctive and most morally significant stage in its development. "The first of these features is the primitive streak, which appears as a heaping-up of cells at one end of the embryonic disc on the fourteenth or fifteenth day after fertilisation". Warnock Committee Report, at 59.

64 eg See Ontario Commission Report at 216; British Medical Association, Working Group on In Vitro Fertilisation, " Appendix VI: Interim report on human in vitro fertilisation and embryo replacement and transfer" (1983), 286 Brit. Med. J. 1594, at 1594; and further discussion post, Chapter IV part (b).

altruistic and/or scientifically important that end may be. As Barnett has maintained,

> "..... once the point is determined, there can be no place for utilitarian calculations, and the embryo cannot be treated in a non-therapeutic and destructive manner".[65]

Such heavy reliance on one particular event in embryonic development as the definite border between legal protection and lack of it is open to severe criticisms. First, pursuant to the discussion above, the status/protection distinction will remain totally unresolved if this approach is adopted in a regulatory framework concerning embryo experimentation. As will be shown later, the effect of implementing a time-limit model may be that before the time (eg fourteen days) allocated the embryo is regarded as possessing no relevant status whatever. Delineating controls as to the nature and purpose of activities involving the conceptus prior to that time then arguably becomes both redundant and illogical.Secondly, even if the approach outlined is to be accepted, with all its inconsistencies, the utilitarian calculations involved in defining the circumstances under which experimentation resulting in destruction of the conceptus is acceptable itself represents a mammoth task. The Warnock Report recommended that "research conducted on human in vitro embryos ..... should be permitted only under licence".[66] When the problems with the present legal regulation of such actions are addressed it will be seen that in a case such as this the type of control imposed is a fundamental issue. For example, a body

65 Barnett, supra n.60 at 165.

66 Warnock Committee Report at 64.

authorising licences for research will be faced with the aforementioned utilitarian calculations. In other words, if no principle as to the moral nature of the pre-implantation embryo is to govern our behaviour toward it, then presumably research projects can be permitted or rejected on a case by case approach, depending on criteria such as the purpose and potential success of the project in hand.[67]

Finally, the arbitrariness of any supposed "marker event"[68] in embryonic development as a guide to its non-human or human status and thus its legal treatment is in the author's view indisputable. Only where pragmatics triumph over reason in this area can such events in the embryo's development form the basis of its treatment by the legal system. While the imposition of a time-limit on growth and use of _in vitro_ embryos may prove to be the most practicable solution to the debate, such a result can never it is submitted be profferred as a solution to questions of what moral status and respect they deserve.

This discussion concerning the embryo's moral status must therefore conclude with a concession, namely that it may indeed be impossible ever to articulate a particular category into which this immature human entity will neatly fall. It could be argued that creation of a so-called "Special Status" would do little to dispel the fears of those concerned with legal protection for the conceptus.

67 For further discussion of the _purpose_ of proposed research as a criterion for approval in recent legislation see _post_, Part C, Chapter II.

68 This was the term used by the Australian Senate Select Committee on the Harradine Bill, a majority of which were not convinced of the ethical validity of using such events in the developmental process to form principles. See Commonwealth of Australia, "Human Embryo Experimentation in Australia", Report of the Senate Select Committee on the Human Embryo Experimentation Bill 1985 [Parliamentary Paper No. 437/1986] [hereinafter referred to as Australian Senate Select Committee Report].

Any declaration of moral status would undoubtedly be judged by the level of rights and privileges flowing from it. If these were so minimal as to permit unregulated destructive research on pre-implantation embryos, opponents could then dismiss the presence of a "Special Status" as euphemistic and ultimately meaningless.

Despite what may now appear as a pessimistic view of the whole 'status' issue, the present writer would propose the use of a distinction which it is believed may have been implicitly understood by those bodies adopting the most pragmatic approach. On the one hand is the commonly recognised notion of status which views it as pivotal in determining permissible and impermissible acts toward a person or thing belonging to a particular class.[69]

Alternatively, one may define acts which are morally or socially acceptable and those which are not, having regard to the nature or status of the person or thing in question (here the embryo) without relying on that status as the source of decision making. The latter method of utilising the notion of status is, it is submitted, more appropriate in the context of making decisions about the treatment of human embryos. Thus while retaining the view that taking a stance on the moral status of the embryo is a pre-requisite to deciding its treatment by the legal system, it is the author's opinion that the use of one's position on status as a reference rather than a foundation could assist in bridging the philosophical ravine which separates the extremists contained within the spectrum of the debate.

69 The Oxford English Dictionary defines status as, inter alia, "The legal standing or position of a person as determined by his membership of some class of persons legally enjoying certain rights or subject to certain limitations ....." (Oxford: Clarendon Press 1961)

CHAPTER II

LANGUAGE AS AN INSTRUMENT OF CONTROL

One of the most interesting and, in the author's view, particularly important aspects of the embryo debate has been the use of terminology by those at the heart of the controversy. Words have themselves been subtly manipulated to convey a meaning advantageous to the party conveying them. The Australian Senate Select Committee acknowledged in its Report that it had been warned,

> "... that definitions operate in this context as behaviour - governing terms rather than apparently descriptive terms".[70]

It has already been illustrated that the status to be accorded the early embryo,

> "is not merely a question of definition since the classification will affect the way human reproductive product is handled".[71]

This chapter will first attempt to demonstrate that not even the language used to describe that post-fertilisation entity is simply a 'question of definition', in that descriptions of it have tended to indicate a particular ethical standpoint; a proposition exemplified by the various Committee discussions on the subject. Secondly, the ambiguity and confusion arising from the words "research" and "experimentation" often obscured the precise intention of a particular recommendation dealing with those actions. Such terms, it will be submitted, ought to be unequivocally defined when the question of regulating certain activities is being tackled. Finally, the largely euphemistic terminology applied by many in describing the destruction of the embryo will be critically examined.

70 Commonwealth of Australia, Senate Select Committee on the Human Embryo Experimentation Bill 1985, Official Hansard Report, Wednesday, 23 April 1986 at p 1271 (Evidence of Professor M A Somerville).

71 I Davies, "Fabricated Man: The Dilemma Posed By Artificial Reproductive Techniques" (1984) 35 North. Ir. L.Q. 354, at 369-70.

(a) Definition and synonyms of "embryo"

The traditional medical definition of the term embryo is, for humans, "... the developing organism from conception until approximately the end of the second month";[72] after eight weeks of gestation the developing entity is referred to as a fetus until birth.[73]

In Britain, the Warnock Committee, when clarifying the term 'embryology', also adhered to this classification, normally used for embryos in utero:

> "We have regarded the embryonic stage to be the six weeks immediately following fertilisation which usually corresponds with the first eight weeks of gestation, counted from the first day of the woman's last menstrual period".[74] (emphasis added)

The Ontario Law Reform Commission gave a looser definition, calling the embryo "An organism in the early stages of development before recognisable human features have been formed".[75] Precise temporal delimitation was thus avoided. Even more interesting was the Ontario Commission's use of the term "fertilised ovum" which, it stated, was used interchangeably with "embryo" throughout the Report.[76] This latter term, it is submitted, cleverly emphasised the suggestion that in its early stages the embryo can merely be regarded as a human gamete with something (ie another gamete) added to it. The reader could perhaps be unwittingly drawn away from what may have been his/her preconception, namely, that a new and distinct entity is formed at fertilisation.

72 Stedmans Medical Dictionary, op. cit., supra, Part A n.4.

73 Ibid.

74 Warnock Committee Report at p.5.

75 Ontario Commission Report, Glossary of Terms, [xiii].

76 Id.

Taking a more restrictive attitude toward the use of embryos in research, the Australian Senate Select Committee described the embryo most elaborately as "... genetically new human life organised as a distinct entity oriented towards further development".[77] This inclusion of an emphasis on the embryo's future within the definition stood as antithetical to the Ontario Commission's insinuation, by using the term "fertilised ovum", that the entity existing immediately after conception is closer in kind to the individual gametes it was in the past than to the "human being" of its future. Not surprisingly, the recommendations of those two bodies exemplified two opposing standpoints. The Ontario Commission's conclusions represented some of the most permissive attitudes toward embryo research, while the Australian recommendations sought to apply the "sanctity of life" principle to the conceptus in vitro and favoured a complete prohibition of experimentation if it resulted in the destruction[78] of the entity.

Thus it may be impossible to define the subject matter of this debate in purely linguistic terms; the language applied tends to represent a carefully chosen springboard for a preconceived line of argument.

Perhaps the most subtle, yet strikingly effective, move was the introduction of the term "pre-embryo". This post-Warnock expression was been widely adopted to describe the conceptus for a period of 14 days after fertilisation. The appropriateness of 14 days growth as a dividing line for protection thereafter can of course be criticised.[79] For the purposes of the present analysis, it is sufficient to ascertain which parties important to the debate instigated the use of the term, and to what end.

77 Australian Senate Select Committee Report at 13.

78 See part (c) of this chapter (post) for a discussion of euphemisms used by other bodies in describing research in which the embryo is destroyed.

79 See ante, Chapter I at (b)(iii) and post Chapter IV at (b).

This author submits that there is considerable evidence that the description of post fertilisation human material as the "pre-embryo"[80] was deliberately devised by the pro-experimentation lobby to convince those wary of such procedures that the entity under discussion is in fact not existent until after fourteen days growth.

During a UK House of Commons debate on Embryology at the height of the political controversy [81] one Member of the House commented most perceptively on the infiltration of this word into the debate. Those in favour of research spoke of the term "as if it were the norm" he noted, "and as though anatomists, doctors and scientists had been using it for centuries. It appears in no book of biology, anatomy or medical dictionary in this country ..."[82] he added, nor to his knowledge anywhere in the world. The term would thus appear to have been coined in order to 'soften the blow' of what many still regard as morally indefensible acts. Advocates of embryo research, driven to counteract the post-Warnock wave of support for the 'pro-life' movement, seem to have adopted the expression "pre-embryo" in the belief that its endless repetition may lead their case to triumph. Convincing the sceptics that in fact embryos were never named as such until fourteen days gestation would strengthen their cause.

One member of the Warnock Committee was quick to refute the inference that the distinction had always existed. Dr David Davies, two years after he sat on the Committee, said of its meetings;

> ".. I am reasonably sure that at least in our discussions the word "pre-embryo" was never used. ..... I can recall no efforts either within or from outside the Committee to redefine the early stages as not yet an embryo. Within the past year,

80 The superfluous nature of the term becomes patent if, conversely, we attach the word post-embryo to the fetus of eight weeks plus. Neither prefix describes an entity which was previously lacking a name.

81 U.K. H.C. Parliamentary Debates Official Report (Hansard) Vol. 126 No 87, col. 1202 et seq. Thursday, 4 February 1988.

82 Ibid at col. 1249. The speaker was the Member for Hyndburn, Mr Ken Hargreaves.

however, the word "pre-embryo" has been creeping in".[83]

We cannot be sure whether or not scientists and others really can "manipulate public opinion by the invention of words that have no true meaning".[84] This author is convinced, however, that words such as "pre-embryo" have hardly been deployed in innocence.

Again in the words of Dr Davies,

> "..... if research on embryos were an uncontentious matter, and if scientists were generally of the opinion that the new terminology helped their understanding, nobody would have any qualms at the name change. But those who are introducing the word "pre-embryo" into the vocabulary know full well that the research is indeed contentious and that fundamental issues have yet to be resolved".[85]

This view was well illustrated by comments on the word in both Houses of Parliament in Britain. In the House of Commons debate mentioned earlier, not one speaker opposed to human embryo research approved of the term "pre-embryo" and some denounced its use vigorously.[86] Proponents of embryo experimentation used and defended it as the correct scientific term for a pre-fourteen day conceptus, without exception.[87] During discussions on the

83 Nature, (1986) Vol. 320, at 208.

84 Supra n.82 at col. 1250.

85 D Davies, op. cit., supra n.83, at 209.

86 For example the MP for Southport, Mr Ronnie Fearn maintained that there is no such being as the pre-embryo, supra n.82 at col. 1229, while two Members acclaimed the wording of the Australian Senate Committee to describe the embryo. See supra n.82 at cols. 1226 and 1238-9.

87 Dr Charles Goodson-Wickes, MP for Wimbledon, referred to the term "pre-embryo" as being "utterly appropriate" to describe the post-fertilisation entity up to 14 days. Supra n.82 at col. 1236. All other Members in favour of research used the term, most without comment on its meaning.

Government's White Paper in the House of Lords, resistance to the practice of embryo research was again coupled with disapprobation of the introduction of the term to the debate.[88] Conversely, those in favour of research went so far as to demand use of the word "pre-embryo". For example, Lord Henderson of Brompton declared that the ethical difficulties had been completely resolved for him by the division of the word embryo into two parts, namely "pre"-embryo and embryo.[89] Baroness Warnock herself summarised the relationship between language and viewpoint from the perspective of the pro-research lobby:

> "I believe that it is our moral duty to make a distinction ..... between the pre-embryo and the embryo which is to become the individual and to act on this distinction".[90]

The present author is of the view that the term "pre-embryo" cannot be presented as a purely scientific, and thus morally neutral, word. It may be that scientific accuracy requires us to differentiate between the various complicated stages of early post-fertilisation growth. The first fourteen days of such growth, contain so many stages that it would be imprecise to use only one label for them all. While scientific investigation of post-fertilisation life has become more sophisticated, however, proponents of embryo research have been busy rewriting reproductive biology to accommodate the new terminology. For example, The Third Report of the (British) Voluntary Licensing Authority contained a separate section dedicated to justifying its use of the term "pre-embryo".

88 U.K. H.L. Parliamentary Debates Vol. 49 at col. 1450 (15 January 1988). The Earl of Lauderdale went so far as to blame the Government's White Paper for joining with those "seeking to obscure" the right-to-life issue by inventing a new thing called the "pre-embryo" col. 1485. The Earl of Halsbury, favouring the Latin conceptus as the most appropriate term was almost as scathing. He remarked, "If you want an excuse for doing what you want to do, you cook up a new term for it and get everybody else into a muddle as to what the new term means. I do not believe in the pre-embryo". Col. 1489.

89 Ibid at col. 1494.

90 Ibid at col. 1470.

Claiming that "..... Fertilisation does not produce an embryo"[91], the Report condemned use of the phrase "test-tube baby" by those opposing embryo research. Such terminology conjures up images of experimenting with tiny human beings, it argued. A scientific description of the first, post-fertilisation days of growth was then issued to illustrate that the 'destiny' of the conceptus only becomes clear with the development of the primitive streak (circa 14 days growth); after that time the entity may be called an embryo. Such a response to the criticism over use of the term 'pre-embryo' served to acknowledge, in the present author's opinion, that the word is indeed value-ridden.

It is submitted that the word 'pre-embryo' has contributed little to our scientific understanding of reproductive biology and nothing at all philosophically. Inventing new words for a debate already loaded with emotive terminology has proved to be unhelpful. It is hoped that the word "pre-embryo" will not form part of future debate and, as will be seen, the UK Parliament ultimately dropped the misnomer, when passing the Human Fertilisation and Embryology Act 1990

To summarise this first point of language there follows a "ladder" of descriptive terms, all used at different stages to identify the post-fertilisation entity. The hierarchical form aims to emphasise the emotiveness of the terms, progressing upwards towards perception of the entity's status as "human".

91 The Third Report of the Voluntary Licensing Authority for Human In Vitro Fertilisation and Embryology (Medical Research Council Publication, April 1988) [hereinafter referred to as 'Third VLA Report'] at p 22-23. The section entitled "Why use the term 'pre-embryo'" was written by Dr P Leach, a Member of the VLA.

LIFE[92]

CHILD[93]

HUMAN BEING

EMBRYONIC HUMAN BEING

GENETICALLY NEW HUMAN LIFE ORGANISED AS A DISTINCT ENTITY ORIENTED TOWARDS FURTHER DEVELOPMENT [94]

HUMAN EMBRYO

ZYGOTE/EMBRYO/CONCEPTUS [95]

EARLY EMBRYO

PRE-EMBRYO [96]

FERTILISED OVUM [97]

COLLECTION OF CELLS

RESEARCH MATERIAL

LABORATORY ARTEFACT[98]

92 "Not only has it a chance for life; the embryo is life". Mr Kenneth Hind (MP Lancashire, West) supra n.82 at col. 1251.

93 Ibid at col. 1229 (Mr Ronnie Fearn MP, Southport).

94 Supra n.77.

95 These three terms represent the most morally neutral ways of describing the entity, and the most scientific. All three terms are commonly preceded by the word "human" to distinguish them from the concepti of animals.

96 As mentioned earlier, this controversial term entered the vocabularly of the debaters at the height of the discussions on possible regulation of embryo research. Examples of Reports which use the word (and which are strongly "pro-research") include The First, Second and Fourth Reports of the Voluntary Licensing Authority For Human In Vitro Fertilisation and Embryology (Medical Research Council publications, April 1986 and April 1987 and April 1989 respectively) (hereinafter referred to as "First VLA Report" and "Second VLA Report" and "Fourth VLA Report") and the American Fertility Society Report (supra n.22). See also Third VLA Report (op. cit. supra n.91).

97 This term, as discussed earlier, was used primarily by the Ontario Commission Report.

98 The lowest three terms in the hierarchy seek to present the view

(b) Parameters of the terms "research" and "experimentation"

Even if one attempts to describe the entity involved in the debate as accurately and unemotionally as possible, the question of what exactly it is that medical scientists are doing to the embryo which requires control, or some have argued, prohibition, arises. Again it seems that language has in some cases confused the arguments of one group, and been applied carefully to the advantage of another. When the Warnock Committee produced its Report, in 1984, it formulated a division of the scope of the term research into two categories,

> "The first, which we term pure research, is aimed at increasing and developing knowledge of the very early stages of the human embryo; the second, applied research, is research with direct diagnostic or therapeutic aims for the human embryo, or for the alleviation of infertility in general".[99]

It was clear from this categorisation, and from the Committee's recommendation that,

> "... no embryo which has been used for research should be transferred to a woman",[100]

that its members either envisaged all research as being of a nature which would necessarily render the embryo unsuitable for implantation, or at least thought it safer to avoid the risk that research would have that result by imposing a blanket ban on subsequent implantation.

98 that the post-fertilisation entity is not endowed with "human" characteristics and aim to devalue its status with terms such as "material" and "artefact". These descriptions are used mainly by those who believe that the early embryo should not be afforded a certain legal status. Mason & McCall Smith (cited supra Part A n.44) have used the term laboratory artefact to assist their proposition that the embryo is lacking in humanity. See p.61.

99 Warnock Committee Report, at p.61.

100 Ibid. at p.66.

Therapeutic intervention for treatment of genetic disorders and such like, prior to implantation, was not considered during the Committee's discussion of "research" and indeed elsewhere in the Report was referred to as a "purely speculative" technique which would in any event be precluded by the controls on "research" they had proposed.[101]

During the "consultation" period of over three years following publication of the Warnock Report in Britain, significant academic and social debate on this aspect of the Report took place. The subsequent UK White Paper on embryology,[102] in proposing a framework for legislative controls, altered the Warnock definitions quite considerably. Despite omitting to suggest that legislation should define the scope of the term "research" in the context of human embryos, its proposals did adopt a more logical categorisation of "research" than Warnock. The Paper noted,

> "The key distinction in the debate surrounding embryo research appears to be between the use of an embryo with the intention of achieving (with that embryo) a successful pregnancy leading to a healthy baby; and its use for other reasons (eg improvement of knowledge about disease").[103]

101 Ibid at p.74.

102 UK, Department of Health and Social Security, "Human Fertilisation and Embryology: A Framework for Legislation" Cm 259 [London: HMSO, 1987] [hereinafter referred to as UK White Paper on Embryology].

103 Ibid. at p.6.

The latter category assumes destruction of the embryo either before or during such use. While procedures which do not cause harm to the embryo, (and indeed are carried out to improve the chances of that embryo developing after implantation into a healthy infant), may still come under the scope of the term "research" they have generally not been attacked by the anti-research lobby. That lobby continues to articulate their primary objections as being directed toward "destructive research" rather than simply "research", as the latter can be seen to be a generic term encompassing everything from scientific observation to creation of embryos purely for testing which culminates in their destruction.

In Australia, those who have favoured a legal prohibition on using embryos for scientific experiments attempted, to a certain extent, to maintain this distinction. Senator Harradine's Bill,[104] on which the Senate Select Committee reported, aimed at criminalising actions with in vitro embryos which interrupted the development of their full human potential, or were inconsistent with that development.[105]

The creation of such embryos in anticipation that their development would be interrupted was also to be prohibited.[106]

The intention behind the proposed legislation therefore seemed to be to prohibit any use which would damage or destroy the embryo. Why, then, did the Bill fail to define concisely the scope of its key expressions? While its intention to protect the embryo from "destruction" [107] may have been relatively clear, it was ambiguous with regard to the parameters of acceptable and unacceptable experimentation.

104 op. cit. supra n.61.

105 Ibid., s.5(2).

106 Id., s.5(3).

107 For a discussion of the euphemisms used to describe this event see the next part (c) of this Chapter.

Russell Scott, a medical law consultant, in presenting comments critical of the Bill before the Senate Select Committee,[108] expressed concern that certain words central to its operation had been left undefined. Contrary to what proponents of the Bill had suggested, the word "experiment", Scott stated, could not be regarded as having a single clear meaning requiring no further clarification in the context of embryo research.[109] He noted that the Oxford English Dictionary offers twelve separate segments of meaning under two entirely separate definitions of the word "experiment".[110] The effect of such a variety of meanings all being attributed to one word has been, of course, that all parties to the debate have used those words in support of their argument. Thus, while Harradine's side favoured the view that "experiment" could be defined as "action taken for the trial of a hypothesis, on the chance of succeeding or to demonstrate a known fact",[111] Mr Scott pointed out that the same dictionary offered a definition of "research" (the words are used interchangeably throughout the debate) as "a search or investigation directed to the discovery of some fact by careful consideration or study of a subject ...".[112]

The insinuation is clear. Both terms could quite correctly be applied to anything from mere observation to random testing on thousands of specially created embryos.

108 Australian Senate Select Committee Hearings at p 360-370.

109 Ibid. at p 364.

110 Id.

111 Mr Scott was here quoting Mr J Munro, Consultant Draftsman to the Australian Senate, who drafted the Bill under discussion.

112 Supra. n.108 at p 365.

It is well-established in common law jurisdictions that statutes which are ambiguous or uncertain as to application must be interpreted in a sense which will not render them nugatory.[113] To avoid constant recourse to the courts on matters of interpretation, statutes invariably devote one section to interpretation, to clarify what particular meaning is intended by certain words and expressions in the context of the legislation. It is in the present author's view essential that legislation covering embryo experimentation provides definitions of 'research', 'experimentation' and related actions such as 'manipulation',[114] in addition to "embryo" (ante) which accurately describe their meaning for the context in which they are being used. Thus, while each party to the debate will continue to favour linguistic constructs which reinforce their claims, the legally enforceable rules themselves can to a great extent disentangle themselves from the complex nuances contained in these generic terms.

Looking to publications from other sources, it is again evident that no consensus was reached as to what "research" in the context of human embryos actually entails.

In Canada, the Ontario Law Reform Commission focused on the acceptability or otherwise of implanting an embryo which had already been used for research purposes. A distinction was drawn between "experimentation that has no direct therapeutic purpose in relation to the ovum" (ie the fertilised ovum) and that conferring "direct

113 See Inland Revenue v Luke (UK) 1963 SC (HL) 65.

114 The term "manipulation" is seen to be rather amorphous in this context. The manipulation of the embryo may or may not render it unsuitable for implantation, may or may not be "therapeutic" and may or may not come within the ambit of the terms "research" and "experimentation".

therapeutic benefit on the embryo".[115] The latter category would seem to cover the treatment of a genetic defect or other abnormality followed by implantation, while the former would probably cover all work which left the subject matter unsuitable for implantation. It is submitted, however, that these two categories could adequately be distinguished by the words "experimentation" and "treatment" respectively. Thus, the Commission also seemed to avoid defining precisely the scope and content of the words "research" and "experimentation". Interestingly, prior to the publication of the Commission's Report, the Society of Obstetricians and Gynaecologists of Canada had utilised entirely different linguistic terms of reference in making their point. While advocating a "strong research component" as part of the IVF programme, the Society had endorsed only the "scientific examination" of embryos prior to implantation.[116] It would seem that "scientific examination" is little more than observation through a microscope, and yet was clearly thought to come within the ambit of "research" by the Society. The example serves to highlight again the variety of meanings which have been ascribed to certain terms according to the user's perspective.

Looking outside commonwealth jurisdictions, the volume of terminology which has been used to describe "research" is further increased. A Report to the Parlimentary Assembly of the Council of Europe in 1986,[117] in drafting rules to govern the use of human embryos (and fetuses), divided those uses into three main

115 Ontario Commission Report at pp.212-2

116 Bulletin of the Society of Obstetricians and Gynaecologists of Canada Volume VI No 3 (May/June 1984), Statement - In Vitro Fertilisation and Embryo Transfer, at p 4.

117 Report on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes. Parliamentary Assembly of the Council of Europe, 1 September 1986, (38th Ordinary Session) Doc. 5615 [hereinafter referred to as 'Council of Europe Report'].

categories: diagnostic purposes, therapeutic purposes and scientific purposes. With regard to the first two categories, the term "operation" for diagnostic/therapeutic purposes was used. Only in respect of the third category were the terms "experiments" and "research" applied. Nowhere in the Report were those words clarified or defined for that context. Confusing the issue further was the Report's tacit suggestion that something could be done to the embryo which constituted "scientific purposes" (ie was not diagnostic or therapeutic) and yet was intended to promote the well-being of the future child.[118] No precise or logical divisions between the categories used in the Report could therefore be ascertained.

The Ethics Committee of the American Fertility Society prefaced its Report with a short list of definitions it had drawn up "...[i]n order to avoid confusion".[119] Using the expressions "clinical trial" and "clinical experiment" the Committee's categories were analagous to Warnock's "applied research" and "pure research" respectively.[120] Again, however, the definitions were wholly inadequate and failed to refer to any particular actions which might fall within their ambit.

The first attempt in commonwealth jurisdictions to define these terms in actual legislation was the Infertility (Medical procedures)

118 Thus, although "research" was seen in the Report as <u>prima facie</u> against the well-being of the embryo, this exception prevented any coherent definition of that word for the context.

119 American Fertility Society Report at vii (Definitions).

120 Clinical trial was defined as ".. a systematic effort to improve the effectiveness of an existing clinical procedure". (Id.) Clinical experiment was considered to be "..... an innovative procedure that has a very limited or no historical record of whether any success can be achieved..." (Id.).

Act of Victoria [121] which interprets "experimental procedure" as,

> "..... a procedure that involves carrying out research on an embryo of a kind that would cause damage to the embryo, would make the embryo unfit for implantation or would reduce the prospects of a pregnancy resulting from the implantation of the embryo".[122]

An initial glance at this definition might deceive the reader: it looks like an unequivocal and comprehensive clarification of the term. It excludes the kind of interference which renders the embryo unsuitable for implantation. But what of acts that may be described as "scientific examination" or "directly therapeutic measures"? What are the outer limits of these categories which will be accepted under the Act? The provision is unclear. In addition, one can only imagine the nightmare of trying to gather proof for litigation that a particular measure carried out prior to implantation had or had not reduced "the prospects of a pregnancy" after implantation.

Some useful observations on the pliability of the term "research" were made by Lord Kennet in the House of Lords debate, mentioned earlier, and may be alluded to by way of summary. The word "research", his Lordship noted,[123] has been used throughout the debate to mean two completely distinct things.

"First, it has been used to mean procedures carried out on a human being or pre-human being for the benefit of that human being or pre-human being. In common usage the word means research carried out on a human being, or living creature of any kind, for the benefit of all the members of that species".[124]

121 Cited supra Part A, n.43.

122 s.6 (4).

123 Supra n.89 at col 1496.

124 Ibid.

Lord Kennet went on to say that the first use of the word was hitherto unknown, and was better described by the term "diagnostic investigation".[125] Interestingly, however, he conceded that the French word "recherches" does include diagnostic interventions, thus obliquely implying that uniform terminology will be even more unattainable where more than one language is involved.[126]

Finally, his Lordship noted that the assimilation of two quite distinct activities under the one abstract noun "research" would only serve to benefit one side of the debate.[127] It is hereby submitted that the attempted incorporation of a countless number of activities within that noun, as has been illustrated above, serves only to create vagueness and uncertainty over what the focus of any regulation really is. Further, as will be argued later in this thesis enactments which seek to sidestep the issue fail to address adequately the fundamentally important priority of carefully defining terminology where regulation of scientific activity is envisaged.

The following table lists some of the plethora of terms used in the context of the debate as synonymous with "research" and "experimentation".

125 Ibid at col 1497. His Lordship perceived "diagnostic investigation" as looking into the condition of the subject or patient concerned in order to decide what is the best treatment.

126 This is, of course, a constant problem in countries such as Canada, where there are two official languages, and in International Organisations such as the Council of Europe. This clearly affects the possibility of negotiating a viable international instrument regulating an issue where language is itself part of the problem..

127 Supra n.89 at col 1497. His Lordship believed this assimilation benefits those who condone embryo research, but the argument could probably also be made the other way.

OBSERVATION [128]
(SCIENTIFIC) EXAMINATION
DIAGNOSTIC INVESTIGATION

TESTING FOR NORMALITY [129]

THERAPEUTIC INTERFERENCE
CLINICAL TRAIL
RESEARCH/EXPERIMENTATION [130]

CLINICAL EXPERIMENT
NON-THERAPEUTIC INTERFERENCE
DESTRUCTIVE NON-THERAPEUTIC INTERFERENCE [131]

MANIPULATION [132]

HUMAN EMBRYO VIVISECTION [133]

128 This action clearly involves the least interference with the embryo in vitro. The problem, however, is that if such observation is a preliminary to a more contentious act (eg observing four embryos through a microscope with a view to discarding the least suitable) it could easily come under a catch-all definition of "experimentation".

129 Supra n.89 at col 1488 (The Earl of Halsbury). The difference between this and mere observation is that such testing may involve physical interference or "handling" of the conceptus.

130 As has been shown, the generic terms themselves can be imputed with radically different meanings when words such as "pure", "applied", "clinical" or "pre-clinical" are placed before them.

131 The Australian Report talked of "destructive non-therapeutic experimentation". See Australian Senate Select Committee Report at 17.

132 This term has, for many people, somewhat sinister connotations in the context of embryo research. It tends to conjure up images of crazy scientists controlling the genetic make-up of their laboratory charges. A satisfactory definition of the word if used in legislation or other rules is therefore crucial. The Harradine Bill failed to define this word, which meaning was central to the whole intention behind the proposed statute.

133 "Upholding Human Dignity: Ethical Alternatives to Human Embryo

(c) How to describe the end of an embryo's existence?

It is difficult to find any morally neutral terms to describe actions ending the existence of an embryo which, for whatever reason, is not destined for implantation. At one extreme, those bestowing on the embryo full human status may renounce such acts as "murder", while on the other, those regarding the conceptus in vitro as a mere laboratory artefact will talk of "flushing away" or simply "discarding" it. Once again, terminology can be a fine instrument to promote and even control the views of all parties to the discussion. Unlike the controversy surrounding description of the conceptus, where the pro-research lobby invented use of the term "pre-embryo" (ante.), here there has appeared to be a reluctance to put any name to actions which "terminate" the embryo. Indeed many groups avoided discussing the ultimate fate of untransferred in vitro embryos altogether.

The Ontario Commission Report, for example, in concentrating on whether or not embryos subjected to research should then be transferred to a woman made no mention of the fate of the embryos deemed unsuitable for such implantation.[134] Further, in determining time limits on the development of concepti in vitro, the Report did not elaborate the method by which the embryos would "expire" after the recommended limit of fourteen days growth.[135] Only when discussing the fate of embryos stored by cryopreservation did the Commissioners articulate what was to happen to them on the expiry of

133 Research" [published by The Parliamentary Medical and Scientific Advisory Committee to the All-Party Parliamentary Pro-Life Group, London: 1988] at p.4. This expression leaves the reader in no doubt as to the stance of those who use it.

134 Ontario Commission Report at 212-214.

135 Ibid. at 214-216.

the ten year storage period favoured by both the Warnock Committee [136] and their own Report.[137] The Commissioners directed that the storage authority should "waste the embryo" and went so far as to recommend that at the end of ten years storage such an authority,

"..... should be under a duty to have the ovum wasted".[138]

Use of the word "waste" as a verb is generally unusual and rather obsolete, but can be defined as "to cause to decline" or "to put an end to".[139] It seems that the Commissioners did not regard the term as one requiring clarification; the glossary of terms in the Report did not define "waste" for the context in question.[140]

The Warnock Committee Report itself had bypassed any direct description of the fate of "spare" or post-research embryos, referring in the context of cryopreservation simply to their "use or disposal".[141] Again, the choice of word was surprising.

Interpretation of "disposal" as "getting rid of" is very much a secondary one; its primary meaning is almost synonymous with "use" or "application to a particular purpose".[142] The Report can only be

136 Warnock Committee Report at 56.

137 Ontario Commission Report at 217.

138 Id.

139 Chambers Twentieth Century Dictionary, rev'd ed., [Chambers: London].

140 Admittedly by the glossary confined itself mainly to medical or scientific terms. It might have been more helpful, however, also to clarify non-scientific terms given a particular definition when applied in a scientific context.

141 Warnock Committee Report at 56-57.

142 Chambers Twentieth Century Dictionary, op. cit. supra n.139.

construed, however, as applying the term "disposal" to situations where the embryo is not to survive, in contrast to "use" which implies possible future implantation.[143] It is thus submitted that substitution of a euphemistic term such as "disposal" for "destruction" or "termination" may have been a deliberate attempt to guide the reader away from thoughts of how the unwanted concepti would be disposed of, and more importantly, whether or not it would be ethical so to do.

Similarly, the UK White Paper on Embryology, in suggesting the imposition of a time limit beyond which research would be prohibited merely stated that,

> "use beyond this time would ... be a criminal offence".[144]

As it was recommended the growth of embryos for any purpose beyond that time limit ought to be impermissible, however, it can be argued that the word "use" was wholly inappropriate for the context. In fact such a limit aims to preclude mere survival of a conceptus in vitro after a certain time or event. Couching activity beyond the limit in terms of "use" was perhaps again designed to evade articulation of the fact that the only "use" permitted on expiry of such a time limit would be "destruction". The U.K. White Paper was more direct, however, in describing the fate of embryos stored by freezing. In certain circumstances, where there was no agreement as to use, the Paper conceded that the embryo in question would be ".....left to perish".[145] While the word "perish" itself is open to more than one interpretation, and can denote either passive or

143 The words "use" and "disposal" were offered as alternatives whenever mentioned in the Report. In other words, "use or disposal" is referred to; "use and disposal" is not.

144 UK White Paper on Embryology at 7.

145 Ibid. at 10. The DHSS document on embryo research 1986, op. cit. supra n.56 also applied the word "perish" to spare embryos not required for implantation.

active loss of life, it is in the present author's view, the most accurate description of what will happen to the unimplanted embryo.

The Report of the Australian Senate Select Committee [146] formulated recommendations on the use and fate of human embryos which contain relatively little ambiguity of language. As has been shown, two main categories of "experiments" can be defined; those leaving the embryo intact and those rendering it unsuitable for implantation. The Australian Report made clear that a vital distinction lay in the ultimate fate of an embryo used for research purposes:

> "..... the ..... distinction 'destructive non-therapeutic experimentation' indicating that such experiments are, in the present state of knowledge, so invasive as to inevitably cause the destruction of the subject of the experiment".[147]

Connotations brought to mind by the word "destroy" are largely negative, and actions resulting in destruction are often attributed with malicious intent. Use of the term was therefore in keeping with the principle, central to the Report, that deliberate frustration of the development of the human embryo was to be seen as unacceptable and should be prohibited.[148] It should be noted, however, that although the word "destruction" may equally be applied to ending the life of humans, plants, animals and buildings, it is less commonly used in describing acts which end human life. Thus its application is less direct than words like "death" and even "murder", which some may feel more strongly imply the end of a human existence.

The Senate Select Committee's choice of terminology marked a deviation from the Harradine Bill in this regard. Sub-section 6(8) of that Bill sought to impose criminal sanctions on those who

> ".....wilfully allow a relevant human embryo to die".[149]

146 op. cit. supra n.68.

147 Australian Senate Select Committee Report at 17.

148 Ibid. at 29.

149 s.6(8), Harradine Bill op. cit. supra n.61.

While the Senate Report had undoubtedly regarded the embryo as "human",[150] it stopped short of describing the end of its existence as "death". Russell Scott, in challenging the Bill's use of the word "die" in relation to an embryo in vitro, stated that s.6(8) required "substantial feats of interpretation".[151] Quoting a common medical definition of death in humans which alludes to loss of heart beat, breathing and cessation of brain activity,[152] Mr Scott criticised use of the verb "to die" as wholly inappropriate in the context of human embryos.[153] The act of allowing something "to die" was meaningless unless it referred to a human being, he contended.[154]

It can be argued against that view, however, that dying itself is not a function exclusively associated with humans. The end of 'life' for plants and animals could also be described as "death". Thus the term may only be deemed inappropriate as regards human embryos if one attributes them with less living status than, say, trees or birds. As has been mentioned, 'dying' has, for many, a stronger human connotation than "destruction". It becomes clear, however, that any meaning assigned to either term is inextricably linked with one's views on where the embryo would stand in a hierarchical structure of all living things. The higher the position of the conceptus in that structure, the more emotive and 'human-related' the terms used to describe the end of its existence.

150 Australian Senate Select Committee Report at 13.

151 supra n.70 at p.367.

152 Stedmans Medical Dictionary op. cit. supra Part A n.4 states "in man, death is manifested by the loss of heart beat, by the absence of spontaneous breathing, and by cerebral death".

153 supra n.70 at 367.

154 Id. Professor Scott was clearly implying that he did not regard the embryo as a human being for this purpose.

Arguments over choice of words in describing the fate of unwanted embryos are largely reminiscent of the abortion debate. Despite the obvious distinctions where the conceptus is ex utero commentators have drawn analogies with abortion in discussing the legality of embryo destruction.[155] Parallels with language used in other medical - ethical dilemmas have been used somewhat indiscriminately. One legal writer, emphasising that 'termination' for an embryo in vitro requires only our passive compliance proposed that,

> "..... active destruction of the embryo is not necessary. The embryo equivalent of a 'do not resuscitate order' can be written, and the fertilised egg kept in culture until it stops dividing and dies".[156]

Such a statement ironically seeks to attribute 'symbolic humanity' to the embryo through sensitivity of language, while suggesting an end result that is generally only favoured by those denying the zygote human status. Focusing on the activity/passivity dimension of destroying the embryo may thus serve to confuse the issue by employing ineffectual euphemisms [157] for an action their authors believe requires no defence.

155 See M L Lupton, "Does the destruction of a blastocyst constitute the crime of abortion?" (1985) The South African L.J. 92; H J J Leenen, "The Legal Status of the Embryo in vivo and in vitro: Research on and the Medical Treatment of Embryos"(1986) 14 Law Medicine & Health Care 129.

156 See Robertson, supra n.16, at 65.

157 The "do not resuscitate" order suggested by J A Robertson supra n.156, brings to mind other euphemisms used by the medical profession in making decisions to let humans die, eg "nursing care only" & "tender loving care", made famous by the trial in Britian of Dr Arthur, who assented to the wishes of a couple who wanted their Down's Syndrome baby to die. R V Arthur, The (London) Times (6 November 1981) p.1-12. It may be unwise to transpose such catch-phrases, with their pre-existing implications, to the situation of the embryo in vitro, without reflecting on the consequences of so doing.

If the embryo in vitro cannot come within existing definitions of "life" and "death", it is submitted that terminology presently applied to abortion, euthanasia [158] and killing [159] is indeed inappropriate in the context of ending the embryo's existence. While the present writer admits to having condemned the invention of the term 'pre-embryo' for use in a debate already over cluttered with terms, it seems that here the striking feature is the lack of a suitable word to describe "the end of being" for the embryo. Perhaps one expression could be coined as the official term for this action, which term would doubtless be colourfully expanded on in the forum of debate. The word 'termination' appears to serve this purpose fairly adequately for the abortion debate. Formal rules relating to embryo research might benefit from a single concise term, obviating the need for more protracted discussion over choice of words. It is submitted therefore that the Australian Senate Select Committee obscured the issue when it sought to maintain that, for an embryo with no hope of survival,

> "..... there is [a] ..... distinction between allowing it to succumb and deliberately destroying it ....."[160]

As will be illustrated, however, the converse approach of leaving methods of "perishing" to the perpetrators, will inspire no confidence in those with stongly held views about such actions. (See Part C (post.))

158 The activity/passivity distinction has been central to the euthanasia debate. See eg D N Husak, "Killing, Letting Die and Euthanasia" (1979) 5 J. Med. Ethics 200. Its application to embryo destruction could again be unwitting and is in any event not terribly helpful.

159 "Mercy-Killing" is the next example here of an existing phrase which is meaningful only in specifically defined situations and cannot simply be adapted to fit the embryo debate.

160 Australian Senate Select Committee Report at 62.

Choosing an acceptable term from the undernoted list is therefore complicated by the possibility of both active and passive construction of most of the options.

MURDER (active only)
KILLING (mercy/malicious)
DESTRUCTION (accidental/wilful)
TERMINATION [161] (passive/active)

DISCARDMENT (bona/mala fide)
DISPOSAL (bona/mala fide)
DE-MATERIALISATION
PERISH [162]

"WASTE" (passive/active)
DEATH [163]
ALLOWING TO SUCCUMB (passive)
ENDING THE EXISTENCE [164] (active)
FAILING TO SURVIVE
EXPIRATION (passive only)

161 Though usually applied as synonymous with abortion itself, this term has also been seen to be controlled by its users. 'Termination of pregnancy' can here be contrasted with 'termination of life'. To distinguish embryo destruction from abortion it may be advisable to avoid using this word.

162 This is, in the author's view the least emotive, sufficiently descriptive, term which has no pre-existing connotations in the medico-legal context.

163 While it may be true that anything which can be said to be 'alive' must, correlatively, be able to "die", existing definitions of death are uniformly inapplicable to the end of an embryo's existence. For a discussion of modern legal definitions of death see Mason & McCall Smith op. cit. supra Part A fn 43, at 289-299. The Council of Europe Report applied the term 'death' to both embryos and fetuses, without comment.

164 This somewhat cumbersome phrase may seem neutral in tone but is too unspecific. It merely begs the question "how"?

Conclusion

The use of language can become a contentious issue in any debate and is in no way confined to medico-legal problems, let alone the embryo research debate itself. Any issue requiring multi-disciplinary comment is particularly likely to be susceptible to terminology abuse, however, and the embryo crisis has represented a particularly apt example. It has become clear that the terms used, both scientific and non-scientific, are particularly fraught with the diverse ideological perceptions of their authors.

It is thus submitted that detailed definition and redefinition of relevant words and expressions ought first to be carried out for every given context, be it Committee discussion, Reports, guidelines or formal legislation. Such definitions, however, are a prerequisite to promoting views and recommendations, not a substitute. Or, as one legal commentator warned the Australian Senate Select Committee, we must be aware of the danger that the central issue being addressed will be pushed aside by redefining it rather than addressing it.[165]

Let us then be aware of, if not unfettered by, linguistic barriers, in turning to examine the possibilities for legal treatment of the conceptus.

165 supra n.70 at 1310 (Evidence of Professor M A Somerville).

CHAPTER III

THE LEGAL STATUS OF THE EMBRYO: PROBLEMS OF CATEGORISATION

The moral status of the embryo has been considered and it was proposed that any legal treatment of the entity should have regard to that status.[166] How, then, is the conceptus in vitro to be classified.[167] Implications of applying existing legal categories must be investigated and compared. If treatment of the embryo by familiar concepts and rules will produce anomalies and even injustice, then an effective case for a separate framework of rules, peculiar to embryo research and disposal, has been made. What must be decided is, to paraphrase one legal writer, whether one's 'interest' in the conceptus ex utero can be qualified as a "proprietary" or merely a "possessory" one.[168] Where anyone other than those genetically related to the embryo claims such an interest, that decision is further complicated.

The extent of a potential power to use, control, experiment upon and/or destroy the embryo created in vitro has primarily been discussed by reference to existing rules of ownership on the one hand and the law of persons, or 'family law' on the other. Not surprisingly, these antithetical classifications produce consequences in application which mirror their irrelation as categories. In addition, as will be shown, attempts to delineate the embryo's status in terms of rigid, traditional legal notions would lead to inconsistent treatment even within the terms of each category.

166 See Supra, Chapter I (b).

167 The issue of classification for the embryo has implications at all levels of the legal spectrum; domestic private law, public health law, constitutional law and international law. The examples given are a selection from many, chosen simply to highlight some of the more extreme consequences of applying various existing legal status' to concepti in vitro.

168 See B M Knoppers, "Reproductive Technology and International Mechanisms of Protection of the Human Person" (1986-87) 32 McGill L.J. 337, at 346.

(a) The Embryo as Person

If the 'personhood theory' adopted in discussing the embryo's moral status is transposed into positive legal norms, its effect on handling, storing and experimenting with human concepti is profound and extreme. One unavoidable consequence of regarding the in vitro embryo as a legal person is that it may not be destroyed with impunity. Whether or not ending the embryo's life could fall within the scope of the crimes of murder or homocide,[169] the inconsistency of placing the embryo's 'life' above that of the more gestationally advanced fetus, in terms of a right to life,[170] is clear. While the circumstances surrounding conception in a laboratory may be sufficient to distinguish embryo destruction from abortion, it is submitted that arguments for such a distinction have been more convincing where they would make embryo termination subject to less stringent rules than fetal termination, and not vice - versa.[171] Most proponents of the view that the embryo should be endowed with legal persona, however, do not wish to see any such distinction. Their belief that life begins at conception is almost always accompanied by total condemnation of wilful termination of that life at any stage of development. The present legal position on abortion stands in opposition to their arguments and those advocating rights for the embryo have tended also to favour a radical reform of the

169 For a discussion of the Canadian Criminal Law relevant to embryo destruction see B M Dickens, "Artificial Reproduction and Child Custody" (1987) 66 Can. Bar. Rev. 49, at 63-65.

170 As previously stated, the fetus cannot be said to have an unequivocal right to life under present International Law. See Sieghart, supra n.12. By implication the embryo is also presently excluded from the protection of such a right until a judgement or legal declaration to the contrary.

171 It has been stated that separate state regulation of embryo research "... will be valid if it does not afford an embryo greater protection than a fetus or live-born viable child ...". See N P Terry "'Alas! Poor Yorick', I knew him ex utero: The Regulation of Embryo and Fetal Experimentation and Disposal in England and the United States" [1986] 39 Vanderbilt Law Rev. 419, at 464.

law resulting in the outlawing of abortion.[172]

172 Interestingly, the liberalisation of abortion in Britain and the United States has been accompanied by the development of extensive legal protection for the fetus. See O'Grady v Brown 654 S.W. 2d 904, at 910. (MO. 1983). In England such protection is provided by the Congenital Disabilities (Civil Liability) Act (UK) 1976; the common law in Scotland has very recently been clarified as recognising fetal rights where the child has been injured in vitro - see Hamilton v Fife Health Board 1993 SLT 624. The parallel growth of abortion rights and fetal rights are not necessarily incompatible. Such rights simply recognise the fetus and mother as separate human beings, both with a retrospective ability to claim damages where medical personnel performed negligently during pregnancy and/or childbirth. Where the two rights conflict, however, as in a decision to abort, the mother's rights will prevail under present rules, and it is the aim of anti-abortionists to reverse that situation.

It is important to note in this context, however, that recent decisions on the abortion issue have all preserved the legality of it.[173]

Unless the present "liberal" abortion laws vanished overnight then, bestowing the legal status of personhood on the embryo would have the anomalous effect of granting full protection to a two cell entity in jurisdictions where little or no right to life is recognised for a twelve week old fetus.[174]

Distinctions between embryos in vitro and in utero notwithstanding, many would regard this inconsistency as positively absurd. The subjugation of the fetus' claim to the mother's rights in abortion law is only a partial explanation if the embryo itself has the full protection of law.

173 For example in Wester v Reproductive Health Services 109 SCt 3040 1989), while the U.S. Supreme Court did uphold a Missouri statute which limited the availability of abortion, it refused to overturn the principles of Roe v Wade (op. cit supra fn.1). In Canada, the full Supreme Court in Tremblay v Daigle 1990 62 DLR/4th) 634 reversed the provincial court's decision to grant an interlocutary injunction to a father to prevent the abortion of his child; the maternal rights were thus seen to prevail. (For the report of the provincial court see (1989) 59 DLR (4th) 509). It should also be noted in this context that section 37 of the U.K. Embryology Act 1990, which amends section 1 of the Abortion Act 1967, at most reduces the time limit within which abortions can be performed, but retains the scope of permissable terminations.

174 Many European jurisdictions, for example, have for some time permitted abortion on demand for the first twelve weeks of pregnancy. See M D A Freeman "Abortion - What Do Other Countries Do?" (1988) 138 NLJ 233.

With regard to embryo research, it is indisputable that if the embryo is a person, in law, then the existing rules governing human experimentation in general, and perhaps experimentation on children in particular, must apply.[175] The Australian Senate Select Committee, while not declaring that the embryo was a person, decided to adopt a distinction, based on the Helsinki Declaration concerning biomedical research involving human subjects,[176] between therapeutic

175 For a useful discussion of the problematic nature of non-therapeutic research on children see Mason McCall Smith, op cit., supra, Part A.n43 at 368-374

176 Declaration of Helsinki, Recommendations guiding medical doctors in biomedical research involving human subjects. Adopted by the 18th World Medical Assemby, Helsinki, Finland 1964 and Revised By the 29th World Medical Assembly, Tokyo, Japan, 1975. (Reproduced in Mason & McCall Smith, op cit., supra Part A n.44 as Appendix F) [hereinafter referred to as "Helsinki Declaration].

and non-therapeutic experimentation.[177] The Report of that Committee did not go so far as to apply the rules of the Helsinki Declaration to the developing embryo.[178] The strict legal effect of the personhood theory would do so, however, again with somewhat bizarre results. That Declaration states that, in the context of non-therapeutic biomedical 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 biomedical research is being carried out".[179]

While it is difficult to envisage many non-therapeutic experiments on early concepti which do not result in their destruction, it is just possible that the 'embryonic biopsy' technique may fall under this category.[180] It cannot be denied, however, that, given the comparatively low success rate of IVF even where the embryo is not tampered with, the chances of survival where any interference whatever has occurred, must be severely diminished. How then, can any intrusive types of embryo research be compatible with the principles of the Declaration when it further stipulates:

> "The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual".[181]

Even where the Declaration states that informed consent of an incompetent person can be given vicariously in accordance with national legislation,[182] such consent will necessarily fall short of permitting experimentation on another human being which will result in that subject's 'death'. And the final paragraph of the

177 Australian Senate Select Committee Report at 17.

178 Ibid. at 18.

179 Helsinki Declaration, Part III, paragraph 1.

180 This is a procedure where a cell is removed from the embryo without affecting the viability of that embryo. The cell is then checked to see if the chromosones are normal. See Australian Senate Select Committee Hearings at 56-59.

181 Helsinki Declaration, Part III paragraph 3.

182 Helsinki Declaration, Part I, 'Basic Principles', paragraph 11.

principles to be followed in non-therapeutic research on humans is firm evidence of their inapplicability to concepti in vitro:

"In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject".[183]

Leaving therapeutic research aside for the moment, it is undeniable that the major justification for proposed scientific research on embryos has always been that science and society will benefit from the results. Embryo experimentation solely directed towards improving clinical IVF also falls under that head. The types of drug testing and experimental surgical procedures which can be carried out on fully grown humans without necessarily threatening their well being would be unlikely to leave the embryo in a suitable state for transfer to a uterus. Clearly these matters were not envisaged when the Helsinki Declaration was drafted. Further, the problem with declaring that an embryo is a legal person is that such rules would have to be adopted by countries recognising them by the letter. A flexible interpretation acknowledging only their symbolic application would be unthinkable if the personhood theory was to be given legal recognition. The fundamental principles of the inviolability and dignity of the human being [184] would automatically extend to the embryo from conception onwards and medical scientists undertaking any such research would lay themselves open to the constant threat of litigation and perhaps criminal charges.

If the embryo is a person, then the law would undoubtedly have something to say about the creation of people solely for research purposes.[185]

183 Helsinki Declaration, Part III, paragraph 4.

184 The Declaration of Oslo, 1970 provides only one exception to the principle of maintaining the utmost respect for human life from the time of conception and that in a situation justifying therapeutic abortion, depending on the conviction and conscience of the individual peforming it. [See the reproduction of that Declaration in Mason & McCall Smith, op cit, supra Part A n.44, at Appendix E, para 5].

185 The distinction between creating embryos solely for research purposes and using only those already in existence for such work is discussed in Chapter IV part a) (post.).

In this context again, issues relating to termination of pregnancy overlap with those raised by assisted reproduction techniques. For example, the significant increase in high order multiple pregnancies (usually following infertility treatment) in recent years has led to the practice of selective reduction of pregnancy. The method used is an injection of potassium chloride which reduces the number of fetuses, usually to two.[186] If the multiple pregnancy has occurred 'naturally', selective reduction raises the ethical dilemmas of therapeutic abortion, though most would justify its use on grounds of lower infant mortality.[187] Where it is a result of multiple embryo transfer during IVF, however, additional moral difficulties abound. Is the physician responsible for failing to limit the amount of embryos transferred? Further if each embryo created is recognised as a legal person, what law could justify the deliberate creation of people followed by their destruction on grounds that there are too many of them?

It may be, however, that laws which pre dated the public debate on embryo research, while not attributing the embryo or fetus with legal personality, were themselves sufficient to outlaw fetal reduction procedures.[188] If this was the case, then there would at least have been consistency of approach in dealing with the destruction of unwanted embryos. But in terms of legal status, if the in vitro embryo was a person and the fetus is not, then selective reduction could present itself as a loophole for physicians who find themselves encumbered with 'spare' embryos; transfer them to the womb of a willing recipient and destroy them once they no longer have legal status. The idea that any entity is not bestowed with legal personhood unless it is outside the uterus, referred to earlier, effectively supports such action.

186 See P W Howie, "Selective reduction in multiple pregnancy" (1988) 297 Brit. Med. J. 433.

187 Ibid., at 434.

188 See J Keown, "Selective Reduction of Multiple Pregnancy" (1987) 137 NLJ 1165, at 1166. Section 37 (5) of The UK Embryology Act now seems to permit this procedure under licence. See Part C (post)for comment.

If the embryo is a person, it can clearly be regarded as 'immature humanity', thus requiring the kind of guardianship and protection bestowed on small children. The Australian Senate Select Committee, for example, recommended "..... that the concept of guardianship be adopted as the most appropriate model to indicate the respect due to the embryo .....".[189] Guardianship was chosen by the Committee as ethically preferable to the 'property model' stated by the Committee to be the other basic way of regarding the relationship between adults and IVF embryos.[190] The guardianship model should apply from fertilisation onwards, a majority of the Committee opined, with the intended social parent exercising all relevant rights and duties pertaining thereto.[191] A direct analogy with guardianship/parenthood would require, inter alia, that the welfare of the ward be the paramount consideration. Thus the recommendation of the Australian Report concluded that, as parents and those in loco parentis may only give proxy consent to procedures which are in the interests of the patient under their charge, they would necessarily be precluded from permitting 'destructive non-therapeutic experimentation' on human embryos.[192] The choice of guardianship as a model for regulating activities with embryos brought the Committee close to regarding the conceptus as a legal person, although it stopped short of a declaration to that effect. Again it must be emphasised that application of concepts of guardianship, custody, access and other parental rights, never intended to relate to a two day old human being, would produce anomalous results. It is clearly bizarre to imagine a court being bound to investigate the health and emotional welfare of an embryo before ruling on a custody dispute! And on what criteria could an intended social parent be denied access to the laboratory to "visit" his or her conceptus? The Australian Senate Committee made an unequivocal statement, in choosing the guardianship model, as to what side of the ethical divide it wished to support, yet this recommendation stood in isolation from the body of recommendations in the Report which set out the type of regulation it proposed.[193]

189 Australian Senate Select Committee Report at p35 (para 3.42).

190 Ibid. at p 33 (para 3.35).

191 Ibid. at p 35 (para 3.41).

192 Ibid. at p 36 (para 3.44).

193 Ibid. Chapter IV, especially p 51 (para 4.38).

It is submitted that those proposals were not dependent on, indeed bore little relation to, the application of the guardianship model. The employment of parental rights and rules of custody and guardianship in disputes over human embryos had already been suggested by the Family Law Counci in Australia in a Report which preceded the Senate Select Committee's recommendations.[194] It is possible that the Committee embraced the notion of guardianship to display its opposition to the application of property rules to human embryos without considering in full the legal implications of adopting that model.

Bringing embryos within the ambit of guardianship would necessarily go beyond prohibiting their use in 'destructive non-therapeutic experimentation'. The approach of certain State legislatures in the United States exemplifies this most acutely. While several states have passed legislation protecting the life of the embryo from conception onwards against harmful interference,[195] it is the law of Illinois which has produced the most extreme type of protection for concepti ex utero. Section 6(7) of a 1981 statute provides:-

> "Any person who intentionally causes the fertilisation of a human ovum by a human sperm outside the body of a living human female shall, with regard to the human being thereby produced, be deemed to have the care and custody of a child ....."[196]

The scope of "custody" includes, by reference to another statutory provision, [197] rendering the custodian guilty of an offence if he

194 Commonwealth of Australia, Family Law Council, "Creating Children - A Uniform Approach to the Law and Practice of Reproductive Technology in Australia", Report of the Family Law Council incorporating and adopting the Report of the Asche Committee on issues relating to AID, IVF, embryp transfer and related matters [Parliamentary Paper No 333/1985] (hereinafter referred to as Australian Family Law Council Asche Committee Report).

195 See the survey of such legislation in Lori B Andrews, 'The Legal Status of the Embryo' (1986) 32 Loyola Law Review 357 esp at 395 et seq.

196 State of Illinois. Illinois Statutes Annotated. Chapter 38 Criminal Law and Procedure $23.54 1981 S 6(7).

197 State of Illinois, Illinois Statutes Annotated. Act to Prevent and Punish Wrongs to Children, Section 4.

wilfully causes or permits the life of such child to be endangered, his health injured, or places the child in such a situation that its life or health may be endangered.

This last provision would impliedly result in uncertainty as to the legality of IVF itself and would place the physician in an unenviably precarious situation as custodian. An infertile woman, her husband and her physician challenged the constitutionality of the Illinois statute claiming that doctors might unwittingly violate its terms.[198] The provision was void for vagueness and uncertainty as to scope, they argued. The defendants countered that the statute was not vague, and that, as it did not prohibit absolutely IVF procedures, it did not abrogate any right of the plaintiffs. It was further contended that if an in vitro embryo was not reimplanted, this would constitute a lawful abortion under the Act, if carried out for medical reasons. The conclusion that destruction of the embryo is tantamount to abortion, while logically consistent with the provision in question, simply illustrated the anomalies created by the imposition of custodian status on those performing IVF. Applying rules of 'care and custody' to a physician controlling an embryo, but not to the parents of a fetus would seem to require detailed justification which the statute failed to supply. The plaintiffs in the Illinois case were ultimately unsuccessful in their claims. Thus the provision remains in force, and is subject to the dubious interpretation that the embryo, while subject to the law of persons, can lawfully have its life terminated by an unrelated person responsible for its care.

In summary, then, indications are that endowing the in vitro embryo with legal personality does not sit comfortably with existing family law concepts. As their application would necessarily be consequential to such categorisation, it is submitted that any attempts to classify the embryo within the law of persons should be rejected.

198 Smith v Hartigan 556 F. Supp 157 (1983). See also the summary of the case in Terry, supra n. 171 at 463-4.

(b) The Embryo as Property

Those who regard the pre-implantation human embryo as "mere human tissue", as an unidentifiable mass of cells, not as an entity meriting any particular status, might logically conclude that the laws relating to property could adequately deal with any conflicts which arise. Thus an embryo might be deemed to be "owned" by its genetic parents, who would automatically enjoy all rights and obligations pertaining to its use, possession, control and disposal.

Effectively such an approach merely exemplifies the consequences of placing pragmatics over ethics; of solving the legal problems without reference to the nature and scope of the subject matter behind these problems. The application of existing laws of property such as sale, gift and rights of possession and control to the embryo would signify an outright denial of its humanity and of any notions of bestowing it with separate status. With regard to the experimentation debate, the ultimate effect would be that no regulation whatever would be necessary. The only conflicts which might arise would be those of ownership; once ownership was established, that owner would clearly be free to use, abuse, experiment with and destroy the embryo as if it were a plastic toy.

The mutual inconsistency of the Warnock Committee's recommendations on this issue have been widely recognised.[199] That Committee's Report declared that the concept of ownership of human embryos was undesirable and that,

199 See eg Knoppers, supra n.168 at 345 and Dickens, supra n.169 at 62.

> "..... legislation be enacted to ensure there is no right of ownership in a human embryo".[200]

The Report went on to propose, however, that a couple who stored an embryo (by cryopreservation) for future use should have legally recognised "rights to the use and disposal of the embryo".[201]

Despite the euphemism, it is clear that the suggestion was that an embryo should belong to its genetic parents, who could do with it what they wished. This would leave Warnock's suggested legislative pronouncement on ownership as the articulation of an ideal which practice would be permitted to ignore.

An inherent facet of property ownership is the right of alienation, through sale, gift, loan or destruction. Again Warnock's proposals failed to tread the path of consistency. The Committee expediently recognised that,

> "the supply of human gametes or embryos might reasonably involve some commercial transaction".[202]

It then proceeded to attempt a compromise between this and its supposed objection to embryo ownership by proposing that any such sales be subject to control by a statutory licensing body.[203] Given the longstanding legal position that commercial transactions involving children are anathema[204], and indeed the Warnock

200 Warnock Committee Report, at 56.

201 Ibid.

202 Ibid at 79

203 Id. (Recommendation 17).

204 See eg Adoption Act (UK) 1976 c.36; Adoption (Scotland) Act (UK) 1978 c.28 Both statutes prohibit commercial adoption.

Committee's own attitude toward commercial surrogacy,[205] it is clear that any acceptance of commercial dealing in embryos is inconsistent with their human status and with "respect" for them. Post Warnock British publications on the subject, such as the 1987 White Paper on Embryology, neither recognised nor sought to explain these inconsistencies. The White Paper simply re-affirmed the standpoint that someone, probably the donors, should have ultimate rights of use and/or disposal of stored embryos.[206] The inevitable conclusion, that such rights to control the fate of an entity amount to ownership, was ignored. With regard to the sale and purchase of embryos, the White Paper re-stated the view that control through issuing licences for this should "avoid the risk of commercial exploitation".[207] There seemed to be no enquiry as to who is likely to be exploited and by whom. If the embryo is to be treated as property, then it is difficult to see the harm caused by caplitalizing on using it for research purposes. It is not the embryo itself which is exploited, but the situation may be used to put pressure on the "unfortunates" in society to produce and part with gametes for economic gain. While this accords with the arguments against commercial surrogacy, it has no bearing on the status of the embryo itself. If embryos are persons, then their use in commercial dealings per se amounts to exploitation. If they are not, then attempts to control the more unsavoury aspects of such transactions cannot lift concepti out of the property sphere into that of persons.

205 The report condemned agency organised surrogacy on the grounds inter alia that people would be treating others as a means to their own ends. See Warnock Committee Report at 46.

206 UK White Paper on Embryology at 9.

207 Ibid. at 11.

The Ontario Law Reform Commission also displayed some ambivalence in classifying the embryo in law. It was there recommended that the embryo in vitro, produced with the gametes of the intended recipient and her partner, should be under the joint legal control of the couple.[209]

That proposal, coupled with the permissive approach of the Commission toward the use of human embryos for scientific research and the call for flexibility in controlling it,[210] would indicate that the Commissioners regarded the embryo as property and wanted it treated as such in law. Conversely, however, they decided that warranties of merchantable quality and fitness should not apply to donation or supply of embryos or gametes.[211] Taken that their Report elsewhere expressed little concern with the purchase, sale, import and export of gametes and embryos,[212] it seems that the Commissioners recommendation as to quality and fitness was not a moral stance against treating the embryo as property but simply an acknowledgement that existing laws were inappropriate when applied to this unique scenario. It appears, then, that the Ontario Commission also focused on questions of control and treatment rather than status and ownership, thus avoiding a clear decision on legal classification.

209 Ontario Commission Report at 280.

210 Ibid., at 211-212.

211 Ibid at 279.

212 Page 174 of the Ontario Commission Report summarises the Commissioners view on the matter. "We see no reason to preclude such flexibility, so long as quality control is not sacrificed in the process".

The Report of the American Fertility Society claimed to have found "... widespread consensus that the embryo is not a person ..."[213] and despite adopting a call of "special respect" for the embryo, was prepared to see the law treat gametes and concepti as the property of their donors.[214] No concern was expressed as to the consequences of regarding the embryo in this way, and uniform rules on the issues of embryo research, storage and discard were not thought necessary.[215]

> "As a matter of law", the Report opined, "... it is reasonable to assume that the gamete providers have primary decision making authority regarding pre-embryos...".[216]

The Report also referred in this context to a dispute which came before the courts there some years ago and which undoubtedly influenced their views on categorisation. In the leading case of Del Zio v Presbyterian Hospital [217] a hospital doctor fertilised the gametes of a couple using IVF. Before an attempt at implantation could take place, however, the Director of the Pediatrics Department, concerned because the procedure had not been authorised by the hospital, destroyed the fertilised ovum. The couple sued for negligent infliction of severe emotional distress and for the tort of wrongful conversion of property. While the judge permitted the jury to consider both heads of claim, the $50,000 finally awarded by the jury was stated to be in respect of the mental distress claim only. The case did not, therefore, set a precedent on classification; on the other hand the suggestion that concepti in vitro are the property of their gamete donors was unchallanged as a logical category in which such human assets may be placed. It has been suggested that a different decision might be expected in such a

213 American Fertility Society Report at 305.

214 Ibid. at 31S.

215 Id.

216 Id.

217 74 Vic. 3588 (U.S. Dist. Ct., S.D.N.Y. April 12, 1978).

case today.[218] In the writer's view, however, it does not follow that a different result would imply a non-proprietorial classification for the in vitro embryo.

As previously stated, one may exercise rights over human beings; children and those suffering mental incapacity are apposite examples. Those rights are of course severely restricted in the modern world by application of human rights doctrine.[219] Classification of the embryo as property would preclude the applicability of human rights principles and, as has been indicated, would likely open the door to the use of human material for commercial gain. Some would argue, however, that such grey areas of categorisation have been presented to the law before and it has adequately responded either through legislation or the extension through the courts of the public policy safeguard.

218 See J K Mason, Medico - Legal Aspects of Reproduction and Parenthood, op. cit., supra Part A n.41 at p211. And see supra Part A Chapter IV (c) for a discussion of the subsequent cases which have a bearing on this issue.

219 See the discussion about the effect on domestic law of International Instruments of Human Rights in P. Sieghart, op. cit., supra fn 12, at Chapter 4.

For example, in considering whether donation of non-regenerative tissues by a living human donor is permitted at common law,[220] the underlying assumption is clearly that body parts 'belong' to that donor. The parts may be 'living', but are not deemed to require separate status. There can be no conflict of ownership and where the donor is a rational adult the only provisos are that the donation should not be for commercial gain or contrary to the public interest.[221] Legislative controls where the donors are children have been introduced in some jurisdictions, but to protect the donor who is a minor, not the body part itself.[222] Perhaps a more pertinent analogy is with the use of the organs of deceased persons for therapeutic, educational or research purposes. The potential

220 Such donations are in general permissible at common law so long as the infliction of injury to the donor can be shown to be in the public interest. See Bravery v Bravery [1954] IWLR 1169 at 1180 and AG's Reference (no 6 of 1980 [1981] 2 All ER 1057.

221 Section 1 of the Human Organ Transplants Act 1989 (U.K.) c.31 prohibits the exchange of money, other than legitimate expenses, for the purpose of organ donatin by the living. But see A Dorozynaski "European Kidney Market" (1989) 299 BMJ 1182.

222 See, for example, Human Tissue and Transplant Act 1982 (Western Australia), ss 12, 13, Human Tissue Act 1983 (New South Wales) s 10 and the discussion of this issue in Mason & McCall Smith op cit, Part A fn 44, at pp 303-305.

conflict arises between the next-of-kin of the deceased, who must consent to such procedures and the medical personnel who wish to carry them out, representing the 'public interest'. No one person or authority is deemed to have ultimate proprietorial rights to the body; competing interests are dealt with by legislatively imposed procedures.[223] Thus the quandary of how to categorise the transplant material is seemingly obviated.

Legal classification of the embryo as property is unpalatable to most. It should be borne in mind, however, that classification and treatment are legal soulmates. Attempts to create a novel category in law within which embryos (and even fetuses) would be placed could disguise a deliberate policy of treating the human embryo as property using a method which appears to remove it from that controversial classification and endow it with a more morally neutral framework of rules. The present writer believes that legislation dealing with human organs, mentioned above, has done no more than that. Property notions therefore remain as a useful benchmark in examining the validity or otherwise of the "separate status" theory, which will now be addressed.

(c) The Embryo as a Distinct Legal Entity

Those who espouse the theory that the embryo has, by its very nature, a "special status" favour separate legal categorisation for the entity. Supporters of this approach recognise that the direct application of traditional legal notions such as "property" and "guardionship" is inappropriate.

Not surprisingly perhaps, separate legal treatment for the embryo has tended to be the most commonly advocated solution to the problem.[223a] The adoption of new codes, statutes and regulations

223 See e.g. Human Tissue Act 1961 (U.K) c.54 and legislation cited supra at fn 222.

223a eg Warnock Committee Report at 63-64, Australian Senate Select Committee Report, Conclusions and Recommendations, Recommendation 17 at xv.

specifically addressing the question of regulating embryo research (and related aspects of assisted reproduction) is the most uncomplicated legal method available.[224] Existing legal categories, as shown, present a myriad of complications, largely caused by the interrelation between those categories due to their originally limited applicability. Attempts to legislate for the embryo as a distinct entity, unaffected by existing laws, may dispel some of the disquiet of pressure groups opposed to casual destruction of human material. The present writer contends, however, that, just as legal protection per se cannot alter legal status nor does the granting of a special status of itself bestow any rights on the subject of that status. Thus legal recognition of the embryo through separate treatment in law does not pre-suppose a higher degree of protection than would be afforded to it were it treated as property; nor can less protection than laws of the person demand be assumed. Separate legislative treatment encompasses a wide spectrum of ethical stances on the issue. The common denominator is the form, the procedure, rather than the substance.

A survey of recent attempts to legislate for the embryo will illustrate that the tendency is to grant lesser or greater degrees of legal protection to it, rather than identifiable, enforceable rights.[225] Implicit in this approach is the belief that because the embryo is so clearly unique there is no need to have recourse to categorisation at all. The in vitro embryo should be dealt with as an anomaly, a product of modern science that requires specifically designed regulation, the argument runs. It can be seen that this theory tends to avoid difficulties caused by the relationship between one protected entity and another by simply disregarding such relationships and their legal consequences. Such a pragmatic approach has several precedents in modern jurisdictions.

224 The legislation examined in Part C, post, all falls into this type of approach.

225 The distinction here is tantamount to that between protection and status, discussed, supra Chapter I (iii).

For example legislation intended to protect certain classes of animals from particular areas of human activity provides an interesting analogy.[226] Protection is the keyword; legal status is thought to be either self-evident or unimportant and therefore unannounced. Turning to the embryo's more closely related brethern, it can be seen that fetuses, severely defective newborn children and adults suffering from serious mental disorders have all to some extent been "recategorised" to enable regulation directed particularly to them to operate in isolation from the general body

226 See for example the Animals (Scientific Procedures) (U.K.) Act 1986 c.14 which now limits scientific experimentation using animals in the UK, passed as a result of significant pressure from animal rights activists.

of laws applying to human beings.[227] Such regulation often severely restricts or even abandons recognised human rights, yet co-exists within the same framework of national and international regulation as protective measures.

Would there be any advantage in distinguishing such categories of human beings on the level of status as well as legal protection? Again, is there not a danger that separate implies lowlier status?

This author has advocated the legislative enshrinement of a statement on the moral nature of embryonic life. Does such a pronouncement require a concomitant position on legal status or is the more abstract categorisation coupled with relative statutory protections sufficient? It is submitted that the latter modus operandi might satisfy the requirements of both clarity and enforceability while reinforcing the inherently human status of early embryonic life. It is submitted that this would be consistent with the recognised duty to treat the embryo with some degree of respect while accepting that to elevate that being above other immature or vulnerable forms of life would be inappropriate. It is significant to note in this context that, traditionally, Western societies have tended to adopt a "laissez-faire" attitude towards the medical profession and associated scientific research.[228] There

227 In relation to fetuses see the provision relating to abortion cited supra Chapter I n. 1-3. The position relating to severly defective newborn children is still unsettled, but various court decisions have expressly or impliedly condoned the withdrawal of life-saving treatment from them. See eg R V Arthur, The (London) Times, (6 November 1981) p1, 12, Weber v Stony Brook Hospital 456 NE 2d 1186 (NY, 1983), Re J (a minor) (wardship: medical treatment) [1990] 2 Med LR 67, dicta of Taylor L J at 75, but c.f. the Canadian position in Re Superintendent of Family and Child Service and Dawson (1983) 145 DLR (3d) 610. For one example of separate treatment for mentally incapacitated adults see Mental Health Act (U.K.) 1983 c.20.

228 See the discussion in M Brazier, Medicine Patients and the Law (Penguin, England, 1987), Chapter 18 "Medical Research" at pp 285-296.

have, of course, been exceptions to this general approach [229] but its two main consequences prevail. First, the regulation of medical practice and scientific advances will, even at its most interventionist, represent a cure rather than prevention of socially unacceptable practices. Secondly, the cause presented by medical scientists is almost always strengthened by arguments that achievements cannot be reversed and that limited success already achieved can only be repeated and improved if the work continues unhampered by restrictive regulation. It would be somewhat naive to assume that legislative bodies which have rejected imposing detailed controls over the aims and objectives of medical science would radically alter their position for a single cause. In the present writer's opinion the most persuasive arguments to date have been those which do not seek to resolve the irresolvable, but rather have as their goal the imposition of principles and guidelines from which more detailed regulation will flow. Again the analogy with abortion is irresistible; if a basic legal principle affording the fetus a certain status and accompanying protection is recognised, then the parameters for regulation of actions towards the fetus are set and any need to vary the regulation must take place within that framework.[230] Without such clearly identifiable parameters, a radical diminution of protection can more easily be enacted, being influenced only by calls for legislation to formalise whatever actions or developments in medical science or practice are already taking place. The argument for a particular status, and thus basic legal protection for, the embryo is similarly based. If, as tends to be the case in UK legislation on issues involving "rights", pragmatic solutions continue to take precedence over enshrinements of principle, then legal treatment of the embryo will have no firm basis and will be dependent on the ever changing nature of medical

229 The Declaration of Helsinki, op. cit., supra n.176 provides one such example where humans are subjected to experimentation.

230 The U.K. rules on abortion have always avoided such a framework by focusing only on the protection of the mother's health, but this contrasts with the approach taken in some European jurisdictions. See M.D.A. Freeman, op. cit, supra n.174.

science.[231] Those jurisdictions with properly defined constitutional protections may find it easier to adopt an enforceable statement of legal standing for the embryo.[232] The rationale behind a constitutional, or simply legislative, pronouncement would be to ensure that certain basic principles would be adhered to, whatever the circumstances. It has already been argued that to have such a pronouncement would be desirable. To test that argument this paper will now examine two of the most difficult single issues in the area of regulation of embryo research. The reader may then judge the value or otherwise of enshrining a principle of special status for the embryo having regard to two examples of specific procedures which might be affected.

231 The legal position of the fetus in U.K. abortion law has been seen to be subject to such developments. The case of Rance v Mid-Downs Health Authority [1991] 1 All E.R. 801 involved, inter alia, an alleged failure to advise termination of a pregnancy of 27 weeks gestation at which point physical abnormality was finally detected. Had the case involved a fetus developing after the passage of the UK Embryology Act 1990 op. cit., supra, Part A n11, the now amended provisions of the Abortion Act 1967 would clearly have prohibited its termination and the lack of advice about termination would not be a failure, but the only possible legitimate approach.

232 The potential for conflict between competing constitutional rights has, however, been an unresolved feature of the abortion issue in the United States of America and any statement about the embryo's position would be likely to be the source of similar conflicts. See R Dworkin, "The Great Abortion Case" (1989) New York Rev (29 June) at p 49.

CHAPTER IV

CATEGORISATION IN PRACTICE: RECOGNISING THE LIMITATIONS OF REGULATION

The basic tenets of those generally in favour of embryo research and those who wish it prohibited have been examined in the context of considering both the moral and legal status of the embryo. In seeking to justify a category of "special status" the writer considers it appropriate to elaborate the most difficult of those issues which cannot be resolved by either the pro- or anti- research lobbies.

Many of the debates about embryo research have focussed on two highly contentious areas; first, the source of those embryos to be used in research and secondly the question of what time limit, if any, should be imposed on keeping embryos "alive" in vitro either for research or indeed for any other reason.

It is revealing, in the present author's view, that these issues were the subject of signficant dissent by certain members of the Warnock Committee.[233] Those members clearly acknowledged the difficulty in reconciling a permissive approach to embryo research with the adoption of a special status for embryonic life. The relationship between the level of status afforded to the embryo and the protection given to it has continued to pervade the reasoning of the various standpoints taken on these issues.

(a) The provenance and purpose of embryos used in research

Four members of the Warnock Committee, representing one quarter of the total number, expressed dissent from the majority view that research should be permitted on embryos brought into existence specifically for that purpose or coming into existence as a result of other research. Their dissent was formally recorded in the publication of the subsequent influential Report of the Committee[234] and the issue has continued to dominate many of the discussions relating to the ethical boundaries of embryo research.

233 Warnock Committee Report at - 90-94.

234 Ibid, at p. 94 - "Expression of Dissent: C. Use of Human Embryos in Research"

For present purposes it is the dissenters' view that it was inconsonant with the special status that the Committee as a whole agreed should be afforded to the human embryo to cause it to exist, yet allow no possibility of its implantation, [235] which must be examined.

The existence of what are, perhaps unsympathetically, referred to as "spare" or "surplus" embryos comes about largely as a result of using superovulatory drugs which stimulate the production of several ova, and consequently allow the creation of several embryos, per IVF treatment cycle. The aforementioned dissenters in the Warnock Committee were not opposed to such spare[236] embryos being used for research purposes; the crucial moral distinction in their judgement was the intention behind the original generation of embryos used in research. They adhered to the philosophical doctrine of "double effect", namely that actions which may be morally wrong per se can sometimes be justified if they occur as a natural consequence of other, well intentioned actions.[237]

235 Ibid. at p 67.

236 The term "spare embryos" has been critisised as implying that extra embryos are akin to commercial products of which "the organised householder would do well to keep extras on hand". - Christine Overall, 'Pluck a fetus from its womb': Critique of Current Attitudes Towards The Embryo/Fetus (1986) 24 Univ. of West Ont L.R.1. The influence of language in the embryo debate has been addressed, supra, Chapter II. The writer's use of the terms "spare" and "surplus" embryos is intended to be neutral.

237 The application of the doctrine to the medico-legal field is discussed in J K Mason, op cit supra Part A n.40 at 215 and 260.

Intention and purpose at the point of creation is thus the central theme of those who have favoured limiting embryo research to what they regard as a legitimate secondary use of already existing embryos which no longer have any chance of survival. Conversely, the importance of intention behind creation has also been used as an argument against research on spare embryos, by those advocating therapeutic experimentation only. This standpoint, while recognising that not all embryos will ultimately be implanted demands that, if they become surplus to requirements or unfit for implantation, then, in the opinion of one commentator, "... no further experiements should be done; until then, such observation or tests as do not necessarily inflict irreversible damage on them may be carried out".[238] That writer continues by emphasising that what matters above all is "... the motive for their generation and their potential for development"[239].

It can be seen, then, that those who denounce all (destructive) research on embryos, while they may regard restricting such research to "spare" embryos as a lesser wrong than creation of them purely for that purpose, view the primary intention as that to create a live human being and anything which does not aim at that goal as unjustifiable. Destructive, non-therapeutic research, even on spare embryos is inconsistent with what has in this work been termed the "personhood theory". It need not be restricted to surplus embryos if the "human tissue approach" is adopted. But if the embryo is to be afforded some protection in law, the 'middle ground' compromise so often adopted as the most pragmatic solution to irresolvable ethical conflicts, would a restriction on research based on the provenance of the research subject be appropriate?

238 Sir Immanuel Jakobovits, "Human Fertilisation and Embryology - A Jewish View" (1987) 27 Med. Sci Law 195.

239 Id.

Looking at some of the proposals and enactments made to date, it seems that, in general terms, those favouring a restrictive approach to embryo experimentation have given the issue of 'spare' embryos greater focus than that given to it by the findings of those bodies holding a more permissive standpoint. Thus the Ontario Commission Report, in recommending that research and experimentation on fertilised ova be permitted until at least fourteen days after creation, made no qualification in relation to their source and made only passing mention of it in the discussion about such research in the body of the report.[240] A diametrically opposed conclusion on embryo research was reached by the Australian Senate Select Committee which, in rejecting all non-therapeutic research, addressed in detail the distinction between embryos created solely for research purposes and those which were surplus to the requirements of a particular IVF programme. After reviewing the evidence given to them on the issue, the following statement was made:

> "The Committee finds any supposed distinction between so called 'spare' embryos and those created specifically for experimental purposes to be ethically unsound ..... and practically most unlikely to be maintained. It therefore recommends that no destructive non-therapeutic experimentation be permitted based on any such distinction".[241]

Such a conclusion on the issue was really inevitable given the strict 'guardianship model' of regulation for treatment of embryos adopted by the Senate Committee. Those who have advocated that research should be permitted only on spare embryos tend to be drawn from the ranks of those acknowledging the need for some research but who are perhaps disquieted by the "laissez-faire" attitude towards medical science in this area condoned by the pro-research lobby. Indeed it was in no small part due to the Senate Committee's cynicism about the attitude likely to be taken by embryo scientists

240 See Ontario Commission Report, Recommendation 29 at p 290 and discussion at pp 207-214. See also, supra in.59.

241 Australian Senate Select Committee Report, paragraph 3.33 at p 33. Recommendation 9.

to proposed restrictions on the source of embryos for research which led them to firmly disapprove of it. While noting that the distinction was morally unjustifiable, then, they emphasised that it would in any event by unlikely to be maintained in practice.[242]
In the present writer's opinion, the considerable political influence of the medical science lobbyists in the United Kingdom limited the discusssion in the post - Warnock years about the types of restriction on research which might be appropriate. Whether or not restricting research to those embryos 'surplus to requirements' would adequately fulfil the demands of a special status approach, it is tentatively suggested that it might be a solution which would satisfy the view that there must at least be a direct link between the status afforded to the embryo and the control of scientists' dealings with them. The effect of the shift in emphasis of the discussion is therefore important.

Two significant indicators of the aforementioned political influence emerged during the mid to late 1980's. First in the United Kingdom was the seizing of the initiative by the Medical Research Council and Royal College of Obstetricians and Gynaecologists in setting up the United Kingdom Voluntary Licensing Authority. This self-regulatory body was promoted as a responsible interim measure, filling the legal lacuna for the period between publication of the Warnock Report which called for regulation and the enactment of primary legislation. Notwithstanding that only nine out of sixteen members of the Warnock Committee recommended the creation of human embryos solely for research purposes, a fact which will be later discussed, the VLA adopted wholeheartedly the approach of that slim majority. It formed the basis for the Authority's "Guidelines" for clinical and research applications of IVF, published annually. Neither those Guidelines, nor any articles annexed to some of the Reports ever suggested that a distinction could or should be made between embryos created through IVF treatment programmes and those generated purely for experimentation.[243] For example no views were ever sought or Guidelines adopted on whether it might be thought

242 Ibid, at p. 32.

243 See the Guidelines published in each of the VLA Reports and the Articles and Responses to Government initiatives published as Annexes to the Reports.

appropriate to restrict the creation of research embryos to projects which sought first to obtain surplus embryos but had been unsuccessful.

In 1989, the VLA Guidelines referred to "Pre-embryos resulting from or used in research"[244] (my emphasis) and in a separate paragraph approved the use of ova fertilised in vitro for a therapeutic purpose but no longer required for it, in 'soundly based research'.[245] It was implicit in these and other examples in the Reports that both sources of embryos were being used. The list of VLA approved centres contained in each annual report confirms that not all those "licensed" to conduct research under the VLA's voluntary scheme offered a clinical IVF programme. This author believes that, by promoting such a form of self regulation, the interested parties who founded it ensured that they defined the parameters within which the argument over research took place. In presenting their own form of regulation as essentially one of only two alternatives, the other being absolute prohibition, they obscured the path of compromise, which might have sought for example, to restrict the number of embryos created for each of certain defined purposes. The second and related influence concerned the subsequent development of draft legislative proposals on the issue of, inter alia, research on human embryos. These proposals offered an unprecedented choice to Members of Parliament who were to be allowed to vote by conscience to permit or prohibit outright projects involving non-therapeutic embryo experimentation. No other options were available, despite recognition by the draftsmen of the Human Fertilisation and Embryology Bill that embryos used in research came from different sources.[246] How then had an issue which had provoked published comment, not only from

244 Fourth VLA Report at 34. Guideline 4.

245 Ibid. Guideline 6.

246 Clause 11(2) of the Bill, if enacted, would have permitted the issue of licences for IVF related treatment and for storage of gametes and embryos, but would have prohibited licenses for research completely. Clause 11 (1) which is now enacted as section 11 permits the additional category of licences under paragraph 3 of Schedule 2 to the Act authorising embryo research projects Schedule 2 paragraph 3 refers to (a) bringing about the creation of embryos in vitro and (b) keeping or using embryos for the purposes of a research project. Thus the alternative sources of embryos are subject to separate authorisation, the reason for which is unclear given that there was never any distinction made in the section permitting authorisation to be granted.

the four members of the Warnock Committee who stopped short of blanket approval of embryo research, but also from the three members who opposed all such research, become so successfully excluded from the central issues open for decision? It is important in this context to recall the words of the three Warnock dissenters most opposed to live embryo research. They had stated the following about surplus embryos:-

"In the event of there being more embryos than is judged right to implant at any one time the remainder should either be frozen with a view to implantation at a later date or allowed to die. They should not be used for experimentation. Still less should embryos be deliberately created for the purpose of experimentation" (emphasis added).[247]

It is this writer's contention that the successful obfuscation of the spare embryo issue by the most ardent supporters of research, the scientists themselves, precluded any chance of the aforementioned moral distinction, acknowledged on both sides of the debate, from gaining legal recognition. This contention finds some support in the records of attempts being made, belatedly, during debates and at Committee stage in both Houses of the United Kingdom Parliament during the passage of the Embryology Bill, to limit the type of embryos used for research.[248] The focus was again on intention at the point of creation and one of the more pertinent arguments was stated by Frank Field, MP, who in support of his own amendment seeking clarification[249] that research would be conducted

247 Warnock Committee Report, Expression of Dissent B, at 91.

248 See generally U.K. H.C. Parlimaentary Debates, vol. 170, cols, 914, 994, Vol 171 cols. 31, 119, 166, vol 174 cols. 933, 1031, 1134, and H.L. Paralimentary Debates, vol. 513 cols. 1002, vol. 515 cols. 711, 805, 1251 1359, vol. 516 cols. 1053, 1155, 1417, vol. 517 col. 198 and vol 522 col. 1036.

249 The amendment proposed can be found at U.K. H.C. Parliamentary Debates Vol 170 at col. 937. It sought to insert a prohibition on "bringing about the creation of an embryo other than in the course of treatment services" to ensure that only spare embryos were used in research which Mr Field stated was what he understood the status quo to be (col. 939). It is not clear from what source he obtained that erroneous information.

only on surplus embryos created during IVF treatment programmes, argued as follows:-

"There is all the difference in the world between creating an embryo, which some of us would say is life but others would say has the potential for life, in an attempt to allow couples who are infertile to have children and using the embryos that are not required for other purposes, and saying that we are so mesmerised by the wonders of science and the blank cheque that we shall give to science that scientific activity is itself a moral stance while the creation of embryos is a secondary consideration. To create embryos for research simply to destroy them is different from using embryos to further fertility and using spare embryos that would otherwise die. The distinction seems so clear and powerful that I am surprised that some hon. members cannot see or support it".[250]

In the House of Lords, the omission from the Bill of a prohibition on the bringing into existence of embryos for the purpose of experiments only was regarded as both "important"[251] and "surprising".[252] All attempts to remedy the matter by amendment were, however, unsuccessful.[253] The safeguards which many thought consistent with special protection, short of actual personhood, for the embryo were therefore never drafted into the legislation. The only restriction on producing embryos specifically for research considered important by the drafters was that the consent of those whose gametes are being used ought to be obtained.[254]

250 Ibid., at col. 970

251 U.K. H.L. Parliamentary Debates, vol. 513 col. 1058 (Viscount Caldecate)

252 Ibid., at col. 1073 (Lord Jakobovits).

253 See U.K. H.L. Parliamentary Debates Vol. 516 col. 1053, where an amendment which sought to limit research to spare embryos donated by a woman who no longer had need or desire for them and to criminalise any other method of obtaining research material, was defeated by 214 votes to 80. See also the arguments reported at cols. 1072 and 1080 of that volume.

254 The provisions requiring such consent are now contained in section 12 and Schedule 3 of the U.K. Embryology Act 1990.

Given that the emergence of the idea of special protection short of a 'right to life' for the embryo stemmed largely from a rejection of absolutism over the issue, it is submitted that the British approach has thus far failed to heed that rejection by narrowing the choice to one of two moral absolutes. Further, if special status is to constitute anything more than empty rhetoric, pre-requisite conditions to justify the creation of an entity bestowed with that status must be formulated in law. The distinction based on provenance of embryos to be used in research programmes has now been applied in certain jurisdictions and the argument is therefore not just an academic one. Most notable are the amendments to the legislation in Victoria, Australia, permitting strictly regulated experimental procedures on early embryos created as part of a clinical IVF programme.[255]

In concluding with a tentative hope that future pressure for change will recognise the scope for basing regulation on protection for the embryo which promotes special, but not human-style, status, the writer considers that that aim should be given due consideration. It is not possible to continue IVF and refrain from destroying human embryos,[256] but it should be possible to insist that all actions towards them are well intentioned at the outset.

(b) Arbitrary Temporal Limits on Embryonic Life - What Justification?

Most proposals for regulation of embryo experimentation have endorsed the imposition of both temporal and qualitative limits. The former are limits on the gestational age of the embryo which is to be experimented on, or simply kept alive, and the latter relate

255 See Section 4 of the Infertility (Medical Procedures) (Amendment) Act 1987 (Victoria, Australia) No 86 of 1987. The effect is discussed post Part C Chapter II (c).

256 Even those who advocate a total ban on research accept that provisions allowing long term storage of embryos and even the practice of IVF itself which creates the 'spare' embryos under discussion necessarily involve the destruction of embryos, whether actively or simply by refraining from implanting unsuitable concepti. This was stated in terms in the relevant Expression of Dissent in the Warnock Committee Report. See supra. n.247.

to the type of experimentation which may be performed.[257] This section will consider only the temporal limits which have been proposed and adopted. It will be suggested that the particular difficulty of reconciling a coherent policy on status and protection for the embryo with a temporal boundary remains acutely unresolved. Turning first to the Warnock Committee, it seems that its real justification for recommending a precise limit of the length of time an embryo should be kept alive in vitro was a political one, namely "..... in order to allay public anxiety".[258] It recognised that there is no critical biological marker event which would form the basis for a stage beyond which the embryo should be kept alive and noted the division of scientific opinion on the matter. The Committee felt able, however, to recommend a fourteen day limit on the growth of an in vitro embryo, despite the foregoing concession.[259] It seemed to rely on an argument that a stage of individual development could be detected, the time before that being essentially "pre-embryonic". One commentator had already sought to link this allegedly vital event to the notion of personhood, arguing that,

> "..... since twinning in human development is believed to be possible as much as two weeks after fertilisation - about when implantation is occurring - the entire pre-implantation period can be regarded scientifically as one of pre-individuality in a development sense. Moreover, developmental individuality appears to be a pre-requisite to personhood, though the two terms are not equivalent".[260]

257 This terminology is used in a thoughtful article by E.H. Kluge, "Experimentation on Human Embryos" in 1 Ethical Problems in Reproductive Medicine 1986, at p 8.

258 Warnock Committee Report at 65.

259 Ibid., at 66 (Recommendation 12 at 11.22).

260 C Grobstein, "The Moral Uses of "Spare" Embryos" (1982) 12 Hastings Centre Report 5, at 6.

The key word, it is submitted, is "scientifically" - that the pre-implantation stage represents a period during which early human life is simply an amorphous entity and not a recognisable potential individual may well be scientifically indisputable. It tells us nothing, however, about the ethical foundation for recommending that a distinction between the pre and post implantation stages should be made in law. Further, is it not inconsistent to prohibit research, presumably even that of a therapeutic nature, on the post-implantation embryo, due to its being thereafter an individual human entity, while at the same time recommending that it be destroyed? If the end of the implantation stage marks a date at which the 'potential human being' becomes a 'total whole individual human being' then should the prohibition of experimentation thereafter not be coupled with a duty to keep that human being alive if at all possible? This inconsistency highlights, in this author's view, that the approach of the Warnock Committee in coupling a temporal limit for research on the embryo with one on keeping it alive in vitro generally was shortsighted. Medical technology may well advance to a stage where it becomes possible to culture a fetus extracorporeally for some weeks before transferring it to a woman for the rest of the gestational period or even continuing to culture it in an artificial womb.[261] What objection could there be to keeping the in vitro embryo alive for that purpose? It is submitted then, that the issues of the period during which research on human embryos should be permitted, if at all, and the length of time they should be cultured in vitro raise different questions which should be addressed separately by the legal mechanisms employed to regulate them. This section is concerned primarily with the first matter, namely the significance, if any, that can be placed on the stage identified in the Warnock report as the time after which research must be prohibited. If special status can be justified in considering legal protection, what kind of temporal limit, if any, might that demand?

261 Reports of serious scientific attempts at partial ectogenesis can be found in eg C Bulletti et al., "Extracorporeal Perfusion of the Human Uterus" (1986) 3 American Journal of Obstetrics and Gynaecology, 683 and C Bulletti et al., "Early Human Pregnancy in vitro utilising a perfused uterus" (1988) 6 Fertility and Sterility 991.

The moral arguments for and against treating the early embryo as a human being have been considered earlier in this paper. Their application to any suggested temporal limit on experimentation depends on whether there can be said to be a stage after which, whatever status is afforded to the embryo, it merits complete protection against (destructive) experimentation.

The attempts of pro-research medical scientists to explain a breakdown of the early stages of human development and pinpoint one of them as the beginning of individual life has been attacked as ethically untenable. It has been persuasively argued that any difficulty about twinning being possible until the primitive streak stage is not a reason for withdrawing the 'epithet' human being from the pre-embryo.[262] It is no more or less 'human' than prior to implantation than it is immediately afterwards. Many proposals for regulation have of course recognised this but opted for a temporal limit anyway, maintaining that to do so secures a firm foothold on what may be a 'slippery slope'. Such a stance presupposes that although experiments on very early embryos might be unobjectionable per se, a failure to monitor the practice would probably lead to an increasingly adventurous and even pernicious type of embryo research in the future. The enforcement of a temporal limit, runs the argument, precludes future events, the fear of which lies behind much of the opposition to the original act.[263] Logically, of

262 See the etremely well argued article on the lack of philosophical justification for temporal limits and a separate, pre 14 day category of embryo, by A Holland, "A Fortnight of My Life is Missing: a discussion of the status of the human 'pre-embryo'" (1990) 7 Journal of Applied Philosophy 25. The conclusion of the argument that twinning is not a reason for withdrawing the epithet 'human being' from the embryo is at 35.

263 The Archbishop of York, an influential commentator in the House of Lords Debates on Embryology, being a qualified biologist and a leading member of the Church, summarised the view in favour of the 14 day temporal limit proposed by Warnock in the House of Lords debate on the UK Embryology Bill. He said "..... The 14 day rule, with all the safeguards surrounding it, seems to me to be a workable basis for such a consensus. It is no more possible to set it up as a totally clear moral dividing line then it is to do the same for the moment of conception. But to make it a cut-off point is morally and biologically defensible. The fact that it is based on an identifiable biological transition will, I believe, protect it against future argument for extending the limits of research. See U.K. H.L. Parliamentary Debates Vol. 513. col. 1022.

course, if the original action is itself truly unobjectionable then that would be sufficient reason for its justification, and vice-versa. The most potent objections to regulation through temporal limitations are made by those who also adopt the imagery of the 'slippery slope' or the 'the thin end of the wedge'.[264] For the anti-research lobby it is claimed that the foothold would be too easily displaced. The prescribed limit would be ignored and extended privately, in the laboratory, while in public there would be increasing pressure to extend it legitimately. Some support for this fear that "..... a gradual whittling away at respect for human life"[265] would result can be found by considering the hope expressed by some scientists that they will be able to use embryo research to examine later stages of development, such as neurology.[266]

The Ontario Commission Report voiced concerns about setting a time limit on growing embryos in vitro on the ground that it would impede scientific progress, pointing out that "..... the time limit proposed in the Warnock Report would preclude critical studies of implantation failure".[267] While it went on to follow Warnock's idea of a fourteen day limit, the Report emphasised that any such role should be adaptable. It even suggested that the researchers should determine the timing and extent of future change,

> "... should the state of medical knowledge at some future date indicate that the fourteen day period is inappropriate, by being either too short or too long, the regulations could easily be amended".[268]

264 The concept of the 'slippery slope' appears in many areas of law as an argument against an act which, while relatively innocent in isolation, may lead to future similar but mere pernicious events or acts. For an analysis of the slippery slope argument generally see F Schauer "Slippery Slopes" (1985) 99 Harvard L. Rev. 361.

265 J Marshall, "Believe in life ..... or believe in nothing" The (London) Times, 11 December 1989, p 17.

266 The extension of embryo research into such other areas was mentioned as a potential future development by the Minister for Health, Mrs Bottomley in the debate on the Bill. See U.K. H.C. Parliamentary Debates vol. 174 col. 963.

267 Ontario Commission Report at 216.

268 Id.

Warnock's proposal that research on embryos of more than fourteen days gestation should be prohibited has been approved of in other jurisdictions permitting human embryo experimentation.[269] Focusing again on the 'special status' approach, can it be said that such temporal limits coincide with any particular status for the embryo?

The view of the Australian Senate Select Committee was that, as there was inconclusive biomedical proof that there was any significant developmental marker event, such chronological limits could not be justified. The Report stated that the Committee was,

> "..... not persuaded of the inherent ethical validity of the marker event authoritatively put forward in Australia, ie the time of the implantation process....."[270]

The conclusion was that the respect due to the embryo from the process of fertilisation onwards requires its protection from destructive non-therapeutic experimentation from the outset.[271] It will be recalled that the Committee was not prepared to countenance a distinction between spare embryos and 'pure research embryos'.

269 See the table of comparable provisions on embryo research in D Morgan & R G Lee op. cit. supra Part A n.90 at p86-87.

270 Australian Senate Select Committee Report at 29.

271 Id.

If a valid distinction can be drawn, however, as already suggested between different purposes for creation of human embryos, do additional limits on the duration of *in vitro* growth also restrict embryo research in such a way that reinforces a commitment to real protection for early embryonic life? Or does the lack of moral consistency that lies behind a rule which gives ultimate protection to a 15 day old being and yet none whatsoever to a 13 day old simply draw attention to the total lack of respect for those who do not fall within the arbitrarily protected bracket? In the present writer's submission, temporal limits on the growth of embryos *in vitro*, and research on them, add nothing to our understanding of what moral and legal status is appropriate for that entity. Unlike the suggested restriction of research to 'spare' embryos, where the focus is on respect for and creation of life *bona fide*, the imposition of a temporal limit tells us only what beings are to be protected, not how they are to be regarded. As there can be no dispute that *concepti* of six, eight, thirteen and fifteen days gestation are all embryos, it can be concluded that the only purpose temporal limits will serve is to allay public disquiet, as the Warnock Committee suggested.

In conclusion of this Part, it can be said that the embryo can be seen to be neither person nor property in law. The legal treatment meted out to it will depend on the context, rather than any particular status bestowed on it. In turning to examine the methods of regulation open to those seeking to impose controls on activities with *in vitro* embryos it should thus be emphasised that existing categorisation has been shown to be unhelpful. The special status recommended as an underlying principle for legal protection will require somewhat special rules.

PART C

ATTEMPTS TO CONTROL: THE NATURE AND SCOPE OF EXISTING REGULATION

The legal regulation of artificial reproductive techniques generally is a politically sensitive issue. Competing claims, such as those of the infertile couple as against those of pressure groups and religious organisations must be reconciled, and the law must accommodate new family structures sometimes based on complex biological permutations.

Some of the least controversial areas have now been tackled. For example, the introduction of simple new rules has resolved the uncertainty about the legal status of AID children[1] by adapting traditional legal concepts to fit the new family. There have been fewer attempts, however, to formulate legislation to resolve the intractable debate about experimentation on human embryos.[2] The wider challenge of the development of a coherent socio-legal policy to control the science of assisted reproduction and related techniques arguably remains unaddressed. This part of the thesis will seek first to examine the various models of regulation which might be appropriate in implementing such a policy, with particular reference to methods of regulation of human embryo research. Thereafter, existing attempts to legislate on that particular issue will be discussed, and their level of effectiveness analysed.

1 See Part A, fn 11 which lists some of the major legislative provisions on this issue.

2 For a table of international comparison of IVF and Embryo Research as at November 1990 which lists those countries still to pass legislation on the issue see D Morgan and R G Lee, op cit Part A fn 90 at 86-87.

CHAPTER I
MODELS OF REGULATION

In attempting to construct a framework within which practices such a AID, GIFT, IVF and embryo research can most effectively be controlled, various types of regulation must be considered and compared.

(a) Professional Self-Regulation

This, the only method of regulation which does not involve the legal process to any real extent, is favoured by those who consider that the body best placed to impose checks and controls on an area of professional practice is one made up largely of personnel associated with, or working in, the particular field in question. Examples in the medical world include disciplinary tribunals, specialist working groups and hospital ethics committees. While membership from persons representing the community is often a feature of hospital ethics committees, there are no statutory or other legal regulations governing them in countries such as the United Kingdom. Thus their membership and the medical practices approved and rejected by them can vary from institution to institution.[3] In the area of scientifically assisted reproduction professional self-regulation was of course the only type of supervision in existence until relatively recently, largely due to indecision as to the nature of legal controls to be imposed.

Following the birth of the first child conceived using the IVF procedure, and the subsequent introduction of IVF services throughout the UK, the medical profession was quick to turn to established methods of self regulation to deal with the ethical questions involved. In 1982, the British Medical Association Council established a Working Group to investigate the social and legal aspects of *in vitro* fertilisation.[4]

3 See British Medical Association, "Local Ethical Committees" (1981) 282 Brit. Med. J. 1010.

4 British Medical Association, Working Group on In Vitro Fertilisation, "Appendix VI: Interim report on human in vitro fertilisation and embryo replacement and transfer" (1983), 286 Brit. Med. J. 1594.

The report which followed touched on the acceptability of embryo research procedures only in very general terms.[5] The Medical Research Council produced early guidelines on the issue, focusing inter alia on the approval of local ethics committees as a prerequisite of embryo experimentation.[6] It was the Royal College of Obstetricians and Gynaecologists, however, which most forcefully commended a purely self-regulatory approach. A 1983 Report from the RCOG ethics committee set up to examine issues arising from IVF and Embryo Transfer concluded as follows:-

"The Committee does not consider that the question of research on or experimentation with early human embryotic material is a matter for the law. The problem is strictly an ethical one, in which it is necessary to be sensitive to public sentiment."[7]

It is certainly the case that some researchers, both in the UK and elsewhere, bemoaned the absence of regulation in the early 1980's which required them to work in a legal vacuum.[8] However, there is no doubt that there were as many influential lobbyists arguing that it was considerations of medical ethics and related decision making which should govern the issue, rather than the wider principles of social control with which the law is concerned. The question of whether the law is ever the appropriate means to implement ethics is a legitimate one. The proponents of such views cited the rapidly evolving nature of IVF and associated research as justification for an non-interventionist policy.[9]

5 British Medical Association, "Annual Report of Council 1983-84" (1984) 288 Brit. Med. J. 25 (special insert).

6 Medical Research Council, "Research Related to Human Fertilisation and Embryology" (1982) 285 Brit. Med. J. 1480

7 U.K., Royal College of Obstetricians and Gynaecologists, Report of the RCOG Ethics Committee on In Vitro Fertilisation and Embryo Replacement or Transfer (1983). See paragraph 14.4.6 at p17.

8 Robert Edwards was quoted in The Guardian (U.K.) 20 November 1985 as follows; "The politicians are letting us down. Someone has got to stick his neck out and make a decision. It's ridiculous having to work without laws. There are no rules, yet we are taking life and death decisions - we need an authority answerable to Parliament" (P7). See also P Steptoe, "The Role of In-Vitro Fertilisation in the treatment of infertility: Ethical and Legal Problems" (1986) 26 Med. Sci. Law 82 at 83.

9 I. Craft, "In vitro fertilisation - a fast changing technique: a discussion paper" (1982) 75 J R Soc Med 253.

Much of the focus of the debate over self or legally imposed regulation of embryo research centred on the issue of temporal limits on keeping embryo alive in vitro for the purpose. Those favouring the least stringent regulations were keen to support a flexible approach to the resolution of that particular matter, rather than have any definitive or unalterable rule laid down about it.[10] Furthermore, there were often threats by those working in the field of reproductive technology, particularly in parts of Australia, where strict legal prohibition was being considered, that excessive intervention by legislation would require them to leave the country, taking their research projects with them.[11] In the present writer's view the strongest argument which could be made for professional self regulation is that those countries which have been slow to enact legal provisions, and have therefore relied on it almost exclusively, have not been seen to slide down the slippery slope towards large scale genetic manipulation of in vitro embryos and other abuses. In the United States where there have been state initiatives but no federal legislation, there have been no reports of a mass exodus of embryo researchers to the more permissive states. Of course it has been noted that ethical guidelines suggested by the various self-regulatory bodies have been remarkably similar, usually favouring a generous temporal limit within which embryo experimentation can be carried out with little or no formal control over the approved research projects.[12] Against that argument, however, it has already been suggested in this thesis that the seizing of the initiative by medical scientists may have promoted self-regulation to an extent where later formal controls

10 Robert Edwards was quoted in the Guardian (U.K) 20 November 1985 as arguing that fourteen days might be too strict a limit where research might be life-saving, such as into the use of embryonic cells in cancer treatment. Also see Ontario Commission Report op cit., Part A fn. 7 at p216.

11 See the discussion about the pronouncements on this by the Monash University team, led by the pioneers Dr Alan Trounson and Professor Carl Wood in R Rowland, op cit., Part A fn 18 at 227 - 229.

12 For example compare the VLA guidelines for the UK with the Australian NH & MRC statement to the Senate Select Committee. See First, Second, Third and Fourth VLA Annual Reports op. cit. supra Part B fn 96, and 91 Australia, Senate Select Committee on the Human Embryo Experimentation Bill 1985, Official Hansard Report, Wednesday 26 February at p350.

were almost bound to do little more than legitimise already established practices.[13] In 1989, the year before legislation was introduced in the United Kingdom Parliament, the Voluntary Licensing Authority there reported that it had approved a total of 53 research projects since its inception. It further noted that of those applying, only one project had been declined such approval.[14] The Authority was clearly grounded in a permissive, pro-research philosophy. However, it took care to justify its stance annually, by pointing to the development and yearly revision of its guidelines, the multi-disciplinary nature of its membership and its continuing support for the Warnock Committee's recommendations. The Reports also stress that the VLA still regarded its very existence as an interim measure, to subsist only until appropriate legislation was enacted.[15] The implication was clear enough; its model of self-regulation could simply be transposed into legally binding rules, thus changing the form but not the substance of control.

The most potent criticism of a model of self-regulation, in the present author's opinion, is that it depends completely on the common sense and decency of the medical science community. The issue has too many possible repercussions for society at large for that to be desirable. Advocates in all sides of the debate have recognised this. In the words of the author of the Warnock Report

13 See Supra, Part B, Chapter 4 (a), especially at fn 249.

14 See Fourth VLA Report op cit., supra Part B fn 96.

15 See First, Second, Third and Fourth VLA Annual Reports op cit., supra Part B fn 96 and 91.

herself:

"People generally believe that science may be up to no good, and must not be allowed to proceed without scrutiny, both of its objectives and of its methods"[16]

While most would applaud such scrutiny, it has been shown that the influence of those practising in the field of reproductive technology may govern the nature and dilute the strength of any legal regulation which follows it. Models for legal regulation must therefore be considered against the backdrop of that influence.

(b) Domestic Legal Regulation

The drive towards legal regulation of IVF and related embryo research has largely been founded upon a reluctance, mentioned above, to rely on the bona fide actings of medical scientists. In indicating his belief that such research should be controlled by legislation, Professor Louis Walker, who had been Chairman of the Victorian Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisation which produced its final report in 1984, subsequently expressed his concern to the Asche Committee about voluntary regulation as follows:

> "..... an honour system can only work where people are honourable. Is honour enough? My feeling is that it is not."[17]

This undoubtedly represents the prevailing attitude towards regulation, namely that only enforceable legal rules will suffice. There are of course various tiers of legal regulation within the framework of domestic law and the role of each of these as applied to the area of assisted reproduction must be considered.

16 M A Warnock "A Question of Life" (Oxford: Blackwell, 1985) at p.xiii.

17 Australian Family Law Council Asche Committee Report, op cit., supra Part B fn. 194 at p79.

(i) Judicial Regulation

While the Courts would always retain a role, albeit limited, in the regulation of a purely "honour" based system, it is perhaps more appropriate to consider their involvement in the context of the development of domestic legal control of artificial reproduction techniques.

Since the introduction of medically assisted reproduction, various issues arising from the new techniques have come before the courts for resolution. In the absence of a comprehensive legislative code, the judiciary were the first branch of the legal infrastructure to be faced with decision making in this area. An early example was the issue of whether AID constituted adultery, decided in the negative.[18] Later illustrations have been provided in the discussions about surrogacy [19] and cryopreservation.[20] The central debate about the status of the human embryo, however, having taken place largely as a result of the legal lacuna over its use and destruction by researchers, is not a matter which the courts have been required to address directly. As legislative provision has thus far been favoured as a model for legal regulation of embryo experimentation, the future role of the courts will principally relate to the interpretation of such statutes and provisions, criminal proceedings where criminal sanctions are imposed, and possibly judicial review of administrative decisions. Traditionally, common law systems such as those of the Anglo-American jurisdictions tend to favour a stronger role for the judiciary than those jurisdictions with a civil law background. It remains to be seen what effect this might have on judicial approaches to legislation on this issue. In Germany for example, where the statute prohibiting embryo research may be expected to be construed restrictively,[21] there is unlikely to be the kind of

18 See MacLennan v MacLennan op cit., supra Part A fn 8.

19 See in particular the cases discussed in the articles referred to supra Part A at fn 62.

20 See supra, Part A, Chapter IV (c).

21 Embryonenschutzgesetz (Embryo Protection Act) 1990 S1(1), which prohibits all destructive embryo research was passed to reflect the continuing German fears about human experimentation which have historical basis.

scope for judicial discretion that will be shown in Chapter II of this part to be available under the legislation in Australia and the United Kingdom. In those countries, 'policing' of embryo research projects followed by criminal trials and civil disputes involving the seeking of injunctions have been envisaged.[22] It is worthy of note that the Australian Senate Select Committee favoured a system of jury trial for alleged offences against legislation restricting experiments with in vitro embryos. The view that a jury might better reflect the community's attitude than a judge was cited with approval.[23] Statutory offences under the U.K. Embryology Act are also likely to involve trial by jury.[24] It seems likely, therefore, that the courts will have a significant and varied part to play in the development of future policy towards the science of assisted reproduction and related techniques.

(ii) Legislative Regulation

Legislative control of IVF, embryo research and related matters has consistently been proposed as the most appropriate model for legal regulation. Most of the major Committee Reports either made detailed recommendations about the scope and content of the legislation proposed,[25] or, as in the case of the Australian Senate Select Committee, had the scrutiny of

22 See the discussion about this in the Australian Senate Select Committee Report, Chapter Four, at pages 46-49.

23 Ibid at p51.

24 The reference to "indictment" in section 41 of the UK Embryology Act and the possibility of imprisonment for a maximum period of ten years both point to the form of procedure for more serious crime in all three jurisdictions of the United Kingdom, namely trial by jury.

25 See for example Warnock Committee Report, List of Recommendations, at pages 80-86, Ontario Commission Report, Summary of Recommendations at pages 275-285, Queensland Report, Recommendation and South Australia Report, particularly recommendation 4.

draft legislation as their 'raison d'etre'.[26] Many thought it desirable to include all reproductive technology law in a single enactment, others were concerned only with particular aspects such as donor gametes,[27] IVF and AID,[28] or embryo research itself.[29] While this thesis is primarily concerned with the regulation of practices involving experimentation on human embryos, the contrast between a comprehensive and a piecemeal approach to legislation is important in relation to the broader challenge of the formulation of social policy in this area. That goal can only be achieved if the views and needs of all those involved in the various aspects of reproductive technology are consulted in the process. There have been many criticisms to date that no attempt has been made to include the particular views of women who are at the centre of the application of the techniques, in the development of such a

26 See preface to Australian Senate Select Committee Report, titled "Terms of Reference".

27 Such as the Waller Donor Gametes Report.

28 Such as the South Australia Report.

29 Such as the Australian Senate Select Committee Report.

policy.[30] The present author's interest is the nature and scope of any legislative intervention on the specific issues of IVF and related embryo research. That intervention must always be viewed, however, in the context of other legal regulation to examine whether the approach can be said to form part of a coherent social policy about reproductive matters generally.

For countries with either a federal or quasi-federal system of government, the choice between a nation wide or state wide approach to resolution of this issue is a difficult one, the decision of which will have far-reaching consequences. The choice arises as a result of the debate over IVF and related research touching on various areas of domestic law; at the level of public health care, in the area of family law, and concerning rights protected by the constitution.[31] Thus in Australia, for example, the Report of the Federal Committee of the Family Law Council on Reproductive Technology tabled in the Federal Parliament in 1985,[32] was premised on the view that matters such as IVF, embryo transfer and related technology were constitutionally within the ambit of the part of the Commonwealth Constitution dealing with the Federal Parliament's legislative powers as to marriage, matrimonial causes and parental rights, including the custody and guardianship of

30 See e.g. R Rowland, op cit, Part A fn. 18, especially chapter 8, G Corea, op cit., Part A fn. 13, especially chapter 16, and P Spallone, "Beyond Conception: The New Politics Of Reproduction" (MacMillan Education Ltd: London 1989), especially Chapter 8.

31 Constitutionally protected rights are available in countries such as the United States of America which has a written constitution and in Canada by virtue the Canadian Charter of Rights and Freedoms. Citizens of the United Kingdom, while having no Bill, or Charter of Rights for such protection, have a certain amount of recourse against infringement of such rights through the Council of Europe.

32 Australian Family Law Council Asche Committee Report, op cit, Part B fn 194.

infants.[33] Throughout the Report it was emphasised that the issues involved in reproductive technology should be tackled on a national basis, and not by a "fragmented" State by State approach.[34] Similarly, the Australian Senate Select Committee Report, while accepting that the States have power to legislate for the regulation of medical practice and research, recommended legislation for the Commonwealth, arguing that, "It is highly desirable that the whole Australian community observe uniform ethical standards in a matter as crucial as human embryo experimentation".[35]

The Committee then detailed its recommendations for a Commonwealth Statute which would set out broad declarations of principle and institute a national body which would implement a licensing system.[36] Despite those recommendations, the situation to date represents the very State by State approach denounced by the Federal Committee.[37] In Canada too, the moves toward regulation have tended to reflect the fact that the provision of health care and child welfare issues are both delegated to the provinces to regulate.[38] The remit of the

33 See the summary of its recommendations, entitled "Report on Reproductive Technology of the Asche Committee of the Family Law Council", 60 Australian L.J. at p 6.

34 See Australian Family Law Council Asche Committee Report at p102.

35 Australian Senate Committee Report at p44.

36 Ibid., at p 51 (paragraph 4.38).

37 The States which have produced detailed legislation on the embryo research issue are Victoria and South Australia. The statutes will be considered in Chapter II, of this Part, post.

38 The Constitution Act, 1867 (U.K) 30 and 31 Victoria C.3, section 92 provides, inter alia, that the establishment, maintenance and management of hospitals and the administration of justice in the province generally are powers exclusive to provincial legislatures (Ssection 92, 7 & 14).

Ontario Law Reform Commission, for example, related exclusively to the practice of human artificial reproduction in that province. In considering approaches to regulation, therefore, only passing reference was made to federal provisions, such as the criminal law, where these affect any proposed reforms.[39]

More recently there has been a (federal) Royal Commission appointed to report on the issues as they affect the Confederation generally.[40] In the absence of federal legislation, however, a piecemeal approach to regulation is again inevitable. The attitude of the Government of the United Kingdom has been that one piece of legislation extending to all three separate legal jurisdictions is necessary, notwithstanding that family law matters are dealt with by separate legislation for each system and that the provision of health care is also devolved.[41] With no written constitution and only one Parliament to legislate for all three systems, however, it is usual for matters of national importance to be covered by U.K. wide legislation. The writer knows of no serious challenge that has been made to a national (U.K.) approach to regulation in the context of IVF and embryo research.

39 Ontario Law Reform Commission Report at p123 fn 39, which notes that, if prohibitions carrying criminal sanctions were imposed this would involve a federal power. It is also there pointed out, however, that the provinces can impose fines, penalties or terms of imprisonment to enforce any valid provincial law in terms of the Constitution Act, supra n41, s92, 15.

40 The Canadian Royal Commission on New Reproductive Technologies appointed in 1989 has not, at the time of writing, released a Report of its findings. For comment on this and an assessment of Canadian public opinion on artificial reproduction generally see C. G. Miall, "The Regulation of Reproduction: The Relevance of Public Opinion for Legislative Policy Formation" (1993) 7 Int. Journal of Law and the Family 18.

41 The Treaty of Union between Scotland and England came into force on 1st May 1707. It was approved by Acts of each Parliament: Scottish Act A.P.S. XI 406, English Act 6 Anne c.11. The significant provision here is Article 18 of the Treaty which guaranteed the continuance of Scottish private law and prohibited the alteration of laws which concern public right, policy and civil government unless such alteration of the existing law would be for the evident utility of the subjects of Scotland. The existing separate systems of education and, to a lesser extent, health care were thus preserved. For a fuller explanation see E C S Wade & A W Bradley, Constitutional and Administrative Law (10th edition) (Longman: England 1985) at Chapter 5., D, pp 84-88.

Whether the approach is "state" or federal, it is inevitable that little more than a framework can be drawn by primary legislation. Detailed rules concerning approval of research centres or projects may be dealt with in delegated legislation,[42] or left to a national body, such as that noted above to have been recommended by the Australian Senate Committee, or both. However, it is essential, in the writer's opinion to guard against over-generality in the primary rules if legislative regulation is to be effective, and able to be relied on by infertile persons, physicians and research scientists working in the field. The parameters laid down by legislation must therefore include all those matters which are so fundamental that flexibility in relation to them would be inappropriate, and decision making on them by anyone other than democratically elected representatives would be contrary to the public interest. This was anticipated by the Australian Senate Select Committee which detailed certain cardinal principles and recommended that these be spelt out in legislation.[43]

Finally, legislatures may be required to address the question of funding for reproductive practices such as IVF and related research. In the context of legal regulation of such practices, the approval or prohibition of certain acts and the means by which those practices will be funded are arguably mutually inextricable. For example, in the United States, Federal funding for embryo research was withdrawn due to concern that its continued provision implied a 'pro-research' policy by the Reagan Administration.[44] In the United Kingdom,

42 Also known as subordinate legislation, this term is here is used to cover any regulation which is authorised by primary legislation but does not require further authority from Parliament to be enacted. See E C S Wade & A W Bradley, op. cit., supra n.41 Chapter 33.

43 Australian Senate Select Committee Report at 51.

44 See L Birke, S Himmelwite & G Vines, "Tomorrow's Child: Reproductive Technologies in the 90's" (Virago Press Limited: London, 1990) at p234 and The Scientist, 6 April 1987, p6, cited therein at fn.1.

where there is widespread availability of clinical IVF, but mostly on a private basis there is presently an attempt to place a duty on district health authorities to secure the provision of infertility services within the National Health Services.[45] Such examples serve to emphasise the importance of trying to adopt a consistent policy towards embryology and related issues and ensuring that any legislative regulation accords with that policy.

(iii) Administrative Regulation

It has already been conceded that a legislative framework regulating some or all areas of assisted reproduction cannot suffice in providing detailed rules to govern its daily practice. Thus there has been widespread agreement between the various bodies which have considered methods of regulation in this context, that some form of licensing arrangement is desirable.[46] The proposals have varied as to the nature and extent of such licensing. In general terms, however, it is the institutions in which artificial conception is carried out, research teams and physicians themselves and the individual projects they wish to undertake, or a combination of these which are likely to be the subject of licence applications.[47]

45 The Infertility Services Bill, a Private Member's Bill, was introduced by Ms Dawn Primarolo MP on 8th June 1993. It is not expected to reach the statute book. See Parliamentary News, (1993) 21 Scots Law Times 212.

46 See e.g. Warnock Committee Report, List of Recommendations at 80-81, (Recommendations 1-17), Australian Senate Select Committee Report, paragraphs 4.17-4.25, Victoria, Australia, Committee to consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilisatoin Report on the Disposition of Embryos Produced by In Vitro Fertilisation, (1984), at paragraph 2.2. The Ontario Commission Report was ambivalent on the issue. While recommending that special licences should not be required for artificial conception procedures (recommendation 4 at 275) it also reommended that sperm banks should be licensed (recommendation 17 (1) at 277).

47 See the discussion about this type of regulation in B Knoppers and E Sloss, "Recent Developments: Legislation Reforms in Reproductive Technology" (1986) 18 Ottawa L.R. 663, at 667 - 673.

The socio-legal significance of the role to be played by any body given power to grant and refuse such licenses will depend largely on two factors: first the amount of discretion afforded to it and secondly the type of provision, if any, for access to the courts for appeal or review of its decisions. These factors are central to the whole question of appropriate models for legal regulation. If a primary statute is expressed in such general terms that it makes no outright prohibitions and pronounces no clear statements of fundamental principles, then the powers of any administrative body introduced by it will be extensive, and the converse proposition holds equally true. Similarly, the level [48] at which judicial review is to take place may indicate the importance of the statutory body, although the effect of constant recourse to the courts by the recipients of its decisions on its standing is something which could only be ascertained after a reasonable period for assessment of its competence had passed. The critical point is the relationship between administrative and judicial regulation. If an unsatisfactory attempt at the former resulted in an increasing exercise of the latter by default, then the role of an administrative body in this area of law would require to be reconsidered. Effective administrative regulation is that which retains the correct balance of power between the legislature's position in making the law and the administrative body's function in implementing it.

Membership of administrative bodies can also give clues as to their role and importance. Another common theme of the proposals for licensing has been the suggestion that any statutory body appointed to administrate in this field should have multi-disciplinary membership.[49] The variety of

48 i.e., the place of the court allocated that task in the judicial hierarchy.

49 See for example Warnock Committee Report at 75-76, Australian Senate Select Committee Report at 54.

disciplines from which the members of such a body would be chosen, the length of their tenure and the background of the personnel appointing them, are all factors which may have a bearing on the viability of the organisation itself. Again it may be considered important that adequate representation on such a body of all relevant interest groups should be ensured. The aforementioned general points arising from administrative regulation will be illustrated in context when the specific provisions involving the delegation of power to statutory bodies are examined in Chapter II of this part.

(c) International Legal Regulation

There has been activity in the area of reproductive technology in most corners of the world. The interest of international organisations has been stimulated [50] and there have been attempts to collate and compare international data on the legal approaches to IVF, emrbyo research and related practices.[51] It has already been suggested that existing instruments of international law which seek to pronounce a general human right to life do not extend to the unborn fetus, or by logical implication, to the in vitro embryo.[52] The question of whether International Law should have something to say about the status of the embryo and the regulation of embryo research and related practices then arises. If it should, then the structure for an international approach must be considered.

The Warnock Committee, reporting in 1984, suggested that while there was a case for an international approach, it would best be formulated,

> "... when individual countries have formed their own views, and are ready to pool knowledge and experience".[53]

50 See e.g., Parliamentary Assembly of the Council of Europe Report, op. cit., supra Part B fn 117.

51 See J Gunning, Human IVF, Embryo Research, Foetal Tissue for Research and Treatment, and Abortion: International Information (U.K., H.M.S.O. Publication: 1989).

52 See supra Part B fn. 11 and 12.

53 Warnock Committee Report at 6.

The Report did not elaborate the case that the Committee considered had been made out for that international approach, or indicate what it might entail. It is first important to distinguish, in this context, between instruments such as United Nations Conventions which represent agreements between signatory states to abide by certain agreed general principles on a subject and legislation emanating from supra national bodies with legislative power, such as the institutions of the European Community.[54] A third tier of international regulation is exemplified by the institutions of the Council of Europe.[55] Countries like the United Kingdom, which is a member of all three organisations mentioned, may find their ability to legislate on a purely domestic level restricted if 'semi-international' regulation on a European level was introduced.

54 See I Brownlie, Principles of Public International Law, (fourth edition) (Oxford University Press: 1990) esp. pp 694-701.

55 See for example the discussion about enforcement of the Council of Europe's Coventary on Human Rights by its Court in O. Hood - Phillips, Constitutional and Administrative Law (Seventh Edition) (Sweet & Maxwell: London; 1989 pp 425-433.

Concerns have been expressed about the possible development of "forum shopping" in the absence of an international approach to the control of embryo research.[56] Countries whose scientists are involved in IVF and related embryo experimentation are most likely to consider the importance of a unified approach, as they have much to lose by imposing conditions on such practices that are so stringent as to leave both practitioners and patients with little choice but to turn to a jurisdiction with a more liberal regime. The difficulties associated with legislating in an area in which there is global activity to an extent which may render prohibition ineffective are not, by any means, restricted to reproductive technology issues. Once again the abortion debate provides an appropriate lesson. Since the passing of the UK Abortion Act in 1967, there has been a steady influx of women entering the United Kingdom for the sole purpose of availing themselves of the access to pregnancy termination facilitated by that statute.[57] A large proportion of those women came from Ireland, a near neighbour whose constitution has consistently denied its citizens access to abortion.[58] The Irish Government managed to ignore the regular exodus of young women travelling, usually to London, for this purpose, until a recent tragic case of a fourteen year old victim of rape being prevented by court order from leaving the country to have her pregnancy terminated in England.[59] Ultimately the Supreme Court of Ireland lifted the travel

56 Forum shopping is the choice of a country or jurisdiction which has the most favourable rules. In the context of IVF related procedures and embryo research the "forum shoppers" may be the infertile couples seeking treatment, but the focus has often been on scientists who will chose a legal climate in which they can work without fear of public pressure and even prosecution. For a survey of the lack of uniformity on the regulation of embryo research worldwide and the difficulties caused see S Downie, op. cit., supra Part A n.35 Chapter 14 "Regulation and Control".

57 See A Mason & S McCall Smith op. cit., supra Part A n.44 at 104-105.

58 The Eighth Amendment to the Irish Constitution inserted Article 40 3.3. See Eire, Dial Debates Vol. 50 Col. 1674.

59 Attorney General v X and Others: High Court 1992 No. 846P (Costello J).

restriction which had been imposed.[60] The Court's decision gained the support of the people of Ireland in a subsequent referendum on the issue and the hitherto illegal and unconstitutional act of terminating pregnancy seems set to be given limited legal recognition.[61]

In the present writer's view such an example serves to illustrate the complications arising from the maintenance of a domestic law or policy which seeks to prohibit an activity largely condoned by neighbouring states and by the international community. The dilemma has been recognised both by the pro-research and anti-research lobbies in the embryo debate. In imploring the House of Lords to support embryo research in the Human Fertilisation and Embryology Bill, Lord Ennals sought to use the argument that it was pointless to outlaw it in one country, leaving others to carry on the work saying,

> "Property controlled research can never be stopped. Britain is at the heart of this research but, of course, it would continue in Germany, in the United States and in other countries".[62]

During the same debate, one of the opponents of embryo research, Lord Kennet, also acknowledged the shortcomings of purely domestic legislation and the possibility of forum shopping. He asked,

> "If embryo rsearch is banned in other countries and allowed here, their researchers will come and work here. If it is banned here and allowed in other countries ours will go and work there. What are the pros and cons of this? It ought to be considered ....."[63]

60 The Supreme Court discision is reported in 1992 12 Irish Law Reports Monthly 401.

61 See The (London) Times, Editorial, 24 June 1993.

62 U.K. H.L. Parliamentary Debates, Vol. 513 col. 1013, Germany has since banned embryo research completely. See post. n.65

63 Ibid., at col. 1025.

He went on to describe the debate on embryo experimentation as a "Community problem" and asked what the European Commission and the European Parliament were proposing to do about it.[64] There has been no legislation, however, emanating from the institutions of the European Community, perhaps due to the diversity of approach of the various Member States, ranging from no legal restriction on research whatsoever to a complete prohibition on embryo research.[65]

This thesis has already attempted to explore some of the conflicting views held about embryo research and the status of the human embryo itself. Given the extensive divisions within nation states on this matter, and within groups of states such as the aforementioned European Community, it is submitted that present indications militate against an international solution. As with other medico-legal problems, such as abortion and euthanasia, which involve issues of individual conscience and belief, there is unlikely ever to be more than a fragile consensus within nation states themselves. In contrast, instruments of International Law tend to apply a "lowest common denominator" method of agreement and seek to uphold fairly basic standards, particularly in the field of human rights. Thus pronouncements of rights to life,[66] to privacy and family life [67] and to be protected against torture and other

64 Id.

65 See the table of International Comparisons of IVF and Embryo Research Legislation in D Morgan and R. G. Lee op. cit., supra Part A in 90 at 86-87. Belgium, for example has no legal restriction, whereas Germany has prohibited embryo research completely.

66 eg Article 3, Universal Declaration of Human Rights and Article 6(1) International Covenant on Civil and Political Rights op. cit., supra Part A n.11.

67 eg Article 8, European Convention for the Protection of Human Rights and Fundamental Freedoms, op. cit., supra Part A n.11.

degrading treatment [68] are more or less universally held aims which the International community has an interest in upholding. The complexity of rights involved in matters of medical ethics, however, seems to render global consensus more unlikely in that area.

Any attempt to marry individual ethical convictions with statements of general principle on such sensitive issues is likely to be little more than empty rhetoric. To take an existing example, the Declaration of Oslo, a World Medical Association statement on therapeutic abortion, was made to modify the principle of utmost respect for human life from the time of conception. It approves therapeutic abortion where allowed by law, but permits individual conscience to prevail where a doctor considers that his beliefs do not allow him to perform a termination.[69] A similar Declaration for IVF related experimentation, namely that it is ethical to conduct embryo research where legal to do so but equally ethical to refuse to conduct it on grounds of individual conscience might comfort the medical scientists involved but would hardly amount to International regulation of their practices.

While it seems naive, then, to hope for an International approach to regulation of IVF related embryo research, there are other aspects of reproductive technology which might more appropriately be addressed internationally. For example, the rights and duties of the various parties involved in assisted reproduction, the protection of women involved in surrogate motherhood agreements, and the rights of children born through artificial conception are all areas which might properly be guided by basic principles of an International Code or Convention. It may be thought extravagant, however, to expend energy and resources formulating International policy for the alleviation of infertility which is to a large extent the "privilege" of First World nations, particularly when

68 eg Article 3, European Convention for the Protection of Human Rights and Fundamental Freedoms op. cit., supra Part A n.11.

69 Declaration of Oslo, statement on therapeutic abortion. Adopted by the 24th World Medical Assembly, Oslo, Norway 1970 (reproduced in Mason & McCall Smith op. cit., supra Part A n.44 as Appendix E) [hereinafter referred to as "Oslo Declaration"] See paragraph 6 of the Declaration.

over-population continues to represent a crisis for the Developing World.[70] Notwithstanding such reservations, alternative methods of reproduction are clearly issues which have at least symbolic importance to everyone and which ought ultimately to be addressed on a global level.

In conclusion, then, it seems that the continuing national debates over protection for the embryo ex utero preclude any international approach to the problem being made in the foreseeable future. Attempts to resolve the debate through domestic legislation will now be examined. Unless those attempts are seen to succeed in providing sufficient controls to quell the disquiet of those who have long called for definitive regulation, then the prospects for future international consensus in this area will be remote.

70 For a discussion of the relationship between reproductive technology and population control in the Developing World see R Rowland op. cit., supra Part A n.18 at 84-87.

CHAPTER II

THE PRESENT LEGISLATIVE APPROACH: STOP GAP MEASURES OR THE ENSHRINEMENT OF FUNDAMENTAL PRINCIPLES?

There can be no doubt that legislative regulation has come late to the field of reproductive technology generally, and IVF related embryo research in particular. It could be argued that the fact that the procedures to be controlled or even prohibited were developed in a legal vacuum had considerable influence on the nature and extent of the controls now imposed. Thus the introduction of statutory regulation may be seen to represent a necessary, albeit belated, response to pressure rather than the development of public policy based on a broad consensus of principle. It has already been suggested that the absence of either a comprehensive policy or legislative controls served the interests of those working in the area of assisted reproduction who were accordingly able to put forward their own self-regulatory system as a model for regulation. In examining the pertinent provisions of some of the legislation now in force, this chapter will seek to analyse their effectiveness in dealing with the fundamental issues at the heart of the embryo debate. The extent to which they have succeeded in so doing can only be determined having regard to the aforementioned pressures imposed by various parties, but particularly by those involved in the activities sought to be restricted.

Most jurisdictions in which medical scientists are working in the field of assisted reproduction have taken some steps towards regulation of IVF and related research. This Chapter will focus on three particular statutes, namely the UK Human Fertilisation and Embryology Act[71], the South Australian Reproductive Technology Act[72] and the Infertility (Medical Procedures) Act of the State of Victoria,[73] and their attempts

71 op., cit., supra Part A n.11

72 op. cit., supra Part A n.108.

73 op. cit., supra Part A n.43.

to address the issues fundamental to resolution of the embryo debate. Reference will be made to the existence (or absence) of legislation in other jurisdictions where appropriate. In conclusion it will be asked whether the regulation thus far implemented is suggestive of the emergence of any comprehensive policy for the future.

The legislative provisions can now be examined with respect to their attempts to resolve three main aspects of the debate.

(a) Defining the Subject Matter

In the present author's opinion, the detailed definition of relevant words and expressions is a prerequisite for effective legislation on a subject which, as has been shown, has proved susceptible to linguistic tactics employed to control the outcome of the debate. To what extent, then, have legislators been sensitive to the dangers of such terminology abuse?

The Victorian legislation, passed in its original form in 1984, did not try to define the term "embryo" at all. Section 3 of the Act, the interpretation section, focused instead on "fertilisation procedure", defining it as any procedure of IVF using a couple's own gametes or those of a male or female donor, and included procedures of fertilisation by artificial means within as well as outside the body of a woman. Section 6(4) made clear that an "experimental procedure" referred to research on an embryo of a kind that would cause damage to it, make it unfit for implantation or reduce the prospects of a pregnancy resulting from such implantation. Only three years passed before both these terms required redefinition and elaboration by amending legislation. The Infertility (Medical Procedures) (Amendment) Act 1987[74] inserts, inter alia, a new section 9A into the 1984 Act which states at sub section (1) that,

> "A procedure to which this section applies is an experimental procedure involving the fertilisation of a human ovum from the point of sperm penetration prior to but not including the point of syngamy".

74 Victoria, Australia, Acts of Parliament, No. 86 of 1987.

Thus the Act would not appear to recognise two related categories of experimental procedures, those falling within the general definition in section 6(4) and a sub-category containing the particular procedure outlined by the new section 9A. Further, the existence of a nameless entity is alluded to, something which exists from the beginnings of fertilisation until just before the point of syngamy. The amending legislation subsequently defines syngamy, somewhat technically as,

> ".... the alignment on the mitotic spindle of the chromosomes derived from the pronuclei".[75]

The background to the substance of the amendment and its purpose will be discussed later in this Chapter. In the present context, it serves to illustrate the importance of defining the subject matter of the regulation to be imposed. For example, section 6(4) uses the word "embryo" no less than four times in describing experimental procedures. The Act as now amended provides no guidance as to whether or not the entity evolving prior to the stage of syngamy could be described as an embryo or not. If the procedures referred to in section 9A form, as they seem to, a sub-category of the general experimental procedures defined in section 6(4) then a logical interpretation demands that what exists pre-syngamy must be an embryo. In the writer's view the amending legislation missed the opportunity to rectify the previous failure to define the embryo it sought to protect and compounded the difficulty by introducing new rules for a separate stage of early human development without defining that stage by reference to the embryo, a term central to the whole question of permissible experimental procedures under the principal Act. It is also interesting to note that as the 1984 Act as first drafted may not have envisaged the destruction of embryos,[76] there is no reference to their disposal after use,

75 Section 4 (4) Infertility (Medical Procedures) (Amendment) Act 1987 amending section 3 (1) of the Principal Act of 1984.

76 Section 19 (2) (f) of the 1984 Act does refer to a situation where an embryo is disposed of otherwise than by implanation in the womb of a woman, but as a result of the interpretation placed on section 6 (5) of the Act (mentioned again post, part (c) of this Chapter) it is unclear what such disposal would entail.

although there is specific provision for gametes being destroyed where those involved in their donation withdraw consent to IVF prior to its being carried out.[77] The new section 9A in setting out various conditions which must be satisfied before the experimental procedure can be undertaken refrains from mentioning the fate of the embryos subjected to such experimentation.[78] If the interrelation of these provisions is as aforementioned, then this amounts to a failure to describe the end of an embryo's existence. In any event, as the practice of research on "spare" embryos prior to the implantation stage seems to be permissible under the auspices of the Victorian legislation, the absence of any reference to their fate following such an activity is particularly unhelpful.

The language of the South Australian Reproductive Technology Act 1988 is no more straightforward. Its long title explains that it is,

> "An Act to regulate the use of reproductive technology and research involving experimentation with human reproductive material".

The term "human reproductive material" is defined by section 3 of the statute as including; (a) a human embryo, (b) human semen and (c) a human ovum. Gametes and embryos are accordingly both included within the same generic term, a surprising approach for an Act which goes on to prohibit all non-therapeutic embryo research. The generic term "human reproductive material" is used throughout the statute in conjunction with general statements about experimentation. The mandatory condition prohibiting research which might be detrimental, however, is directed only at embryo research.[79] Thus there would appear to be nothing to prevent

77 Section 19 (2) (0) 1984 Act.

78 Section 9A (2) requires consent of the couple whose gametes are involved, counselling by a medical practitioner and specific aims of the experiment as pre-conditions for such procedures, but their aftermath is not referred to.

79 Section 14 (2) (b), Reproductive Technology Act 1988.

research which destroys individual gametes in the context of an approved research programme, although this is not stated in terms. It is difficult to see what purpose is served by the creation of this blanket term "human reproductive material" when the level of protection afforded to one type of "material" is almost absolute and the other types have no such security. The existence of that protection itself denotes a vast difference in status between the embryo and unfertilised gametes. It is submitted, then, that a definition of the term "human embryo" itself might have been more informative, particularly as fertilisation, the process which metamorphoses the partially protected gametes into the indestructible embryo is used throughout the statute without clarification.

The South Australian legislation also stops short of defining the terms research and experimentation. Despite the use of the somewhat anomalous expression "research involving experimentation"(emphasis added) in both the title to the Act and in the provisions regulating such activities,[80] nowhere is it explained what might be included within the ambit of that expression. Indeed the statute envisages that the kinds of research which will be authorised will be defined at the point of granting a licence rather than by any pre existing regulation.[81] While the mandatory condition prohibiting 'detrimental' research certainly restricts the scope of the kinds of research which will be permitted by licence, it is submitted that, if the type of research sanctioned is so restrictive, then clarification of the precise activities falling within that term would have been of assistance. It seems incongruous for a piece of legislation regulating such an important and politically volatile issue to contain such scant references to the activities sought to be controlled.

80 Section 14 (1), 16 (4), and 17 (1), Reproductive Technology Act 1988.

81 Section 14 (2) provides that a licence will be subject to (a) a condition defining the kinds of research authorised by the licence and (b) a condition prohibiting research that may be detrimental to an embryo.

In the more recently enacted UK Embryology Act,[82] the terms "embryo", "gamete" and associated expressions are defined at the outset. Section 1(1) provides,

> "1 - (1) In this Act, except where otherwise stated -
>
> (a) embryo means a live human embryo where fertilisation is complete.
>
> (b) references to an embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote".

The provision is perhaps overstated in that the reference to fertilisation being completed in part (a) is futile given the inclusion of the earlier stages of fertilisation in the definition by virtue of part (b) and the absence of any different rules for the "pre-completion" stage of fertilisation. Notwithstanding that criticism, the sub-section does at least confirm that an embryo exists, for the purpose of the Act from the process of fertilisation onwards. There is some ambiguity about the stage at which the developing human entity ceases to be an embryo, however. Section 2(3) provides,

> "2 - (3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted".

On first reading this would appear to suggest that at the implantation stage the embryo becomes a child, with all the emotive implications that might have for the abortion debate. It would appear, however, that the purpose of the subsection is to clarify the position of the recipient woman after uterine lavage procedures.[83] The use of the word 'child' instead of 'fetus' may be explained by the focus of the provisions relating to surrogacy

82 The UK Embryology Act received the Royal Assent on 1st November 1990.

83 The words "carrying a child" appear in sections 27 and 28 of the Act (meanings of "mother" and "father"). The effect is that the mother of a child who developed from an embryo obtained by lavage shall be the woman in whom the embryo was ultimately implanted and not the woman in whom it was fertilised.

arrangements on the woman carrying the child.[84] It is also interesting to note the absence of the term "pre-embryo" in the legislation, given the protests during the debate by the pro-research lobby and discussed earlier in this paper that the early entity couldn't be described as an embryo at all.

There is again an absence of definition of research in the UK legislation. Section 11 (1) (c) refers to the grant of licences,

> "... authorising activities for the purposes of a project of research",

permission by those whose gametes formed the embryo being essential to the issue of such a licence under the Act.[85] The scope of licences for research on human embryos is detailed in paragraph 3 of Schedule 2 to the Act. The emphasis is on increasing knowledge about the creation and development of embryos, or about disease, such aims being pre-requisite to an application for a specific licence.[86] The activities which may be authorised are enumerated in

84 Sections 27, 28 and 29 make clear, inter alia, that in surrogacy arrangements the woman who carries and gives birth to a child is his mother for legal purposes. Thus the focus is on the later stage of birth rather than fertilisation.

85 Schedule 3, 2 (1) (c) of the 1990 Act.

86 Schedule 3, 3 (3) of the 1990 Act.

paragraph 3 (2) of Schedule 2, although the list is subject to any other purposes of research projects

"... as may be specified in regulations".

Thus the paragraph serves only to provide examples of suitable purposes for research. It does not define the parameters of research itself, the focus being on the project's aims rather than the uses to which embryos will be put during its performance. Further there would appear to be an inconsistency between the stipulation in paragraph 3 (2) that a research activity must be necessary or desirable for certain purposes before a licence can be granted and the requirement in paragraph (6) of the Schedule that the proposed use of embryos be necessary for the purposes of the research. Paragraph (6) may be intended to prohibit the use of human embryos for research which could equally efficiently use animal embryos, although again it does not say so in terms. In any event, the difficulty remains about the position of a project which, for example, has the aim of making advances in the development of new contraceptives, but which can satisfy only the test of desirability and not necessity. Could such a project satisfy the requirement that the use of embryos for that research is necessary when the work itself cannot be said to be necessary?

The breadth of decision-making power delegated to the Human Fertilisation and Embryology Authority by the UK Legislation will be considered in due course. It can be sufficiently stated meantime that the lack of detailed definition of research activities themselves and the scope for additional purposes of research projects to be specified in delegated legislation seems to represent an acknowledgement that the limits of research have yet to be circumscribed. This implicit acknowledgement is well illustrated by the relationship between the specific prohibitions detailed in section 3 of the Act and the remit given to delegated legislation.

A statement that a licence cannot authorise,

> "... keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use".[87]

has no meaning until those regulations prescribe the prohibited activities to which it refers. Thus the language of the statute is suggestive of stop-gap measures which require to be supplemented by detailed rules.

It can be seen, therefore, that none of the legislation examined thus far has fulfilled the crucial task of imposing watertight definitions in regulating an area which has been particularly susceptible to control through the use of language.

(b) Status and Categorisation

The embryo debate has, by and large, revolved around disputes over the status to be afforded to the early human embryo and the legal category into which it falls or which should be created for it. It is accordingly quite remarkable that there is no definitive pronoucement about status or categorisation in any of the Australian or UK legislation. This lacuna contrasts both with the recommendation of the influential Warnock Committee that such a pronouncement be made in primary legislation and with the approach taken by some of the State Legislatures in the United States.[88] During the passage of the Human Fertilisation and Embryology Bill through the UK Parliament there was an attempt to bestow on the embryo the legal status of a person. This was rejected, and the whole idea of determining the embryo's status denounced, in the House of Lords.[89]

87 Section 3 (3) (c) UK Embryology Act 1990.

88 See the references in L Andrews, op. cit., supra Part B n. , at 395-340, and in particular the discussion of prohibition of embryo research when carried out in connection with abortion.

89 See the argument of Lord Hailsham of Saint Marylebone, U.K. H.L. Parliamentary Debates Vol. 515 col. 751.

The most influential argument against classification for the embryo was delivered by the Archbishop of York, who summarised the rationale behind avoiding it as follows.

> "One of the difficulties in the debate is that embryology, to coin a phrase, is sui generis. We are constantly trying to apply distinctions which pertain in ordinary life but whch do not actually apply in a particular respect. For example, lawyers try to put eveything in one of two baskets, it is either a person or thing. However, there are entities which are neither persons nor things. What we are referring to in the case of a conceptus is an organism of human origin which given the right conditions has the potential to develop and may become a full human person".[90]

The present writer has argued that a legislative declaration about the embryo's status might assist in quelling the disquiet on both sides of the debate. The effect of permitting research on human embryos prior to the development of the primitive streak and to place certain restrictions on the type of research allowed is to treat the embryo as "partially protected species". There would appear to be a reluctance to recognise the effect of the rules imposed by explaining their purpose through categorisation. The tendency is rather to afford greater or lesser degrees of protection for the embryo from which unspoken conclusions on status and categorisation can be drawn. It is worthy of note in this context that, during debate of the UK Embryology Bill the sub-section prohibiting authorisation by licence of activities involving,

> "... placing an embryo in any other species of animal" (emphasis added).[91]

90 U.K. H.L. Parliamentary Debates Vol. 515 cols. 955-6.

91 Clause 3 (3) (b) of the UK Embryology Bill.

was objected to on the basis that it effectively classed humans as animals ie, that placing an embryo in any other species of animal than a human being suggested that human beings fell to be categorised as a species of animal. No point about whether the embryo could be so categorised seems to have been taken and the prohibition was amended so that it is now forbidden to place an embryo in any animal.[92] The term animal is not defined in the Act.

The legislation emanating from Victoria, Australia is similarly silent on the question of status and categorisation. No attempt was made to clarify the status of and concomitant protection for, the embryos involved in the procedures to which the 1984 Act applies, and the opportunity to rectify this was not taken by the subsequent amending legislation. The Act's failure to comment on the embryo's status is particularly relevant given the vast amount of confusion which arose over whether its effect was to prohibit experimental procedures which would destroy an otherwise implantable entity.[93] A pronouncement that the embryo's existence was to be protected or partly protected on account of its status might have averted the ongoing uncertainly about it.

It is again a notable feature of the South Australian Statute that, despite its blanket prohibition on research which would be

92 Section 3 (3) (b) of the UK Embryology Act. For the objection taken see U.K. H.L. Parliamentary Debates Vol. 515 col. 784.

93 See the summary of the arguments over this in J Mason, op. cit., supra Part A n.41, at 113-115 and the discussion of the scientist's view that it did prohibit such procedures in R Rowland op. cit., supra n.18 at 227-229. Also further comment post Chapter II (c).

detrimental to any embryo,[94] it omits to adopt a category, or model of protection, for the entity itself. The failure to articulate the status of human material given the highest level of protection by the Act is particularly anomalous due to the discussion about the guardianship model of regulation undertaken by the Federal Senate Select Committee and the Australian Family Law Council to which reference has already been made. While the level of protection granted to the embryo under the South Australian Reproductive Technology Act may be indicative of its standing in law, legal protection is not the equivalent of status, a point discussed earlier in this paper.

In the present author's submission, the failure to enunciate special status for the embryo renders the legislation examined thus far more in the nature of stop gap measures than the enshrinement of fundamental principles. Rules concerning approved research projects and conditions for the grant of a licence may quite easily be altered. Indeed, the Victorian Statute has arguably been altered in an important respect by way of amending legislation.[95] Altering a category or the pronouncement of status is more controversial and therefore more difficult. The drawbacks of regulation by alterable rules will now be addressed by looking at some of the controls sought to be imposed by them.

94 Section 14 (2) (b) Reproductive Technology Act 1988.

95 See post Chapter II (c) for a survey of the substantive amendments made to permit limited embryo research.

(c) The Mechanics of Control

The form of control of research on human embryos adopted by all three statutes under consideration has been to delegate authority to a statutory body set up by primary rules. The South Australian legislation established a State-wide Council on Reproductive Technology, to consist of eleven members.[96] The enumerated sources of nominations for posts on the Council encourage multi-disciplinary membership, although their particular responsibility is given to the Government Minister with five such nominations to ensure,

> "... that the Council has available to it from its own membership expertise in the various facets of reproductive technology".[97]

A similar responsibility is given to the Secretary of State for the Department of Health in the United Kingdom legislation. There is no restriction imposed on total membership of the UK Human Fertilisation and Embryology Authority (hereinafter referred to as HFEA), but minimum numbers of medically qualified representatives and those involved in IVF related procedures are required.[98] Both the South Australian and UK statutes recognise the importance of having representation from both sexes. The former, however, seeks

96 Section 5 (1) and (2), Reprodutive Technology Act 1988.

97 Section 5 (4) (a), Reprodutive Technology Act 1988.

98 The UK Human Fertilisation and Embryology Authority (HFEA) was formally established by Section 5 of the UK Embryology Act 1990. Schedule 1 to the Act deals with membership, tenure of office, remuneration and other such details. Schedule 1 paragraph 4 (1) provides that all the members of the Authority shall be appointed by the Secretary of State. Paragraphs 4 (3) and 4 (4) of Schedule effectively require at least one third but fewer than half of the members to be medically qualified and/or involved in the use of in vitro gametes and embryos.

to ensure equal numbers of men and women if practicable,[99] whereas the latter asks only that the Secretary of State, in making appointments, has regard,

> "... to the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women".[100]

The distinction is notable in the present writer's view, given that persistent criticism of the feminist lobby that, despite women's crucial role in the area of conception and childbirth, they are sidestepped in the decision making process.[101] In formulating policy in this area, a judgement must be made about what purpose is served by the presence of women on such a regulatory body. If it is to be a statement about the need for control in this field to be representative, then a categoric requirement might have been more appropriate than the somewhat nebulous expression in the British legislation . The Standing Review and Advisory Committee established by the Infertility (Medical Procedures) Act in 1984 has no statement about the gender of its members,although it is quite specific about the various disciplines from which appointments are made.[102]

Each of the three bodies set up by the legislation have their general functions stipulated in the Acts themselves. All are given power to licence, or approve, research and experimentation within the accepted limits of the particular statute.[103] Only the South Australian Council has, as one of its stated functions,

99 Section 5 (4) (a) Reproductive Technology Act 1988.

100 Schedule 1, paragraph 4 (2), UK Embryology Act 1990.

101 See the writings referred to supra n.30.

102 Section 29 (1) Infertility (Medical Procedures) Act 1984.

103 See Section 29 (6) (b) Infertility (Medical Procedures) Act 1984 and Section 29 (6) (ba) inserted by the Infertility (Medical Procedures) (Amendment) Act 1987; Section 10 (b) Reproductive Technology Act 1988; and Sections 8, 9, 10 and 11 of the UK Embryology Act 1990.

> "....to carry out research into the social consequences of reproductive technology".[104]

Again in the context of creating social policy, such recognition of one of the greatest concerns of many commentators and pressure groups, seems commendable. Similarly, the promotion of informed public debate on the ethical and social issues arising from reproductive technology as a function of the Council stands in contrast to the absence of any reference to social debate or input from the public in the functions listed for HFEA in section 8 of the UK Act.[105]

The most detailed provisions of the British legislation relate to the granting, variation, suspension and revocation of licences, for which the Authority is required to maintain special "licence committees". Section 11 of the Act restricts the type of licences which the Authority may grant to those authorising treatment services, storage of gametes and embryos and projects of research.[106] Paragraph 3 of Schedule 2 to the Act, which Members of Parliament were given an option to exclude, contains the key provisions on the issue of licences for research. There is no doubt that what is covered by that paragraph is research in the pure sense, which will lead to embryo destruction. This is due to the separate category of;

> "... practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose",

104 Section 10 (1) (c) Reproductive Technology Act 1988.

105 Section 10 (1) (f) of the Reproductive Technology Act 1988 makes promotion of such debate another function of the Council. Section 8 (b) of the UK Embryology Act 1990 requires only that the Authority publicise the services provided by it to the public or services provided in pursuance of licences granted by it.

106 Section 11 (1) (a) (b) and (c) of the UK Embryology Act 1990.

which are classified as treatment under paragraph 1 of the Schedule.[107] The approved purposes of research listed in paragraph 3 (2) are all subject to the overriding general purpose stated in paragraph 3 (3) which stipulates that the aim must be to

> "... increase knowledge about the creation and development of embryos, or about disease or enable such knowledge to be applied".[108]

The diverse purposes which are specifically listed and approved by paragraph 3(2) are the following;

(a) promoting advances in the treatment of infertility,
(b) increasing knowledge about the causes of congenital disease,
(c) increasing knowledge about the causes of miscarriages,
(d) developing more effective techniques of contraception, or
(e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Thus there is embodied in the Act an underlying notion that a research project must have decent, scientifically justifiable, aims, yet there is no real attempt to set out the parameters of acceptable research by reference to the embryos which are to be subjected to it. It could be argued that the list of activities in paragraph 3 (2) is superfluous, not because of the more general purpose mentioned above, but due to the lack of status for the embryo implicit in its use as research material. If the pre-primitive streak stage embryo has no right to protection from being used for destructive non-therapeutic research and there is no real acknowledgement of its importance as an entity, how important is it to restrict the type of research project it can be subjected to? The wording of paragraphs 3 (2) and 3 (5) has already been discussed with reference to the terms "necessary or desirable". Such prerequisites provide no protection at all for the individual embryo, but they may be seen to satisfy the general notion of respect for early human life that the Warnock Committee endorsed.

107 Paragraph 1 (1) (2), Schedule 2, UK Embryology Act 1990.

108 Paragraph 3 (3), Schedule 2, UK Embryology Act 1990.

One of the most interesting provisions relating to embryo research in the UK Act concerns the controversial practice of tampering with the genetic structure of the cells from an embryo. The first technique developed in this category of research was embryo biopsy, the removal and culture of cells from an in vitro embryo to determine their genetic make-up, in order to detect defects which might result in the birth of a handicapped child. The fears about genetic engineering and the creation of designer babies which have been at the root of much of the anti-research argument centre on such innovative techniques and their far reaching social implications. Against that background, it is perhaps surprising that the legislation is non-committal about future control of such practices. Paragraph 3 (4) of Schedule 2 provides that,

> " (4). A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations".[109]

On one view that paragraph restricts the power of HFEA by imposing a general prohibition on the practice which can only be altered by regulations made with governmental authority. The striking feature, however, is the breadth of scope given to future delegated legislation to determine the limits of, and conditions for, permitting this highly politically sensitive type of research.

As the options open to Members of Parliament voting on the alternative pro-research and anti-research clauses in the Embryology Bill did not include a choice between restricting research to 'spare' embryos or allowing research both on those and on embryos specially created for research purposes, it is the latter position which is reflected in the legislation. Accordingly, while the statute specifically prohibits the creation, storage or use of embryos without licence, the culture of embryos solely for use in

109 Paragraph 3 (4), Schedule 2, UK Embryology Act 1990.

research is sanctioned by a licence granted for that purpose.[110]

Any limit on the scale of such a project is a matter solely within the discretion of HFEA. For example, if the number of embryos sought to be created for research in a given project seemed to exceed the amount which could properly be said to be necessary, the Authority could impose such conditions on the grant of a licence as it thinks fit.[111]

The licence system established by the South Australian Reproductive Technology Act 1988 involves similar levels of responsibility being bestowed on the Council on Reproductive Technology. While the licences themselves are granted by the South Australian Health Commission, it is the Council's role both to advise the Commission on the conditions to be included in licences authorising artificial fertilisation procedures and to formulate appropriate conditions for licences authorising research involving experimentation with human reproductive material.[112] In addition, the Council has a duty to

110 Paragraph 3 (3) provides that,

> "A licence under this paragraph may authorise any of the following:-
>
> (a) bringing about the creation of embryos in vitro and
> (b) keeping or using embryos for the purposes of a project of research specified in the licence"

It is a licence under (a) which can permit the creation of embryos solely for research.

111 Paragraph 3 (7), Schedule 3 UK Embryology Act 1990.

112 See Sections 10 (i) (b) and 13 (e) of the Reproductive Technology Act 1988.

formulate, and keep under review, a code of ethical practice governing clinical artificial reproduction and related research.[113] This is also a function of HFEA in the UK, and this effectively gives legislative force to the guidelines previously issued by the interim Licensing Authority.[114] The South Australian legislation imposes far greater restrictions on its regulatory body than does its UK counterpart. Section 14 of the Reproductive Technology Act provides, inter alia, that all licences will be subject to a condition prohibiting research that may be detrimental to the embryo. The scope of licences which can be granted in terms of the type of research which may be authorised is therefore fairly limited. No distinction need be drawn of course, between "spare" and specially created embryos where intervention is required to be of a therapeutic nature. There are provisions equivalent to those in the British legislation[115] authorising the variation or revocation of licence conditions and the suspension or cancellation of licences themselves. This latter power is granted both to the

113 Section 10 (1) (a) Reproductive Technology Act 1988.

114 Section 25 of the UK Embryology Act 1990 which obliges HFEA to maintain a Code of Practice envisages that a wide range of matters, not restricted to issues arising from embryo research, will be covered by it: see U.K. H.L. Parliamentary Debates Vol. 513 Col 1010, (Lord Mackay of Clashfern). Nevertheless the provisions on embryo research rely on the previous Guidelines for their content.

115 Section 18 of the UK Embryology Act 1990 provides that, on being satisfied of certain facts stated therein, a Licence committee may revoke or vary a licence granted by it. Section 22 allows temporary suspension of a licence where revocation is under consideration.

Council and the Commission.[116]

The Council established by the South Australian legislation clearly has more limited powers than HFEA due to the prohibition on destructive research mentioned above. Nevertheless, the method of delegating authority for determining the conditions to be attached to licences and the type of research to be permitted is the same. The real safeguard in the Reproductive Technology Act, however, is the prohibition on detrimental research, enshrined in primary legislation, which would require amendment, with concomitant Parliamentary and public debate, in order to be lifted. That prohibition makes the South Australian legislation appear to enshrine a fundamental principle adopted by Parliament in a way that is perhaps not possible under a more permissive set of rules.

An example of amendment of primary rules governing issues at the heart of the embryo debate can be found in the legislation emanating from Victoria, Australia. The 1984 Act in its original form provided at section 6 (5) that,

> "(5) Where ova are removed from the body of a woman, a person shall not cause or permit those ova to be fertilised outside the body of the woman except for the purposes of the implantation of embryos derived from those ova in the womb of that woman or another woman in a relevant procedure in accordance with this Act".

116 Section 14 (3) (b) of the Reproductive Technology Act 1988 provides that licence conditions may be varied or revoked by notice in writing given personally or by post to the licensee. Section 15 thereof deals with the powers to suspend or cancel a Licence.

That sub-section was largely regarded as prohibiting any non-therapeutic experimentation, although section 19 (2)(f) did envisage the registration of embryos disposed of otherwise than by implantation in the womb of a woman. Such embryos would include those subject to experimental procedures authorised by the Standing Review and Advisory Committee.[117] The confusion which arose following the enactment of the Victorian legislation provides in the writers view, more support for the adoption of special status for the embryo, with detailed rules on legitimate actions towards it. In any event, the concern of the medical scientists that all destructive research fell foul of the Act led to calls for amendment, resulting in the passing of the Infertility (Medical Procedures) Amendment Act 1987.[118] The amending legislation inserted into the Principal Act (the 1984 Act) two new sets of provisions. First, the old section 6 was extended to permit fertilisation for the purposes of a section 9A procedure. Section 9A essentially allows the Standing Review and Advisory Committee to approve an experimental procedure rendering a fertilised ovum unfit for implantation. Such a procedure can only be carried out prior to but not including the point of syngamy.[119]

117 See Section 29 (6) (b) of the Infertility (Medical Procedures) Act 1984.

118 op. cit., supra Part B n.

119 In addition to requiring approval by the Standing Review and Advisory Committee, Section 9A (2) lists conditions which must be met before such a procedure can be carried out.

Secondly, the amending legislation inserts into the Principal Act a new section 13 A to deal with GIFT and related procedures.[120] Given that Victoria was the first jurisdiction to pass legislation covering the issues of embryo research and IVF, it was perhaps inevitable that lacunae would surface and require to be filled by new rules. As stated earlier, amending primary legislation at least has the weight of public and parliamentory debate behind it. Is it acceptable, however, that regulation of issues as fundamental as those involving dealings with post conception human life be the subject of change every few years? Was it not the basis of the slippery slope argument, referred to in the context of the fourteen day limit on research, that regulation stopping short of outright prohibition would ultimately result in the permissive approach favoured by the pro-research lobby?

The statutes passed by the State of South Australia and the United Kingdom prohibit the culture of a human embryo in vitro beyond about fourteen days. That temporal limit is stated to coincide either with the stage at which implantation would normally occur or the appearance of the primitive streak.[121] The arbitrary nature of such limits has already been the subject of comment in this paper. In considering the effect of the legislation which embodies these limits, however, the possibility of future amendment must again be addressed. None of the statutes envisage the raising of the temporal limit by regulation or otherwise. The prohibition on keeping embryos beyond the allotted time is an outright one, along with embryos on cloning and the creation of hybrids forbidden by the UK legislation.[122] However, the very real possibility of its representing merely a shaky foothold on the slippery slope is exemplified by the UK legislation's provisions on termination of pregnancy, in the present writer's opinion.

120 Section 4 (3) of the amending legislation introduces the said Section 13A.

121 Section 10 (3) (d) Reproductive Technology Act 1988, and Section 3(3) (a) and 3 (4) UK Embryology Act 1990.

122 Section 3 (3) (b) and (d) UK Embryology Act 1990.

The long title to the Embryology Act makes clear that in addition to regulating aspects of reproductive technology it is concerned with the "subsequent development of embryos", words thought broad enough to permit the amendments to the Abortion Act 1967 by Section 37 of the 1990 Act.

Section 37 was introduced into the Act at a late stage in its passage through Parliament. Its effect is to impose a temporal limit of twenty four weeks gestation on aborting a fetus where the ground for doing so is inter alia, risk of injury to the physical or mental health of the pregnant woman. The difficulty with drawing any moral distinction between the "product" of in vivo and in vitro fertilisation has been discussed, and the decision to include a provision imposing a limit for aborting a fetus in legislation providing (implicitly) ultimate protection for embryos against research after 14 days further highlights that strange dichotomy. The significance of the abortion provision for present purposes, however, is that it illustrates again the relative ease with which the rules constituting the boundaries of protectable humanity can be altered. Whereas the 1990 Act arguably reduced the stage at which a developed fetus can be lawfully aborted,[123] future legislation governing embryology may well increase the temporal limits on embryo research so that the gap between the two gradually narrows. One side of the argument that both or either of the in vivo fetus and in vitro embryo deserves protection would justify this. The ambivalence of the draftsmen of the 1990 Act on this point can be seen in the provision thought to restrict selective reduction of pregnancy. Section 37 (5) renders unlawful anything done to procure the miscarriage of a fetus or fetuses unless it complies with the rest of the Abortion Act. The responsible Secretary of State for Health told Parliament that when the fetus was inside the womb, the position was different from that of ordinary abortion, and must be

123 It has been argued that, notwithstanding the new 24 week limit the law has been made more liberal as a result of the effective removal of limits where the grounds of grave permanent injury to the mother or child are relied on, and the wide discretion given to medical practitioners. See K. McK. Norrie, "British Abortion Rules Altered: Or Are They"? 1992 Scots Law Times 41.

termed miscarriage instead, hence the separate provision.[124] The provision again highlights the complicated interaction between protection for unborn life created naturally and that cultured in the laboratory.

All three pieces of legislation under consideration impose criminal penalties for breach of licence conditions.[125] The writer knows of no criminal proceedings which have been brought to date, and the question of whether such penalties have successfully acted as a deterrent is therefore unknown. There are, in addition, provisions for appeal in the civil courts by the licence holders, or those making applications for them, to appeal against decisions to refuse to grant such licences, or to vary or revoke them.[126] It would appear, therefore, that there is still potentially wide scope for judicial regulation, particularly under the UK Legislation. For

124 The then Secretary of State for Health, Mr Kenneth Clarke, justified his stance thus. "We have taken advice from parliamentary counsel and others. The difficulty of deciding exactly what selective reduction is, when the foetus is killed inside the womb, makes the position different from that of ordinary abortion. Therefore, miscarriage is regarded as the legally correct description. I am advised that the amendment is correctly drafted to catch selective reduction which can be carried out only if the practitioner complies with the abortion legislation in whatever form it emerges from Parliament". U.K. H.C. Parliamentary Debates, Vol. 174, col, 1198.

125 Section 28 Infertility (Medical Procedures) Act 1984, Section 14 (4) Reproductive Technology Act 1988, Section 41 UK Embryology Act 1990.

126 Under Section 31 of the Infertility (Medical Procedures) Act 1984 the application is to the Administrative Appeals Tribunal for review of a decision. Section 16 of the Reproductive Technology Act 1988 provides for appeals to the Supreme Court, and sections 20 and 21 of the UK Embryology Act respectively provide for initial appeal to the Authority itself and subsequent appeal to the English High Court or the Scottish Court of Session. The applicant is therefore bound to appeal to the court of his residence.

example, if a licence is refused because the Authority is not satisfied that the proposed use of embryos is necessary,[127] the courts have power to overturn that decision, on the basis that the Authority was incorrect in law to refuse the grant of a licence.[128] Again there are no reported decisions which can be used to assess the approach the courts will take in such situations, but it is submitted that the power of review of administrative decisions given to the courts in this field is likely to shape future policy and possible subsequent amendment of the primary legislation. Any decisions made will carry the legal weight attributed to the courts at the upper end of the hierarchy which have been allocated this power.[129]

In conclusion it is submitted that none of the legislation examined provides more than short term answers to long term, expanding problems. It is the writers further argument that, in spite of the detailed and complex investigations undertaken into the question of status of the embryo in vitro and appropriate categorisation for it, the central theme of the debate remains unaddressed by the statutory provisions introduced to resolve it.

127 See paragraph 3 (6) Schedule 2, UK Embryology Act 1990.

128 Section 21 (a) UK Embryology Act 1990.

129 Section 16 of the Reproductive Technology Act 1988 provides that appeal is to the highest court in the jurisdiction. The provisions of Section 21 of the UK Embryology Act permit appeal to the highest courts of first instance. A further appeal to the House of Lords would, however, be available at common law.

CONCLUSION

The attractions of creating a permissive legal climate within which medical scientists can continue to achieve success in the field of reproductive technology are self-evident. Emotions are easily swayed by the sight of babies born as a result of years of uncontrolled research. It has been said that the practice of clinical IVF and related embryo research prior to statutory regulation has revealed no abuse. As with issues raised by the abortion debate, however, the controversy over protection for the in vitro embryo is unlikely to subside. The scientific aspects of embryo research are more difficult for the lay person to understand than the concepts involved in taking life through termination of pregnancy. There can be no ultimate consensus on the morality of embryo research, just as there can be no reconciliation of the competing rights involved in abortion. The regrettable feature of attempts to legislate on the embryo debate is, in the writer's view, the continuing failure to make hard decisions about what we think the embryo is, and what we consider should be done to bring it within a protected species.

The author of the still influential Warnock Committee Report, writing some time before the Embryology Act was drafted, commented that,

> "The question legislators must ask is whether the present situation in which research is uncontrolled, is satisfactory. If it is not, then must there be a total ban on research of this kind, or can some lesser restriction be envisaged, which will recognise the special status of the human embryo, yet not treat it as if it were a child or a person"?[130]

130 M Warnock, "The Enforcement of Morals in Embryology" (1986) 39 Current Legal Problems 17, at 28.

This thesis has attempted to address some of the moral and legal difficulties with pronouncing any status for the in vitro embryo, and with categorising it using existing concepts. Nevertheless, the conclusion remains that to shy away from making pronouncements on status and categorisation is to perpetuate the errors of earlier debates on appropriate protection for pre natal life and as such should be discouraged.

It has been suggested that the legal status of the conceptus should depend on desired social outcomes, not on positivistic discussions about whether it is a "person".[131] The present writer's view is that such an approach should underline general policy considerations in the area of reproductive technology but should not be used as an opportunity to evade the crucial issue of status and concomitant protection for early human life. The nature and implications of reproductive technologies affect individuals and families as well as society as a whole. Decisions on the fundamental moral, legal and social issues reviewed in this paper ought to reflect a consistent policy in relation to both the parties directly affected by them and the aim of producing a morally acceptable framework of rules for the treatment of incipient human beings. The stark provisions of the legislation thus far enacted makes no real attempt to achieve that. The UK legislation in particular,

> "..... allows for a flexible development of the art under the control of peer and lay review",[132]

in regulating the research which precipitated the intractable debate.

The implications for society of the possibilities opened up by embryo research are as exciting and disturbing as they were in 1978. The inability of society to weigh up those implications and decide whether or not the integrity of vast numbers of embryos ought to be sacrificed in the name of scientific advancement remains as acute today as it was then.

131 See J Bercovitch, op. cit., supra Part A n.93.

132 J Mason & A McCall-Smith, op. cit., supra Part A n.44, at 62

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