INTERNATIONAL PERSPECTIVES ON HUMAN EMBRYO AND FETAL TISSUE RESEARCH

Commissioned By The National Bioethics Advisory Commission

Lori P. Knowles, BCL MA LLM
Associate for Law & Bioethics, The Hastings Center, NY

INTERNATIONAL PERSPECTIVES ON HUMAN EMBRYO AND FETAL TISSUE RESEARCH

Introduction

The National Bioethics Advisory Commission is charged with the task of researching and analyzing the ethical implications of primordial stem cell research (human embryonic stem (hES) and germ (hEG) cells),[1] and recommending directions for future regulation of this research. In order to acquit itself of this task, the Commission must first answer one fundamental question, "How do we understand where primordial stem cell research fits in the existing regulatory scheme?"

hEG cell research, which uses tissue from aborted fetuses, is analogous to the use of fetal tissue in transplantation. This is not only because it involves the use of fetal tissue, but also because it is research directed at developing therapies for the benefit of people which are unrelated to the facilitation of human reproduction.[2] Consequently, hEG cell researchers and funders should be aware of safeguards and guidelines regarding the use of fetal tissue in research.[3] These guidelines will be discussed briefly, later in this paper.[4]

---

[1] See *Nature* 391, 325:1998 and James A. Thomson et al., "Embryonic Stem Cell Lines Derived from Human Blastocysts" *Science*, vol 282, November 6 1998, pp. 1145-1147, Michael J. Shamblott et al., "Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells," 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).

[2] It is anticipated that the benefits of primordial stem cell research will be aimed at the replacement of damaged or diseased tissues, such as is currently the goal of skin grafting and organ transplantation.

[3] In the United States see *DHHS Regulations for the Protections of Human Subjects*, 45 CFR 46 §46.210, and NIH Reauthorization Act (1993) Sections 111, 112 amending *Public Health Service Act*, 42 USC 289 et seq. For international regulations see for example: United Kingdom. Committee to Review the Guidance on the Research Uses of Fetuses and Fetal Material. *Report* (The Polkinghorne Report) London: HMSO, 1989 [hereinafter *Polkinghorne Report*]; World Medical Association *Fetal Tissue Transplantation Statement*, 1989, Canada, *Tri-Council Policy Statement*, at 9.4 and *Proceed with Care*, vol 2 at 967-1015; Australia, National *Health and*

Existing federal law in the United States which prohibits the use of human embryos in research[5] can be interpreted to permit the use of stem cells derived from that research.[6] That legal interpretation however, does not provide the answer to how we should understand and situate hES cell research within the existing policies on the use of reproductive tissue in research. It is clear that since deriving hES cells requires the use and destruction of human embryos, hES cell research involves embryo research. Ethical issues of hES cell research, therefore, encompass those issues which arise in embryo research.

If the National Bioethics Advisory Commission deems that hES cell research is ethically acceptable and should be publicly supported and privately permitted, then it would be appropriate to revisit the current ban on federal funding in embryo research. Recommending that hES cell research be permitted would require that the use of human embryos in research be sanctioned in certain circumstances.[7] A recommendation to lift the prohibition on federal funding of human embryo research requires that the Commission express its opinion on the principles, and some of the restrictions and guidelines which should govern that research. Examination of international embryo research policies can provide guidance in this endeavor.

Medical Research Council Statement on Human Experimentation and Supplementary Notes, 1992, Supplementary Note 5 - The Human Fetus and the Use of Human Fetal Material; France, *Opinion No. 53*. .

[4] See *infra*, at 32-36.

[5] *Departments of Labor, Health and Human Services, and Education, and Related Agencies in the Omnibus consolidated and Emergency Supplemental Appropriations Act*, Fiscal Year 1999, Public Law 105-277, S.511

[6] See "Embryonic stem-cell research exempt from ban, NIH is told", *Nature* vol 397, 21 January 1999 at 185.

[7] I do not entertain the option of permitting public funding of embryo research on existing hES cell collections but maintaining that embryo research is unsuitable for public funding. That position is not only disingenuous but ethically untenable. See the French statement on the paradox of forbidding research on embryos yet permitting human embryo research. *Opinion No. 53*.

As most embryo research takes place in the context of assisted reproductive technology (ART), discussion of embryo research ethics and policy takes place primarily in that context. In addition, as embryo research involves the use of tissues of men and women, some issues of concern are also discussed in the context of human subjects research policy and regulation.

Numerous countries have grappled with setting policies in both the areas of ART and human subjects research; one of the areas of greatest conflict is the permissibility and regulation of the use of human embryos in such research. Controversy and diversity of opinion continue to dominate discussions about embryo research regulation to a much greater extent than the use of fetal tissue for therapy. For that reason, international perspectives on embryo research, and their implications for hES cell research, will be the main focus of analysis and discussion. This paper will examine policies and regulations on human embryo research in the following countries: Canada,[8] Australia,[9] the United Kingdom,[10] and France.[11] I will also study statements from the European Union.[12]

---

[8] *Proceed With Care*: The Final Report of the Royal Commission on New Reproductive Technologies, Vols. 1 & 2 Minister of Government Services Canada, 1993 [hereinafter *Proceed with Care*]. Legislation was drafted based on the Royal Commission's Report, however, it died on order paper in April 1997. There has been no comprehensive legislation regulating ART passed in Canada to date.; Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, August 1998 [hereinafter the *Tri-Council Policy Statement*].

[9] The National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology*; 1996 [hereinafter *NHMRC Guidelines*] Supplement to *NHMRC Statement on Human Experimentation*, 1992; The Australian Academy of Science, *On Cloning Humans; A Position Statement*; 4 February 1999 [hereinafter, AAS *On Cloning Humans*].

[10] Report of the Committee of Inquiry into Human Fertilisation and Embryology, HMSO London, 1984 [hereinafter The *Warnock Report*]; *Human Fertilisation and Embryology Act 1990* [hereinafter HFE Act].

[11] Lois 94-653 and 94-654 29 July 1994 [hereinafter Loi 94-654] French National Consultative Ethics Committee for Health and Life Sciences, Opinion No. 53, "Opinion on the establishment of collections of human embryo cells and their use for therapeutic or scientific purposes", March 11, 1997

[12] European Commission, Opinion of the European Group on Ethics in Science and New Technologies, 23 November, 1998 [hereinafter *EGE Opinion*].

These countries have been chosen for a number of reasons. Canada (with the exception of Québec), Australia and the United Kingdom share the same legal tradition in Common law as the United States. The United Kingdom produced the first policy statement of any European country,[13] which lead to the *Human Fertilisation and Embryology Act 1990* [the HFE Act]. The HFE Act has been the blueprint of successful, thorough ART legislation for other countries drafting policies in ART.

In contrast to the United Kingdom, which has a strong tradition of promoting scientific freedom, resulting in very liberal regulation of embryo research, France currently has a very restrictive policy on embryo research. France also represents a different perspective; it is a predominantly Catholic country, a country with a Civil law tradition, and has a long history of thoughtful and prescient leadership in the area of bioethics. Finally, I have chosen to analyze the policies of the European Union, as statements from the European Commission and European Group on Ethics in Science and New Technologies (EGE) reflect the diversity of opinion in and among the member states of the European Community.

Each country under examination has struggled to develop clear policies with respect to embryo research. The task is made difficult in part due to confusion in terminology, but primarily due to the great diversity of opinions on the moral status of the embryo. From the determination of moral status flows the possible responses to the questions on the permissibility, restrictions and prohibitions of embryo research. Despite the great cultural,

[13] The *Warnock Report*.

social and religious differences within and among the countries examined, it is possible to find commonalties in their responses.

The question of whether to permit embryo research is characterized everywhere by a tension between the desire for therapeutic benefits derived from that research and the need to prevent abuses. In addition, similarities in international human embryo research policy exist in guiding principles, recommendation strategies, limitations on permissible research and uses subject to prohibition. The importance of examining and adopting standards on which there is international consensus must be respected. The reputation of human embryo research conducted in the United States depends on the standards under which it is performed. In addition, as research is increasingly conducted in multi-center trials and with international cooperation, agreement on appropriate standards will be necessary.

Context of Embryo Research Policy And Regulation

Regulation of the use of human embryos in research falls into ART or human subject research oversight and sometimes in both. Very occasionally, legislation is drafted which deals solely with embryo research. The majority of international policies on embryo research are developed in the context of ART regulation, as is illustrated in the table below.

Assisted Reproductive Technology	Human Subjects Research	Specific Embryo Research Legislation
Canada[14]	Canada[22]	Germany[24]
Australia[15]	Australia[23]	(Belgium)*
United Kingdom[16]	(Finland)*	
Austria[17]		
Denmark[18]		
Spain[19]		
Sweden[20]		
France[21]		
(Italy)*		*legislation in progress
(Netherlands)*		
(Portugal)*		

[14] *Proceed with Care.*
[15] *NHMRC Guidelines.* Although these guidelines are supplementary to the Australian Guidelines on Research Involving Human Subjects they stand alone as guidelines with respect to ART.
[16] HFE Act
[17] *Reproductive Medicine Law*, Federal Law of 1992 (Serial No. 275)
[18] Law No. 503, 24 June 1992 amending Law No. 353 3 June 1987, Order No. 650, 22 July 1992
[19] Spanish Law 35, *Health: Assisted Reproduction Techniques* 24 November 1988 (NUM.282)
[20] Swedish *In Vitro Fertilisation* Law, 1988.
[21] Loi 94-654

[22] *Tri-Council Policy Statement*
[23] *NHMRC Guidelines*, see note 15 above.

[24] German *Embryo Protection Act*, 1991

Regulatory Background

Examination of the background of embryo research regulation in many countries shows that scientific developments, resulting public interest and concern, and considerable diversity of opinion have prompted the appointments of national commissions to explore and discuss the issues surrounding the use of ART. These commissions have traditionally been multi-disciplinary and have been appointed to study the social, legal and ethical issues of concern in ART, including human embryo research.

The mandates of the national commissions have included the pursuit of knowledge, identifying current areas of public concern and ethical problems, making recommendations for oversight, outlining guiding principles and updating norms about ART and human subjects research. Other common mandates include:

- Identification of future developments and issues of concern
- Outlining guiding principles and basic standards of practice
- Encouragement of continued reflection and thoughtful consensus around more contentious ethical issues
- Advancement of knowledge and understanding

Generally, the commissions required a period of two to four years, marked by numerous public meetings, calls for submissions, issuance of drafts for comment and consultation before

submitting a final report.[25] Most commissions stated that they would not offer definitive answers to contentious ethical issues, but would outline the issues and elucidate guiding principles and the application of those principles in specific contexts.

For the most part, the national commissions have produced reports which are wide-ranging in scope and exhaustive, examining all issues surrounding ART, including embryo research.[26] In discussing embryo research the reports include an examination of the uses of embryos in research, the sources of embryos (including creation of embryos for that research), and prohibitions and limitations on embryo research. In many countries once a report was issued by the national commission, legislation was drafted and implemented.[27]

The National Bioethics Advisory Committee does not have the necessary time within which thoroughly to examine the issues and make comprehensive recommendations concerning the regulation of embryo and primordial stem cell research which balance public and scientific opinion. Consequently, a partial response to the President's request for clarification of the ethical issues may be more appropriate, to be followed by a more thorough examination of the issues surrounding embryo research. Such a partial response might set out principles and strategies to guide policy and regulation, areas of special concern and areas requiring further inquiry.

---

[25] For example, the *Warnock Report* required approximately two years to complete, and the Canadian Royal Commission on New Reproductive Technologies took four years from Order in Council until submission of its final report, *Proceed with Care* from 1989 to 1993.
[26] *Cf.* The German *Embryo Protection Law*, 1991.
[27] For example, the *Warnock Report* led to the HFE Act in the United Kingdom. Similarly, the Committee to Consider the Social, Ethical and Legal Issues Arising from *In Vitro* Fertilisation (Report 3: Report on the

The Need for Clear Definitions

Rapidly changing technology, resulting public anxiety and diversity of firmly held beliefs, make thoughtful, intelligent analysis of ART and embryo research regulation extremely difficult and politically sensitive. One further difficulty in developing domestic policy, and in understanding international policy, stems from the lack of precise or consistent use of terminology. In many countries the term "embryo" is not defined in the legislation which regulates embryo research. In those countries which do define the term, the definitions vary greatly. For example, in Australia (Victoria) the "embryo" is understood as differing from the "zygote," and as coming into being at syngamy (the alignment of the chromosomes on the mitotic spindle) - approximately 22-24 hours after fertilization.[28] Consequently, as only creation of "embryos" for research is prohibited, ova may be fertilized and research conducted until syngamy.

By contrast the United Kingdom HFE Act defines "embryo" as, "a live human embryo where fertilisation is complete, references to an embryo include an egg in the process of fertilisation, and fertilisation is not complete until the appearance of a two-cell zygote."[29] Canada's Royal Commission on New Reproductive Technologies underlines this terminology problem:

Disposition of Embryos Produced by *In Vitro* Fertilisation) [hereinafter the *Waller Report*] in Victoria, Australia was followed by the *Infertility (Medical Procedures) Act, 1984* (replaced by a 1995 Act).

[28] Victorian *Infertility Treatment Act, 1995* at S.3 (1).

[29] HFE Act, S. 1(1)(a)(b)

> In the language of biologists, before implantation the fertilized egg is termed a "zygote" rather than an "embryo." The term "embryo" refers to the developing entity after implantation in the uterus until about eight weeks after fertilization. At the beginning of the ninth week after fertilization, it is referred to as a "fetus," the term used until time of birth. The terms embryo donation, embryo transfer, and embryo research are therefore inaccurate, since these all occur with zygotes, not embryos. Nevertheless, because the terms are still commonly used in the public debate, we continue to refer to embryo research, embryo donation, and embryo transfer. For accuracy, however, we also refer to the developing entity during the first 14 days as a zygote, so that it is clear that we mean the stage of development before implantation and not later.[30]

Clearly, how a commission decides to define "embryo" impacts greatly the resulting interpretation and impact of any recommendations. There is a danger if the terminology is manipulated to achieve certain ends indirectly which could not be achieved directly. For example, in the United States, attempts to define "embryo" as coming into existence at syngamy or fourteen days after fertilization would surely be criticized as sophistic. The appearance of "skirting the issue" by an appeal to mechanistic approaches or legalistic interpretation should be avoided; transparency of findings and reasoning is required. Terminology should respond to public understandings and concerns. Whether 'embryos' are viable or non-viable, hybrid or human, exist at fertilization or sometime thereafter, the fertilized human egg and developing human form is the locus of ethical concern regardless of its name.

Guiding Principles, Vision and Strategy

Guidance on framing the issues involved in human embryo research can be found by examining the commonalties in guiding principles and recommendation strategies among

[30] *Proceed with Care,* Vol. 1 at 581.

other countries. Many national commissions articulated guiding principles and values which informed their policy decisions and provided a framework for their recommendations on embryo research. Common principles in the reviewed reports, policies and laws include:

- Respect for human life and dignity
- The quality, including safety, of medical treatment
- Respect for free and informed consent
- Minimizing harm and maximizing benefit
- The relief of human suffering
- Freedom of research
- Non-commercialization of reproduction

In making decisions about using embryos in research or ART, most commissions adopted a long-term vision. This means that recommendations should be drafted in general terms and allow for flexibility and adaptability in the face of future developments. For example, the *Warnock Report* adopted the following recommendation strategy:

- Frame recommendations in general terms, leaving matters of detail to be worked out by government
- Indicate what should be matters of good practice
- Indicate what recommendations, if accepted, would require legislation
- Any proposed changes should apply equally throughout the United Kingdom.[31]

[31] *Warnock Report* at 6-7.

Treatment of Moral Status Arguments

The central finding from public consultation about embryo research is that there is a great diversity of opinion on the acceptability of that research. The diversity of opinion reflects a lack of consensus on the moral status of the embryo. This lack of consensus is acknowledged openly in most reports, for example, the Canadian Royal Commission states:

> Canadians have differing views on the moral status of the zygote and embryo. Although there is strong agreement on a commitment to the principle of respect for human life, Canadians differ about what form that respect should take and what level of protection is owed to human life at its different stages of development. These is also a wide range of answers to these questions in the history of moral philosophy.[32]

The European Commission states that, despite the diversity of views on the moral status of the human embryo among its member states, one can find two conflicting tendencies emerging with respect to the moral status of the embryo and the legal protection which should be afforded the embryo with respect to scientific research. These two positions are:

1. Human embryos have the same moral status as human persons and consequently, are worthy of equal protection.
2. Human embryos do not have the same moral status as human persons and consequently have a relative worth of protection.[33]

[32] *Proceed with Care*, at 631.
[33] *EGE Opinion*.

As the European Commission Working Group on human embryos and research stated in its 1992-1993 Report, "these views are fundamentally different and it is difficult to see how, at these extremes, the differences can be reconciled." In the face of this fundamental disagreement, the most common response has been to state that no definitive answer can yet be given to the question of when life beings or whether the human embryo is a 'person' using scientific information.[34] The *Warnock Report* states,

> Although the questions of when life or personhood begin appear to be questions of fact susceptible of straightforward answers, we hold that the answers to such questions in fact are complex amalgams of factual and moral judgments.[35]

After highlighting the insoluble nature of the problem the common response is to adopt a position the reports characterize as a "compromise" between the two positions. This pragmatic approach seeks to balance the scientific and medical cost of not pursuing embryo research with the moral cost of permitting such research. Where embryo research is permitted a common solution is to provide some protection to human embryos in the form of certain prohibitions and limits on research.

In light of how the two positions are expressed above, the decision to permit embryo research is less a "compromise" and more a clear choice. Just as those countries which prohibit embryo research are choosing between the two positions, in favor of the former position (embryos are full human persons, entitled to the same protections against harmful

[34]The Canadian Royal Commission states, "Commissioners recognize that no amount of deliberation on our part will definitively answer the question of the moral statue of the embryo. Philosophers and theologians have grappled with the issue for centuries." *Proceed with Care*, at 632. The *EGE Opinion* states "The legislations of the EU Member States differ considerably from one another regarding the question of when life begins and about the definitions of "personhood". As a result, no consensual definition, neither scientifically nor legally, of when life beings exists." Art. 1.15.

research), those countries which sanction any embryo research[36] are also making a choice between the two positions - rejecting the position that human embryos have the same status and rights of full human persons.

Setting up the two positions as greater extremes allows the "compromise" position to be a clearer compromise. The *Warnock Report* provides a good example. After stating that the definitive determination of the status of the embryo is not open to resolution, the Committee states:

> Instead of trying to answer these questions directly we have therefore gone straight to the questions of *how it is right to treat the human embryo*. We have considered what status ought to be accorded to the human embryo, and the answer we give must necessarily be in terms of ethical or moral principles.[37]

The moral arguments against the use of human embryos in research are then laid out: the embryo has the same status as a child or an adult by virtue of its potential for human life; as it is unacceptable to make use of children and adults in research which could harm or kill them, it is also wrong to use human embryos in such research. The arguments on the other side of the debate are then presented: it is only *human persons* that must be respected and human embryos are not persons, or even potential persons, but simply a collection of cells; there is therefore no reason to accord embryos any protected status. Setting up the dichotomy as such, permits the report to choose a compromise, based on rejecting both positions and stating that the embryo must have special status, less then full personhood and more than simply a mass of cells.

---

[35] The *Warnock Report*, at 60.

[36] Here I am not referring to those countries in which only "therapeutic research" is permitted, as this effectively prohibits true embryo research. See the discussion below at 22-23.

Interestingly, the *Warnock Report* and others, appeal to the legal status of the human embryo, which is less than that of a legal person in nearly every country in the Western world. This fact is used to bolster the argument that embryos are not moral persons, but without much explanation why the legal interpretation informs the question of moral status. It would seem that the wide-spread legal agreement that embryos ought not to be accorded the same rights as children and adults could be used as evidence of an international norm, however, this is not explicitly stated.

Limits to Embryo Research

Although there is no consensus about the moral status of the embryo, there is agreement that if embryo research is permissible limitations are necessary and appropriate.[38] As such, limitations on research reflect a compromise between the acceptability and unacceptability of embryo research and are a means of allaying public anxiety. Many of the fears of abuse in embryo research are shared and have resulted in considerable consensus about what uses should be prohibited. There is less consensus, although some commonalties, about what limitations on embryo research are required to allay public concerns, promote beneficial research, and respect the connection between human embryos and the rest of the human

[37] The *Warnock Report*, at 60.

[38]The *EGE Opinion* states that the prerequisite for European funding of embryo research "must be the respect of strict legal and ethical principles." The Council of Europe Conversion on Human Rights and Biomedicine failed to reach consensus concerning the definition of "person" or the admissibility of embryo research - it accepted however the "principle of research on embryos *in vitro*, and moreover, provided that if national laws permit

community. These limits represent both acknowledgments that public fears are respected and are a "sign of respect for the special status of the embryo without the cost of an outright ban."[39]

The following restrictions exist in most countries which permit embryo research:

1. ***Informed Consent Of Gamete Donors***

This condition reflects the principle of respect for individual autonomy, as well as a desire to protect vulnerable people, including patients undergoing infertility treatment who may be subject to emotional stress. Of course, a formal requirement of consent may not be enough to protect female patients from feeling subtle coercion to consent to the removal of ova for research at the same time that ova are being removed for IVF. This is especially true where it is the physician treating the woman or couple who makes the request to remove additional ova for research. It is easy to imagine that patients may consent to the removal of extra ova for research in order to appear compliant and establish or maintain a good doctor/patient relationship. For this reason the Canadian Royal Commission makes the recommendation that:

> [a] woman's or couple's consent to donate zygotes generated but not used during infertility treatment for research never be a condition, explicit or implicit, of fertility treatment. Potential donors must be informed that refusal to consent does not jeopardize or affect their continuing treatment in any way.[40]

---

research on human embryos, they shall ensure that such laws provide "adequate protection of the embryo". Article 18.1.

[39] Lori B. Andrews and Nanette Elster, *Cross Cultural Analysis of Policies Regarding Human Embryo Research,* at 11 quoting John Robertson.

[40] *Proceed with Care,* at 640.

An additional recommendation worth consideration is the recommendation by the Royal Commission that no additional surgical procedure be permitted to retrieve eggs for the creation of embryos strictly for research.[41]

2. ***Time Limits Within Which Research Must Be Conducted***

In keeping with the changing physical status of the embryo, many countries have stipulated that as embryonic development progresses greater protections are required. A common line drawn is 14 days after fertilization, the point believed to represent the last opportunity for twinning to occur; the point in time beyond which the primitive streak (precursor to the central nervous system) begins to develop, and before sentience is attained. While recognizing that any line is, to some extent, arbitrary, this is a line which is adopted by most countries permitting embryo research.[42] Broad international adoption of the 14 day limit is another reason for adopting such a standard. The Canadian Royal Commission concedes that "it is appropriate to agree to a standard that enjoys broad international support, if only to ensure that research done [nationally] will be as respected as that done in the rest of the world."[43]

[41] Recommendation 188: Zygotes be created for research purposes only if gametes for this purpose are available without conducting any additional invasive procedures. *Proceed with Care,* at 640.
[42] "Although no one single identifiable line exists, a true limit on keeping embryos alive must be imposed to ally public anxiety." The *Warnock Report*, at X. Perhaps the best evaluation of the 14 day limit is contained in the Canadian Royal Commission *Proceed with Care,* at 632-637.
[43] *Proceed with Care,* at 636 citing Law Reform Commission of Canada. *Biomedical Experimentation Involving Human Subjects*. Working Paper 61. Ottawa: Minister of Supply and Services Canada, 1989.

3. ***Embryos Must Be Necessary For The Research***

Limits on the necessity and often the significance[44] of the research involving human embryos simply underline the need to ensure that protocols which use human embryos have scientific validity. The Australian *NHMRC Guidelines* suggest that where embryos are destroyed in research, the number used in such a protocol must be restricted.[45] In addition, the Canadian Royal Commission has indicated that "necessary" means that no other animal research or model is available or appropriate to conduct the experiment.[46] The *Warnock Commission* explicitly links this limitation to the special status and consequent protection of the human embryo: "the embryo of the human species ought to have a special status… no one should undertake research on human embryos the purposes of which could be achieved by the use of other animals or in some other way.[47]

4. ***Protocol Review***

Australia, Canada, the United Kingdom, France and the European Union all require review of the protocol by a local or national body or both.[48]

5. ***Regulatory Oversight***

In addition to protocol review, several countries have recommended the establishment

[44] *NHMRC Guidelines* mandate that approval of research involving destruction of embryos requires "a likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the proposed research." Article 6.4.
[45] *Ibid*.
[46] *Proceed with Care*, at 630.
[47] *Warnock Report*, at 63.
[48] Spain, Finland, Sweden, the United Kingdom all require approval by a national authority. Canada, the United Kingdom, Australia, Denmark, France and the European Union require national or local ethics committee approval. See *EGE Opinion*.

of a regulatory board or national commission to license and regulate infertility treatments and embryo research. Although national oversight is desirable, the use of law to regulate (rather than set limits) in this area would be inappropriate given the rapid development in uses of technologies. A national commission or authority coupled with subcommittees responsible for various areas of ART would provide flexibility and adaptability and relieve the need to campaign for removal of legislative bans and prohibitions as technologies and attitudes change.[49] In addition, national regulation ensures more consistent application of safeguards and can ensure greater public accountability and transparency.[50]

The need for national as well as local oversight of primordial stem cell research has recently been echoed by the Australian Academy of Science. No such system currently exists in the United States with reliance placed on a system of review by local institutional review boards (IRBs). The ability of IRBs to adequately assess the merits and ethics of primordial stem cell protocols given their time and resources is surely limited. A national review mechanism which reviewed not only primordial stem cell research but also research protocols using human embryos would ensure strict adherence to guidelines and standards across the country.

6. ***Use Of Only Spare Embryos From IVF For Research***

The issue of whether to create embryos for research purposes or to limit the supply of

[49]This is the recommendation of the Canadian Royal Commission and the system used by the United Kingdom Human Fertilisation and Embryology Authority.
[50] *EGE Opinion* at Art. 2.11. See also the Australian *NHMRC Guidelines* advocating complementary national ART standards or legislation be adopted in the Australian States.

embryos to surplus embryos from *in vitro* fertilization treatment (IVF) is an issue on which there is no consensus. Very few of the national commissions discuss the ethics of creating embryos for research in a detailed manner. The opinion of the EGE states simply, "There is a debate on the distinction between research on donated spare embryos and on eggs donated for research and subsequently fertilised in vitro."

The primary objection to creating embryos specifically for the purposes of research is based on the notion that there is a qualitative difference between creating an embryo which may have a chance of implantation and creating embryos without even that chance of implantation. The *Warnock Report* acknowledges that the Committee was divided on this issue. Some Committee members argued for this qualitative difference:

> This argument in part rests on the doctrine known to philosophers as "double effect"…According to this view, therefore, there would be no general acceptance of research on embryos, but acceptance only in the limited circumstance of the existence of "spare" embryos. Other members…argue that if research on human embryos is to be permitted as all, it makes no difference whether these embryos happen to be available or were brought into existence for the sake of research.…In both cases, the research would be subject to the limitations outlined above and the moral status of the embryo would be the same.[51]

Despite the dissent of four of the Committee members, the use of embryos created *in vitro* for research purposes was endorsed, and under the HEF Act creation of research is permitted within the regulatory scheme of the Act.[52] The Canadian Royal Commission endorsed creation of embryos for research purposes if conducted within the strict

[51] The *Warnock Report* at 66-69.
[52] The *Warnock Report* at 67-68. HFE Act Schedule 2 S.3.

regulatory scheme proposed, and subject to the Commission's proposed restrictions such as those on use and time limits.[53]

Objections about creating embryos for research often appeal to arguments about respecting human dignity by avoiding instrumental use of human embryos. Creation of embryos without intentions of implanting them is argued by some to be disrespectful. Others believe that the limitations on embryo research such as the necessity of human embryos to conduct the research, the 14-day limit and the importance the research ensure appropriate respect. With respect to this point the following statement from the Canadian Royal Commission is worth reproducing:

> On the one hand, we believe that [the creation of embryos for research purposes] would create the danger of promoting instrumentalization of zygotes, thereby potentially undermining commitment to respect for human life and dignity. On the other hand, it is not clear whether we can distinguish effectively between zygotes that become available because they are "surplus" to the needs of couples undergoing IVF treatment and zygotes created specifically for research. Some commentators argue that the distinction is unworkable, since doctors can stimulate the maturation of more eggs than are needed for purposes of IVF by using fertility drugs. According to one submission to the Australian Senate Select Committee, "any intelligent administrator of any IVF program can, by minor changes in his ordinary clinical way of going about things, change the number of embryos that are fertilized So in practice there would be no purpose at all in enshrining in legislation a difference between surplus and specially created embryos."[54]

When deciding how to deal with this issue, there are a number of points to keep in mind. First, most of the reports acknowledge that the creation of embryos provides the only way to conduct certain research, such as research on the process of human

[53] *Proceed with Care*, at 638.

fertilization. Second, as techniques for IVF improve it is possible that the need to create surplus embryos will be eliminated; one of the frequently approved uses of embryo research is the improvement of IVF techniques.[55] At the same time that legislation permits embryo research it is advocating that research improve IVF techniques and that fertility experts try and reduce the surplus of embryos created for infertility treatment.[56] As this happens, and if embryo research is dependent on the existence of spare embryos donated with informed consent, it is possible that the supply of embryos for research will dwindle.

If the research supply is limited to surplus embryos from IVF, two other results are possible. First, in light of the tremendous interest in hES cell research, there is little doubt that demand for embryos and ova for research will increase.[57] Increased demand will only augment incentives for fertility clinics and physicians to ensure a supply of ova is available. This is particularly true where physicians and clinics are also engaged in embryo research themselves, and also if ova and embryos can be bought and sold between clinics and research institutions. Demand for embryos could translate into pressure on women undergoing IVF to donate ova or embryos specifically for research when having ova

---

[54] *Proceed with Care,* at 636, citing Australia, Senate Select Committee on the Human Embryo Experimentation Bill 1985. *Human Embryo Experimentation In Australia*, Canberra: Australian Government Publishing Service, 1986 para. 3.31.

[55] The *Warnock Report* echoes this thought "A further argument for the generation of embryos for research is that as the techniques of freezing become more successful there would be fewer spare embryos available for research." at 68.

[56] *NHMRC Guidelines,* Art. 6.5.

[57] The British HGAC advises that "there are likely to be increased proposals using CRT to create embryos for research" at para. 5.5.

removed for IVF.[58] Alternatively, clinicians might simply create more embryos than are necessary for treatment purposes to ensure a surplus.

Second, if the IVF supply ever were to dwindle, and creation of embryos for research purposes has been explicitly prohibited, it would be necessary to revisit the issue of creating embryos for research which could prove difficult both logistically and politically. Finally, since much hES cell research is aimed at the creation of tissues and organs to replace damaged or diseased tissues, it is likely that autologous tissue transplants will be the desired procedure to reduce risk of rejection in transplantation. This treatment would require the creation of embryos using the patients' genetic material. If this procedure is perfected, a prohibition on the creation of embryos would eliminate the possibility of autologous organ or tissue transplantation.

In light of the foregoing, the National Bioethics Advisory Commission ought to consider endorsing the use of spare embryos where possible, and to permit the creation of embryos for research where research is dependent on that creation to achieve its objectives, or in situations in which access to spare embryos is not possible. This does not fully address the concerns over possible coercion of infertility patients; these concerns require greater analysis and specific guidelines or recommendations.

Appropriate Uses of Human Embryos in Research

[58] The Canadian Royal Commission recognizes this by saying "Doing research on the zygotes could put women enrolled in IVF programs under pressure to consent to donate unused eggs or zygotes. This pressure could be

The search for appropriate limits in embryo research regulation can also be seen in the regulation of the scientific ends to which the research must be directed in order to be acceptable for funding or licensing. Upon examining international polices, it becomes clear that how a country determines the uses for which embryo research may be approved is a crucial issue when determining the implications for embryonic stem cell research.

Therapeutic and Non-Therapeutic Research

Confusion similar to that over the definition of "embryo" exists with respect to the definition of "research". Again, many countries simply do not define the term. A few countries draw a distinction between "non-therapeutic" and "therapeutic" research on embryos.[59] For example, the Australian *NHMRC Guidelines* define "therapeutic research" as "research aimed at benefiting the well-being of the embryo" and "non-therapeutic research" as research "not intended to benefit the embryo and which may or may not be destructive."[60]

This distinction results in part from the fact that in the field of ART there is considerable overlap between clinical practice and research. For example, research on new techniques for cryopreservation and fertilization has been used in clinical practice for years. It is difficult to draw a clear line between innovative clinical practice and research since much of this area is based on technologies which are new or developing. Both the Canadian Royal Commission

---

particularly acute if the creation of zygotes for research purposes were prohibited." *Proceed with Care* at 639.

[59] See the laws of France, Victorian *Infertility Treatment Act, 1995* at S.3 (1). and Australian *NHMRC Guidelines*.

[60] *NHMRC Guidelines* at vi.

and the Australian NHMRC note this overlap and recommend that innovative or experimental therapies fall under the rubric of research in this area in order to be regulated.[61]

The distinction between human embryo research which is therapeutic and that which is non-therapeutic is particularly unhelpful and should be avoided in the context of ART. The EGE and the Canadian Royal Commission have suggested that this distinction is not only unhelpful but may even be unethical. As the EGE suggests, some countries where the distinction is used:

> only allow an IVF embryo to be used for research if the research is intended for the benefit of that particular embryo, and if the embryo is subsequently replaced in the uterus. If there existed the possibility that procedures might damage the embryo, this would amount to experimentation on the fetus or the baby and mother, and would be clearly unethical.[62]

The Canadian Royal Commission echoes this view:

> [T]he only way to develop therapeutic embryo research is to allow for some non-therapeutic embryo research. Allowing therapeutic research while at the same time prohibit non-therapeutic research would not be workable, nor would it be ethical, because of the risks it would create for women and children.[63]

Drawing distinctions between appropriate and inappropriate uses of human embryos, such as the distinction between therapeutic and non-therapeutic research is emblematic of the ambivalence about the permissibility of human embryo research.

Therapy Unrelated to Human Reproduction: Primordial Stem Cells

[61] *NHMRC Guidelines* at iv. *Proceed with Care,* at 614.
[62] *EGE Opinion*.
[63] *Proceed with Care,* at 614.

As most policies or laws regulating embryo research are directed at regulating ART, the closer the relationship to human infertility and reproduction, the more acceptable the research is likely to be regarded. Many countries sanction embryo research aimed at:

- Improvement of infertility treatments
- Development of contraceptive technologies
- Improvement of detection of genetic/chromosomal anomalies in embryos before implantation
- Advancement of knowledge about congenital diseases, causes of infertility and human development

Conversely, the more attenuated the relationship to human infertility the more controversial the research. So, for example, where research is aimed at therapeutic approaches to disease or tissue damage, many laws or policies make no provision for these uses, particularly as most policies or acts are specifically directed at reproductive technologies. This lacuna is also a function of recent scientific developments; possibilities like those presented by primordial stem cell research were not envisaged when most of the acts were drafted.

The British HFE Act, arguably the most liberal act, makes no explicit provision for research of this sort. However the British provided a mechanism to add research not currently available for licensing through amendment of the regulations to the Act. Consequently, the Human Genetics Advisory Commission/Human Fertilisation and Embryology Authority (HGAC/HFEA) statement of December, 1998 states:

> [W]hen the 1990 HFE Act was passed, the beneficial therapeutic consequences that could potentially result from human embryo research were not envisaged. We therefore recommend that the Secretary of State should consider specifying in regulations two further purposes to be added to the list [of approved purposes], being:
>
> - developing methods of therapy for mitochondrial diseases
> - developing methods of therapy for diseased or damaged tissues or organs.[64]

In addition, the HGAC/HFEA specifically recommends permitting research of this sort, advising that it would be unwise to rule out absolutely research using Cell Nucleus Replacement (CNR) involving embryos "that might prove of therapeutic value."[65]

The Australian Academy of Science (the Academy) issued a position statement *On Human Cloning* on February 4, 1999. This statement is aimed at distinguishing between "*reproductive cloning* to produce a human fetus" and "*therapeutic cloning* to produce human stem cells, tissues and organs."[66] The Academy, which speaks for the Australian scientific community, states that the reproductive cloning of humans is unethical and should be prohibited but that it must be distinguished from therapeutic cloning which holds the potential of "great benefit to mankind."

> For Australia to participate fully and capture benefits from recent progress in cloning research, it is necessary to review the [*NHMRC Guidelines*] and repeal restrictive legislation in some States. This could be done in the context of establishing a national regulatory arrangement, taking into account recent advances in biomedical research and advocated best practice elsewhere. Human cells, whether derived from cloning techniques, from ES cell lines or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology.[67]

---

[64] *HGAC/HFEA Statement* at para. 9.3.
[65] *HGAC/HFEA Statement* at para. 5.4.
[66] Australian Academy of Science, *On Human Cloning: A position Statement*, 4 February, 1999 [hereinafter *On Human Cloning*] at 4.
[67] *On Human Cloning*, at 5.

The Academy goes on to recommend that, "if Australia is to capitalise on its strength in medical research, it is important that research on human therapeutic cloning is not inhibited by withholding federal funds or prevented by unduly restrictive legislation in some States." The recommendations also suggest that primordial stem cell research should be subject to a two-tiered regulatory approval process, passing a local ethics committee and then requiring national approval.

The World Health Organization *Draft Bioethics Guidelines, 1999* also assert that the use of cloning techniques for non-reproductive means should not be foreclosed:

> As recognized by the World Health Organization, non-reproductive, in vitro cloning research, with the clinical objective of repairing damaged tissues and organs has important potential benefits. Relevant animal research would be acceptable provided it was carried out in accordance with the CIOMS ethical guidelines on the use of animals in biomedical research. Guidelines addressing the possible involvement of human gametes or embryos must be developed.[68]

The German *Embryo Protection Act, 1991* also protects human embryos from harmful research. However, unlike the Australians, in discussing the use of hES cells, the German government came to the conclusion that there was no need to relax the strict embryo protection laws to permit hES research, since hEG cell research is permitted under laws relating to the use of fetal tissue.[69] This is, of course, an option open to the National Bioethics Advisory Commission, however, whether significant research differences exist between hES and hEG cells is not currently known.

[68] World Health Organization Draft Bioethics Guidelines Art. 28. [hereinafter *WHO Draft Guidelines*].

Perhaps the most interesting statements directly on the use of primordial stem cells are those which issue from the French statement on bioethics. The French have banned non-therapeutic human embryo research, which effectively bans all research. Since destruction of human embryos is not possible, creation of embryonic stem cell lines is also not possible. The French National Commission says the following:

> We are approaching a paradoxical situation as a result of legislation: … experimentation or therapeutic research on [stem cells] from embryos *in vitro* are banned, but it is possible to import cells from collections established without any observance of specific ethical law applicable in France to embryonic cells.

The French commission has suggested that, taking into account the prospects for therapeutic research, the ban may be modified this year when the existing law is up for review to permit hES cell research.

A similar paradox exists in the United States. In this country there is a ban on federal funding for research which would destroy an embryo, which therefore, bans funding for the creation of hES cell lines, but permits the uses of hES cell lines created without reference to national protections and oversight. The National Bioethics Advisory Commission should take steps toward eliminating this paradoxical situation and outline a consistent set of protections with national application. There is room for leadership on this issue both here and around the

[69] DFG *Statement concerning the question of human embryonic stem cells*, March 1999.

world - other counties will be watching the response of the National Bioethics Advisory Commission on this issue.[70]

Prohibitions on Human Embryo Research

One of the most important facts that can be gleaned from an examination of international embryo research polices is that near unanimity exists with respect to practices that should be prohibited as unethical. The following practices are widely regarded as unacceptable and many are deemed to be offensive to human dignity:

- Cloning for reproduction

All the countries under examination have prohibited the use of cloning techniques for the purposes of human reproduction either in law or in policy recommendation.[71]

- Creation of hybrids/chimeras (also described as cross-species fertilization)

There is ambiguity over whether the prohibition on creating hybrids and chimeras refers to the creation of individuals or embryos. For a number of years hamster ova have been fertilized with human sperm as a test for human sperm motility. It can be argued, therefore, that it is the creation of hybrid or chimeric *individuals* which is the prohibited

[70] *EGE Opinion* at 12.

practice prohibited. However, there are a number of countries which explicitly exempt the fertilization of hamster ova from the prohibition which would indicate that creation of all other hybrid embryos is prohibited.[72] This issue remains unclear, but given the conservative legislation in many countries, it is arguable that any creation of hybrid embryos would be considered unethical and therefore, prohibited in many countries.

- Cross-species implantation
- Germline interventions
- Sex-selection for other than prevention of hereditary disease

All three of these prohibitions are widely adopted in the countries under examination and in international organization statements.[73]

- Transfer of embryos used in research into a woman

This practice is clearly unacceptable as it would amount to conducting research on women and any resulting children.

- Commercialization of embryos/gametes

---

[71] For a comprehensive account of current legal and policy statements prohibiting the cloning of human beings for reproduction see Elisa Eiseman, *Cloning*, RAND, 1999.

[72] The *Warnock Report*, expressly exempts the use of cross-species fertilization for the purposes of alleviating infertility or assessment of subfertility, from the prohibition on creation of hybrids, at 71.

[73] See Council of Europe, *Convention on Human rights and Biomedicine* (1997): "An intervention seeking to modify the human genome may only be undertaken for preventative, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." Article 13; "The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a futures child's sex, except where serious hereditary sex-related disease is to be avoided." Article 14 [hereinafter the *Convention on Human rights and Biomedicine*]; *WHO Draft Guidelines*, "Sex is not a disease. Except for severe sex-linked genetic disorders, the use of genetic services for the purpose of sex-selection is not acceptable."

Most countries also abhor the commercialization of embryos and fetal tissue: this has lead to prohibitions on sales of ova, sperm, and embryos (both nationally and internationally)[74] fetal tissue[75] and a recommendation that research on embryos not be conducted for commercial gain. In fact, the *WHO Draft Guidelines* suggest that countries which have not already done so should take steps to regulate the patenting of genetic materials and life forms, in keeping with the stated guiding principle that:

> Patents are designed to protect intellectual property and stimulate innovation and they are part of the product development process. The private sector, however, also has public responsibilities. A balance must be sought between the need for patent protection and the obligation to ensure society's access to the health benefits of new knowledge and technology.

With respect to the use of primordial stem cells which are already subject to patent protection the issue is particularly complex. The French National Ethic Committee Opinion on embryonic stem cells notes that prohibitions exist on the sales and patentability of embryonic and fetal cell collections, but not explicitly on embryonic stem cell collections. Given the strong endorsement of the principle of non-commercialization of genetic and reproductive materials it is likely that many countries will extend these prohibitions to embryonic stem cells. However, in the United States where private research is often funded by pharmaceutical companies lured by lucrative patent rights this provides a complex and difficult area of regulation. The British *HGAC/HFEA* expresses this tension:

> A significant number of respondents expressed fears and reservations about the possible commercialization of therapeutic uses of [cloning] techniques…. There is an

[74] *NHMRC Guidelines,*. Art. 11.9 "Commercial trading in gametes or embryos (is prohibited)", S. 11.10 "Paying donors of gametes or embryos beyond reasonable expenses (is prohibited)." *Convention on Human rights and Biomedicine,* Art. 21. Loi 96-327 16 April 1996 extending the principles of non-commercialization and non-patentability to human embryo cell collections. In Canada, the non-commercialization of reproduction is listed as a guiding principle to the Royal Commission's report, *Proceed with Care,* at X.

[75] World Medical Association, Statement on Fetal Tissue Transplantation, Adopted by the 41t World Medical Assembly, Hong King September, 1989 [hereinafter *WMA Fetal Tissue Transplantation Statement*]

> understandable desire on the part of the public that curative process should not simply be exploited as sources of financial gain for their developers, but that there should e respect for the public good and corresponding access to these techniques for those who would benefit from the. A balance has to be struck between affording a reasonable recompense to those who have exercised initiative … and ensuring that the needs of the sick are properly met. They system of patenting is intended to provide a degree of such safeguard, for it requires that knowledge relevant to the new invention is available in the public domain, whilst granting the discoverer a limited period of protected benefit.[76]

While the issue of recommending specific changes to the United States patenting system is beyond the scope of the National Bioethics Advisory Commission's current mandate with respect to primordial stem cells, the issue of patenting of human body materials needs to be revisited and modified in the United States.

- Use of fetal eggs and eggs from female cadavers

This prohibition is discussed below in the context of prohibitions on the use of fetal tissue for research.

USE OF FETAL TISSUE IN RESEARCH

The use of fetal tissue to isolate hEG cells is less problematic than the similar use of human embryos for three reasons. First, the removal of the fetal germ cells does not occasion the destruction of a live fetus. Secondly, there is no question of creating fetal tissue for research. Thirdly, the use of fetal tissue to develop therapies for people unrelated to

[76] *HGAC/HFEA*, para. 5.11.

reproduction has been raised before in the context of fetal tissue transplantation, and therefore a number of laws and policies exists regarding this use.[77]

The fact that fetal tissue can only be derived from aborted fetuses means that the ethical dilemma which marks the debate on the permissibility of using fetal tissue in therapy is the issue of complicity with the abortion. Due to the ferocity of the abortion debate in the United States, legal restrictions were enacted which blocked the use of fetal tissue in research on transplantation therapy. The only permissible source of tissue for such research was tissue from spontaneously aborted fetuses or ectopic pregnancies. As little of that tissue proved suitable for such research, the ban on using other aborted fetal tissue effectively ground that research to a halt.

In 1993, President Clinton lifted the ban on the use of fetal tissue from elective abortions for fetal tissue transplantation research. Consequently, there are no legal prohibitions which would inhibit the use of that tissue for hEG cell research.[78] In addition, there is considerable agreement in the international community that the use of fetal tissue in therapy for people with diseases, such as Parkinson's disease is acceptable.

[77] See note 3 page 2.

[78] Use of fetal tissue in research is also permitted in Canada, the United Kingdom, Australia, and in most countries in the European Union. German, for example which permits no embryo research and permits the use of fetal tissue for the derivation of germ cells. The DFG statement concerning human embryonic stem cells upholds the ban on destructive embryo research effectively banning the derivation of hES cells because the option of deriving hEG cells exists in that country. See DFG Statement concerning question of human embryonic stem cells, March 1999 at 8-10.

Policies which address the use of fetal tissue for therapy indicate consensus exists with respect to the following:

Guiding principles:

- Respect for human life
- Respect for the woman's dignity and integrity

Limitations:

- A final decision to terminate pregnancy is made before initiating discussion of possible donation of the fetal tissue for use in transplantation

Clearly, with respect to hEG cell research the same restriction should be in place. A woman's decision to terminate her pregnancy should be neither induced nor coerced by the possibility that the resulting fetal tissue can be used for research or therapy which will benefit others.

- Informed consent
- Establishment of a regulatory and licensing scheme[79]

The establishment of a regulatory scheme which licenses the use of both fetal and embryonic tissue in research has been suggested with respect to primordial stem cell research.[80]

[79] See for example *Tri-Council Policy Statement* at 9.4.

Prohibitions

- Donation of the tissue to a designated recipient

The prohibition on directed donation reflects a fear that women will get pregnant and seek abortions with the aim of donating the fetal tissue to a loved one or relative in need of fetal tissue for therapy. Although this largely misunderstands the motivations of women making choices to terminate pregnancies, it is not outside the realm of possibility some situations of this type could arise. Consequently, to avoid this scenario many countries have foreclosed the possibility by removing the woman's ability to designate that a particular person receive the tissue donated for therapy.

The WMA Fetal Tissue Transplantation Statement nicely sums up the ethical justifications for the above limits and prohibitions:

> Prominent among the currently identified ethical concerns is the potential for fetal transplants to influence a women's decision to have an abortion. These concerns are based, at least in part, on the possibility that some women may wish to become pregnant or the sole purpose of aborting the fetus and either donating the tissue to a relative or selling the tissue for financial gain. Others suggest that a woman who is ambivalent about a decision to have an abortion might be swayed by arguments about the good that could be achieved if she opts to terminate the pregnancy. These concerns demand the prohibition of: (a) the donation of fetal tissue to designate a recipient; (b) the sale of such tissue; and c) the request for consent to use the tissue for transplantation before a final decision regarding abortion has been made.[81]

- Commercialization of Fetal Tissue

Most countries explicitly prohibit the commercialization of human fetal tissue. The Canadian Royal Commission states that the non-commercialization of reproduction is one of their

---

[80] *NHMRC Guidelines*

guiding principles. They recommend that no for-profit trade be permitted in fetal tissue and recommend that the "prohibition on commercial exchange of fetuses and fetal tissue extend to tissues imported from other countries."[82] This prohibition is in place to prevent the exploitation of poor women, especially in developing countries, who might be persuaded to begin and end pregnancies for money.[83] With respect to patenting the Royal Commission states,

> Commissioners believe strongly that fetuses should never be an appropriate subject for patents. However, if they are intended to benefit human health and if the safeguards we have recommended for obtaining and using fetal tissue are in place, innovative products and processes using fetal tissue as a source may warrant some limited form of patent protection.[84]

This limited patenting protection should be considered with respect to primordial stem cells and other living tissue patenting, especially patents involving reproductive tissue.

- Use of fetal eggs

Both Australia and Canada have both prohibited the use of fetal eggs for the creation of embryos[85], as the Canadian Royal Commission states:

> We would object strongly to fertilisation of eggs obtained from female fetuses, even if it becomes technically feasible to retrieve and mature them. We find this suggestion deeply offensive to all notions of human dignity and have recommended that it be among the activities prohibited outright in the *Criminal Code* of Canada.[86]

---

[81] *World Medical Association Statement on Fetal Tissue Transplantation.*
[82] *Proceed with Care,* at 1003.
[83] *Proceed with Care,* at 1001.
[84] *Proceed with Care,* at 1003.
[85] Australia, S. 11.4
[86] *Proceed with Care,* at

By contrast the United Kingdom HFE Authority has stated that creation of embryos from fetal eggs, if acceptable, could provide unlimited sources of hES cells.[87]

It is likely that the use of fetal eggs would be unacceptable to the majority of Americans; including not only those who oppose the use of fetal eggs, but also those Americans opposed to the creation of embryos for research and of course, those who oppose embryo research at all. If adequate safeguards are in place for the creation of embryos for research, there are good policy reasons to argue that the use of fetal eggs should be prohibited.

Conclusion

Primordial stem cell research offers the potential for life-saving technology. Restricting research, therefore, on these cells has both scientific and moral costs; such restrictions must not be imposed in ignorance of the costs involved. Deriving hES cells means sanctioning the destruction of human embryos for that purpose. This action also has moral costs. With respect to the derivation of hEG cells, the use of human fetal tissue is less controversial. Although human fetal tissue is obtained from aborted fetuses, the process of deriving the hEG cells is not itself implicated in the death of the fetus and is legally sanctioned.

[87] Check Interim Authority report.

The possibilities presented by primordial stem cell research serve to illustrate the great need for comprehensive and thoughtful regulation of ART in the United States. Although the National Bioethics Advisory Commission has not been asked to undertake that task, it is clear that the recommendations of the Commission with respect to primordial stem cell research must be designed with reference to the regulation of human embryo and fetal tissue research. Consequently, the recommendations made by the Commission will also lay the groundwork for regulation of embryo research and fetal tissue research in the United States. This is a great responsibility.

Commonalities in international policies on human embryo and fetal tissue research clearly exist. Countries with different religions and with diverse social and cultural backgrounds share views on the principles and strategies which should guide regulation of this research. Much can be gained from following the lead of those countries who have examined these issues with in-depth public and scientific consultation.

Those responsible for developing policy in this area need to address the rapidly changing techniques in genetics and ART. The *WHO Draft Bioethics Guidelines* state:

> Hurried and premature legislation in the rapidly-evolving field of genetics can be counterproductive. Legislation and guidelines should be based on full and sound scientific and ethical assessment of the techniques concerned. They should be general enough to accommodate new developments, and the should be reviewed periodically. [88]

[88] at Article 6

It is imperative to provide mechanisms for accommodating change within the regulatory structure, and to anticipate the wider application of human embryo research by looking at the state of relevant animal research. The need to anticipate changes within the near future is crucial; the goal is to build a framework which anticipates rather than reacts.[89]

[89] *Proceed with Care*, at X.