ANNEX G

WRITTEN SUBMISSIONS TO HUMAN STEM CELL RESEARCH (HSR) CONSULTATION PAPER

A. MEDICAL AND HEALTH ORGANISATIONS

1. National Arthritis Foundation
2. Singapore Dental Association
3. Obstetrical and Gynaecological Society of Singapore

B. RELIGIOUS GROUPS/ORGANISATIONS

The Inter-Religious Organisation of Singapore ('IRO') obtained views from the Hindus, Taoists, Roman Catholics, Sikhs, Bahai faith, Jewish faith:

1. Hindu Endowments Board *(submitted under the IRO)*
2. Taoist Mission (Singapore) *(submitted under the IRO)*
3. St. Anthony's Canossian Convent *(submitted under the IRO)*
4. Sikh Faith view *(submitted under the IRO)*
5. The Spiritual Assembly of the Baha'is of Singapore Ltd *(submitted under the IRO)*
6. The Jewish Welfare Board *(submitted under the IRO)*
7. Singapore Buddhist Federation
8. The Catholic Medical Guild of Singapore
9. National Council of Churches of Singapore
10. Singapore Council of Christian Churches
11. Majlis Ugama Islam Singapura

C. PROFESSIONAL GROUPS

1. Law Reform Committee, Singapore Academy of Law
2. The Law Society of Singapore
3. Singapore Hospice Council
4. Singapore Medical Association
5. Singapore Medical Council
6. Singapore Nurses Association
7. Singapore Nursing Board

D. SCIENTIST/RESEARCHER GROUPS

1. Biomedical Engineering Society (Singapore)
2. Science Teachers Association of Singapore
3. Singapore National Academy of Science
4. Singapore Society for Biochemical and Molecular Biology

E. OTHER

Personal View from an IRO member *(submitted with the IRO response)*

A. MEDICAL AND HEALTH ORGANISATIONS

1. National Arthritis Foundation
2. Singapore Dental Association
3. Obstetrical and Gynaecological Society of Singapore

19 December 2001

Professor Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

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#06-302
New Bridge Centre
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Website: www.arthritis.org.sg

Dear Prof Lim Pin

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

I refer to your letter dated 8 November 2001 regarding the above.

The National Arthritis Foundation thanks you and your Committee for asking our views. This matter was tabled at our regular Executive Committee meeting on 13 December 2001.

The members concur very much with the views of the Bioethics Advisory Committee as laid out in your statement. We are mindful of the great potential of Stem Cell Research in terms of therapy of certain diseases but at the same time, controls and guidelines need to be in place.

The Foundation will support in full any measures the Bioethics Advisory Committee feel necessary in the context of Singapore's religious, patient, medical and scientific organisations and groups.

With best regards

Yours sincerely

Prof Feng Pao Hsii
Chairman
National Arthritis Foundation

SINGAPORE DENTAL ASSOCIATION

15th December 2001

Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101
Attn: BAC Secretariat

Dear Prof. Lim

Re: Feedback on Human Stem Cell Research in Singapore

There are numerous issues involved in embryonic stem cell research. Aside from the push from some scientific communities towards less impediment in research on embryonic stem cells, and our government is also pushing for developing biotechnology as a cornerstone of our future economy. We need to struck a suitable balance between ethics and relentless pursuit of science.

An embryo has all the innate potential to be a viable being. Many questions and issues must be answered before attempts to conduct any experiments on any embryo.

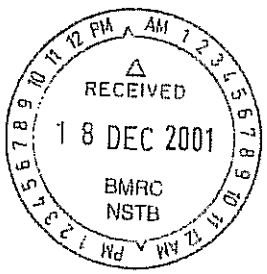
1) It is preferable for us to avoid having to work on embryos for the purpose of obtaining stem cells.

2) Although it is proven to be more difficult, emphasis or added effort should be applied to explore other methods to source for stem cells.

3) If a decision is made to use embryos as a source of stem cells then air-tight controls must be in place to ensure an absolutely transparent and acceptable protocol in sourcing for suitable embryos.

Yours faithfully,

Dr Chung Kong Mun
Singapore Dental Association
Committee Member



2 College Road, Singapore 169850 Tel: 2202588, FAX: 2247967
E-mail: sda@pacific.net.sg Website: http://www.sda.org.sg

Obstetrical & Gynaecological Society of Singapore
Unit 8K38 (Level 8), Women's Tower
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e-mail: ogss@pacific.net.sg

30 November 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road #15-01/02
Raffles City Tower
Singapore 179101

Dear Prof Lim,

Request for Feedback regarding Human Stem Cell Research in Singapore

Thank you for your letter dated 8 November 2001, inviting our society (The Obstetrical & Gynaecological Society of Singapore - OGSS) to give our feedback.

Within the short span of time given, our society has circulated the BAC paper among our over 300 members to invite written comments and has conducted a meeting for members to air their views.

With regards to the positions on research of adult stem (AS) cells and on reproductive cloning, the views of those who expressed themselves in written comments or in the meeting thus far, are in general agreement with BAC. We are generally thus far, for research of adult stem cells but are not in favour of reproductive cloning.

However with regards to the views on research of embryonic germ (EG) cells, on research on early embryos < 14 days old and on therapeutic cloning, the members of our society have differing (for, neutral or against) views, reflecting the diversity of opinions among our members. This would not be surprising, considering that our members, though professionals (mainly obstetricians/gynaecologists as well as obstetricians/gynaecologists in training, scientists and doctors) have differing backgrounds in terms of age, sex, race and religion. Our members also have differing views on abortion. A number of our members have conscientious objection to participate in treatment to terminate pregnancy under the Termination of Pregnancy Act, Singapore. We are therefore unlikely or rather it is impossible to forge a consensus opinion

on these 3 issues among our members, especially when developments within these issues are also rapidly evolving in the whole world.

It is timely that the BAC is looking closely at issues involving stem cell research in Singapore. We feel that there would be a constant need to review recommendations, policies and regulations in human stem cell research, in view of the very rapid developments in this area, around the world.

We will compile and send you the comments from individual OGSS members or groups of OGSS members once we have the consent from them within 2 weeks.

Yours sincerely

Dr Tan Kok Hian, Kelvin
President

ogss/letter/149

Obstetrical & Gynaecological Society of Singapore
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15 December 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road #15-01/02
Raffles City Tower
Singapore 179101

Dear Prof Lim Pin

Human Stem Cell Research in Singapore Feedback - follow-up letter

Thank you for your letter of 4 December 2001. As mentioned in our letter of 30 November 2001, we are attaching the views of the 5 OGSS members who gave written submission.

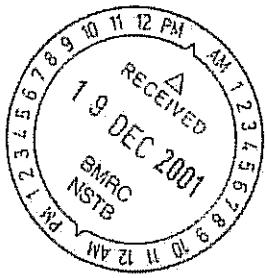
We are also attaching the results of a simple survey (including the survey form), which was sent to 300 of our members on 5 December 2001 for them to air their views. A total of 58 OGSS members responded within a week and the results of these early respondents were compiled.

We would not be requesting for a dialogue session but would be pleased to answer further queries you may have.

Thank you and warm regards. Merry Christmas!

Yours Sincerely,

Dr Tan Kok Hian Kelvin
President



Reply to the BAC Position Paper on Stem Cell Research

The progress in stem cell research has brought with it new hopes in the treatment of diseases, tissue regeneration and engineering. This will bring about significant changes in the management of clinical diseases. Should this form of therapy become a reality, national security should be considered and Singapore should not fall behind in this biotechnology frontier. Since we already have a head start with the development of embryonic stem cell lines, it would be imperative to develop research in differentiation of these stem cell lines for therapy and we appreciate the BAC's stand allowing research using embryos up to 14 days for this purpose. This is similarly approved in the United Kingdom.

The use of fetal germ cell lines for the production of stem cells should come under strict regulations that also apply to fetal tissue transplantation. Consent for termination of pregnancy should be independent of the creation of stem cell lines. Thus, it would be imperative that cadaveric fetal tissue and embryos should not be bought or sold for research purposes.

We certainly support the concerns of the BAC with regard to reproductive cloning and agree that this should not be allowed in Singapore. However, it is indeed an enlightened opinion to allow the use of therapeutic cloning to produce embryos from nuclear transfer for production of stem cells. As there can be a potential move from therapeutic to reproductive cloning, we feel that the ethical approval for such research work should come under a common body (eg. BAC) which would also facilitate close monitoring of such activity and the enforcement of guidelines. If the ethical approval for research work involving nuclear transfer and stem cell production is decentralised to the various funding bodies, active monitoring and policing may not be as efficient.

Prospective donors of embryos for stem cell research should receive timely, relevant and appropriate information to make informed and voluntary choices regarding the disposition of their embryos. They should also be given the equal options of storing the embryos for their own future use, donating them to other women or discarding them. Information sheets and appropriate consent forms could be drafted by the BAC for common use in the various assisted reproduction centres in Singapore.

We feel that the need for national oversight and review of human stem cell research is crucial. This body would serve to constantly review the ethical and legal issues and ensure strict adherence to guidelines and standards in the country. A registry of approved research projects, facilities and established stem cell lines should be kept and monitored.

It is indeed timely that the BAC has been set up to look closely at issues involving stem cell research. We applaude the painstaking efforts that the BAC has taken in culling a variety of opinions on this issue. With your guidelines, we hope that stem cell research in Singapore can be taken to new heights.

Dr Christine Yap
OGSS Member
22 Nov 2001

Founded 1905

THE NATIONAL UNIVERSITY *of* SINGAPORE

Department of
Obstetrics & Gynaecology

22 November 2001

Dr Tay Eng Hseon,
Honorary Secretary,
OGSS,
C/o KK Women's & Children's Hospital,
Unit 8K38 (Level 8), Women's Tower,
Singapore 229899

Fax: 65-229-1969

Dear Eng Hseon,

FEEDBACK: HUMAN STEM CELL RESEARCH IN SINGAPORE

I write in response to your letter of 16 Nov 2001 regarding the BAC's paper on the above.

It is a measured and balanced opinion on this very fast-expanding field. I support the conclusions made in the document. I must also state that I was in the sub-committee that prepared the background paper for the BAC, though I was not in the Committee that proposed the final draft.

To prevent abuse (especially to prevent human reproductive cloning) I support the need for a watch-dog body with adequate disciplinary powers. How this is formed and the composition of this body needs to be carefully thought-out. Reproductive cloning should be allowed for other species, especially in wildlife conservation, agricultural animals and animals of high value (eg pets, and race-horses).

Therapeutic cloning has tremendous potentials, and should be allowed. It is likely that it will blossom into a new life-science industry for Singapore. Hence, allowing it will be beneficial to Singapore's survival in a highly competitive world. Ethically, there is still an intermediate stage where embryos are created. But just as unwanted extra human embryos from IVF programs are allowed to be used for the generation of embryonic stem cells, they should be allowed to develop stem cells that are genetically from the donor, to be used by the donor ("autologous" use).

Yours Sincerely,

Ng Soon Chye, MD, FRCOG,
Professor.

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KK WOMEN'S
AND CHILDREN'S
HOSPITAL

22 November 2001

Dr Kelvin Tan
President O&G Society
Singapore

Dear Dr Kelvin Tan

RE: FEEDBACK ON PAPER ON HUMAN STEM CELL RESEARCH

Thank you for asking our feedback.

1. Personal

I am of the opinion that the paper that has been prepared has been carefully done. They contain current views of world experts in the field concerning the matter. Also, I was happy to note the conservative stance of the committee. This reflects our Singaporean multi-ethnic and multi-religious society with our own convictions on ethical standards.

I would not agree on obtaining stem cells from embryos, but would not oppose others who would. I would agree with a suggestion in the Forum page that we should research more into umbilical cord stem cells; also adult stem cells. The processes to encourage proliferation and usefulness of the latter two types of stem cells have yet to be exhausted.

With our existing system of reporting on IVF and other ART procedures, it should not be difficult to incorporate details of reporting stem cell research and its outcome to the central repository. This would provide for public accountability.

2. OGSS stance

Although time is short, it would be good to have a debate on paper by interested members from the Society, especially from the O&G departments from NUH, SGH and KKH. We could also ask Prof Arif Bongso to speak of his experience and discovery. Following this we could then collate personal replies as well as conclusions arising from the debate. We would then have an OGSS stand on human stem cell research.

Best wishes,

Yours sincerely,

Dr Lawrence Chan

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VIEWS ON HUMAN STEM CELL RESEARCH

Embryonic stem cell (hES) lines derived from the inner cell mass of blastocysts holds promise of tremendous benefits to mankind.

SCIENTIFIC VIEW: From the scientific point of view, I would encourage research on hES cells because research on ES cells would lead to the cure of many diseases human beings suffer from. Research should be carried out using the existing stem cell lines. Since the existing lines are derived using mouse feeder layers, there is concern about virus and genetic contamination of ES cells. Whether the final product derived from such cell lines can be used for human transplant (Xenograft) should be addressed clearly. This is not allowed in the USA.
If the existing stem cell lines cannot be used due to the above reason or due to other reasons such as immuno-rejection, which necessitates the use of more embryos to produce new stem cell lines, then strict monitoring is required. Institutes, particularly fertility centres should seek the permission of BAC after obtaining consent from the patient who donates embryos for such purpose and necessary documents must be in place.

ETHICAL VIEW: Human oocytes after fertilization form zygotes, which in turn form embryos and blastocysts on day 5 or 6 after which the inner cell mass are used to derive the ES cells. From the time of fertilization, zygotes are considered as a living being. It deserves moral attention and is considered as having the potential to become a human being. However the neural tube develops after 14 days of its life, it doesn't feel the pain until then. In Singapore, according to the guidelines to practice IVF, research can be carried out on embryos until 14 days and similar guidelines should be place for ES cell research with strict monitoring on the use additional embryos for research. My views are not in favour of any kind of research on human cloning.

Dr. Christopher Chen
O & G Society Member

23 Nov 2001

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Fax Cover Form (Medical Data) – Medical In Confidence

To: A/ Kelvin Tan / Fay EH
OTC Society

Fax: 299 1969
Date / Time: 29 Nov 2001

Number of Pages (including this page) – 7

MESSAGE: STEM CELL RESEARCH FEEDBACK

Dear Kelvin / Hoon .

Thanks for taking the time to read this.

I would greatly appreciate your support on this feedback. As you know the Bioethics Advisory Committee has asked for feedback on stem cell research. They have also asked the O&G Society for feedback. I intend to send this letter to both OGSS as well as direct to BAC.

The essence of this paper is that it :

a) Approves and supports adult stem (AS) cell research
b) Is neutral about embryonic germ (EG) cell research
c) Is against embryonic stem (ES) cell research
d) Endorses Bioethics Advisory Committee stand against all forms of reproductive cloning
e) Is against any form of therapeutic cloning
f) Requests government oversight on stem cell research
g) Requests information to be open to public scrutiny
h) Endorses the right of the embryo as a human being regardless of stage of development

I would appreciate your help in the following ways:

a) If you are an OBGYN, to allow me to append your name and MCR to the letters to OGSS and to BAC
b) If you are non OBGYN to allow me to append your name and MCR to the letter to BAC.

Grateful for your support. My personal thanks.

Doug

IMPORTANT - Please call us if you have received an incomplete fax :

28 November 2001

Dr Tay Eng Hseon
Honorary Secretary
Obstetrical & Gynaecological Society of Singapore
C/o KK Womens and Childrens Hospital
Unit 8K38 Womens Tower
100 Bukit Timah Road
S'pore 229899

Dear Dr Tay,

Human Stem Cell Research in Singapore - Feedback

Thank you for your letter inviting feedback from members on this subject.

The subject of stem cell research and human cloning is without doubt one of the most divisive and contentious issues to face our generation. We are profoundly aware of the diverse and strongly held views and would like to share our personal insights.

With specific reference to the consultation paper issued by the Bioethics Advisory Committee (BAC), we have the following points to raise:

1) We recognize that genuine steps have been taken by the government to assure appropriate dialogue and feedback. In particular we welcome the establishment of a watchdog body with no conflicting interest in the development of stem cell research. We appreciate their work and time invested thus far.

Ethical and Social considerations:

2) We welcome the BACs view of "the special status of an embryo as a human being". While we should support research that can ameliorate and ultimately cure disease, we need to start from the premise that those who are seen to hold the key to these problems are fellow human beings with inherent worth.

3) However, BAC takes the view "that it is justified to use early embryos, not more than 14 days old" based on the principle that "human embryos which are less than 14 days old have no pain or sentience".

    a) This view, propagated in the UK Warburg Report of the late 1970s was even at that time held to be controversial and was seriously challenged. Despite objections, it was used as the basis for the UK Human Fertilisation and Embryology Act 1990. Nonetheless it has been since been accorded the dignity of time. In light of scientific advances, it would be appropriate to re-examine, challenge and debate this relatively old piece of research which many countries have since adopted as fact.

    b) The use of pain as a means of differentiating the value of life is fallacious and worthy of condemnation. Taken *in extremis*, persons born with congenital absence

Further, absence of pain does not mean absence of life. Plants are undoubtedly alive. Gametes are undoubtedly alive. In the same vein, embryos less than 14 days old are undoubtedly alive.

c) We hold the view that life is a continuum.

In 1994, the chief scientist advising the NIH Human Embryo Research Panel on modern embryology testified "that human development is a continuum from the moment when the nuclei of sperm and egg combine in the new embryo".

4) Rights of the embryo – BAC has drawn its position widely from many countries "including the UK, USA, Australia, New Zealand, Israel and Japan". In particular, embryo protection is addressed in extensive reference to the Human Fertilisation and Embryology Authority (HFEA) in the UK.

a) While authoratitive in its derivation, the list is not exhaustive. We would like to draw BAC's attention to other position papers:

i) UNESCO's *Universal Declaration on the Human Genome and the Protection of Human Rights* maintains that: "no research applications should be allowed to prevail over the respect for human dignity and human rights, in particular in the fields of biology and genetics."

A universal declaration, when adopted, is an international statement of principles that eventually may become part of customary law and so have force of law, but *ab initio* serves a hortatory function and is meant to guide nations in their domestic legislation.

ii) Council of Europe –

In 1996, the Council of Europe (40 countries) *Convention on Human Rights and Biomedicine* stated "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."[1]

In 1990, the Council also stated in its preamble to *Medical Research on Human Beings* that "medical research should never be carried out contrary to human dignity."[2]

In 1989 the Council, in their *Recommendation on the Use of Human Embryos and Fetuses in Scientific Research* provided that "the removal of *cells*, tissues, or embryonic or fetal organs, or of the placenta or the membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited"[3]. This last statement is relevant as it addresses the issue of removal of cells from human embryos

At the international level, then, there is no doubt that respect for human dignity and respect for the intangibility of the human body, its constituent parts, reproductive tissues, and even down to the cell(s) are irreparably linked.

b) The BAC correctly points out that "disagreements arise regarding ... what form such respect (of human life) should take and what level of protection is required". These references make a clear stand from broad based groupings such as the UN and Council of Europe - as opposed to views from individual countries.

c) We note that no reference has been made to any of the countries where embryo research is banned or severely restricted. Four countries prohibit experimentation with fertilized eggs (Norway) or with human embryos (France), or experiments which have as their purpose "developing methods for achieving potentially hereditary genetic effects" (Sweden), that is, to "develop certain characteristics" (Switzerland). Such policies should also be examined to provide some balance to BAC's work.

d) We hold the view that the embryo deserves the full protection of society because of its moral status as a person. There is no such thing as a "potential human being" inasmuch as one cannot be "slightly pregnant".

Research on AS (Adult Stem) cells

5) We agree completely with BAC's stand that there should be no ethical objections to AS cell research.

Research on EG (Embryonic Germ) cells

6) BAC correctly states that "there are no new ethical issues arising from the use of such cells so long as the decision taken to abort is taken separately and independently from the decision and consent to extract EG cells".

We do not condone abortion. However, for persons who choose to abort their child, in this respect we are in agreement. We hope that requirements for donation of cadaveric fetal tissue for research should be clearly spelt out. In particular, these should address the issues of:

a) Assurances that there are no inappropriate incentives in the decision to abort.
b) Assurances that there are no direct therapeutic incentives to create or abort.
c) Prohibition of monetary incentives or purchase, sale or directed donation of such tissue for commercial purposes.

Research on ES (Embryonic Stem) cells

7) Our view of research on embryos less than 14 days old has been addressed earlier. We are opposed to all forms of ES research on ethical and moral grounds.

8) However if BAC holds to its position as outlined in its consultation paper, then we hope for the following issues to be addressed:

a) Detailed legislation on
    i. the derivation and

ii. use of ES cells

b) ES cells are to be derived solely from excess embryos intending to be discarded after IVF for infertility treatment.
c) Legislation should be provided against direct therapeutic incentives to create or abort such embryos.
d) Legislation should be provided against monetary incentives or purchase, sale or directed donation of such embryos for commercial purposes.

Research on Human Reproductive Cloning

9) We strongly support BAC's stand against reproductive cloning. We are similarly opposed to the Kantian view of the utility of human life as a means to an end.

10) In its paper, BAC appears to restrict its overview of cloning to cell nuclear transfer. We wish to point out that presently, cloning may also arise from a technique called nuclear splitting and hope that this and other future techniques will be addressed by the BAC.

11) We note that there may be deficiencies in explicit legislation of definitions in a rapidly developing science. Perhaps a blanket cover would be preferable to narrow definitions which may be outdated faster than legislation can change.

Research on Human Therapeutic Cloning

12) The BAC has left open the issue of human therapeutic cloning noting that "it appears to be an essential part of human stem cell research" and is prepared to support its use under strict supervision.

13) We disagree with this stand for the same reasons as we disagree with ES research. We hold that all forms of human cloning be banned. We put it to the BAC that a more coherent policy may be achieved through an outright ban on all forms of cloning, therapeutic or reproductive.

14) Should BAC maintain its recommendation, we wish to see that initiation of therapeutic cloning (if and when it occurs) should be subject to the same review and open dialogue as has occurred with human stem cell research – and not as BAC currently recommends "on a case to case basis with proper consent and under appropriate governmental oversight". Such decisions should be subject to open feedback and not left in the hands of a few.

In an ethically sensitive area of emerging biomedical research it is important that all members of the research community, whether in the public or private sectors, conduct their research in a manner that is open to appropriate public scrutiny.

Government oversight

15) We welcome the BACs recommendation for "a well established and effective framework for the control of research involving embryos in Singapore".

16) We hope to see the establishment of a formal oversight committee equipped with the relevant authority to review, supervise, investigate and enforce such research and policy.

17) We look to the adoption of recommendations such as those from the American National Bioethics Advisory Commission's guidelines on Ethical Issues in Human Stem Cell Research.[4] These currently include:

a) A public registry of approved protocols and certified ES and EG cell lines,
b) A database linked to the public registry of information submitted by research sponsors that includes all protocols that derive or use ES or EG cell lines.
c) The use of such database to track the history and use of these cell lines for policy assessment and formulation.
d) A report at least annually with an assessment of the current state of the science for both the derivation and use of human ES and EG cells, a review of recent developments in the broad category of stem cell research, a summary of any emerging ethical or social concerns associated with this research, and an analysis of the adequacy and continued appropriateness of the recommendations.
e) Institutional review of protocols to ensure compliance to Human Stem Cell Research Subcommitee / BAC policy.

Conclusion

18) It would appear that the embryo, with a full complement of human genetic material, is not yet capable of rendering consent for experimentation, regardless of the potential benefit to the rest of humanity. It is our hope that we draw the line at this time against embryo research, and reaffirm our societal moral precedent which should consistently support the inherent value of human life, rather than a value which is somehow measured by a simplistic human standard.

19) To quote Dr Dan Brock[5], "While moral and even human rights need not be understood as absolute, that is, as morally requiring people to respect them no matter how great the costs or bad consequences of doing so, they do place moral restrictions on permissible actions that appeal to a mere balance of benefits over harms. For example, the rights of human subjects in research must be respected even if the result is that some potentially beneficial research is made more difficult or cannot be done, and the right of free expression prohibits the silencing of unpopular or even abhorrent views; in Ronald Dworkin's striking formulation, 'rights trump utility'[6]."

20) Philosopher Joel Feinberg[7] has argued for a child's right to an open future. This requires that others raising a child not close off future possibilities that the child would otherwise have, thereby eliminating a reasonable range of opportunities from which the child may choose autonomously to construct his or her own life. We consider this as a basic truth that applies equally to an embryo as to a liveborn infant.

21) It is the nature of a being, not how it is created, that is the source of its value and makes it worthy of respect.

Yours sincerely,

References:

1. *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,* Directorate of Legal Affairs, Strasbourg, November 1996, DIR/JUR (96) 14.

2. *Recommendation No. R (90) 3 of the Committee of Ministers to Member States Concerning Medical Research on Human Beings*, adopted by the Committee of Ministers on February 6, 1990, at the 443rd meeting of Ministers' Deputies, (1990) 41 (3) *IDHL* 461.

3. *Recommendation 1100 (1989) on the Use of the Human Embryos and Foetuses in Scientific Research*, in text adopted, Parliamentary Assembly, 40th Session, Party III, a. D. 9. in Appendix.

4. *Ethical Issues in Human Stem Cell Research* National Bioethics Advisory Commission – Executive Summary 1999.

5. *Cloning Human Beings - An Assessment of the Ethical Issues Pro and Con* Commissioned Paper for the National Bioethics Advisory Commission. Dan W. Brock, Ph.D. Brown University 1999

6. *Taking Rights Seriously*, Dworkin, R., London: Duckworth, 1978.

7. *Whose Child? Children's Rights, Parental Authority, and State Power*, Feinberg, J., W. Aiken, H. LaFollette (eds.), Totowa, NJ: Rowman and Littlefield, 1980.

Name: Date:

Opinion for or against
Yes (Y) ,
No (N) ,
No but would not object to others pursuing this research within guidelines (P)

Survey on Stem Cells Issues	**Options - Y, N, P**
1. Animal Cloning	-
Human Stem Cell Research	
2. Adult Stem (AS) Cells Research (bone marrow, umbilical cord blood, brain etc)	-
3. Embryonal Germ (EG) Stem Cells Research (from aborted fetuses)	-
4. Embryonic Stem (ES) Cells Research (Early Embryo <14 days)	-
5. Therapeutic Cloning	-
6. Reproductive Cloning	-
7. Constant need to review policies (on a regular basis in view of rapid development in this area)	Y or N
8. Conscientious Objection to participate in TOP Under Termination of Pregnancy Act	Y or N

SURVEY RESULTS 56 respondents 15/12/2020

ANIMAL CLONING

	Frequency	Percent
n	10	17.9
p	4	7.1
y	42	75
Total	56	100

ADULT STEM CELL

	Frequency	Percent
n	2	3.6
p	2	3.6
y	52	92.9
Total	56	100

EG

	Frequency	Percent
n	8	14.3
p	10	17.9
y	38	67.9
Total	56	100

ES (<14d)

	Frequency	Percent
n	22	39.3
p	9	16.1
y	25	44.6
Total	56	100

Therapeutic Cloning

	Frequency	Percent
n	16	28.6
p	13	23.2
y	27	48.2
Total	56	100

Reproductive Cloning

	Frequency	Percent
n	42	75
p	11	19.6
y	3	5.4
Total	56	100

CONSTANT REVIEW

	Frequency	Percent
n	1	1.8
y	55	98.2
Total	56	100

TOP objection

	Frequency	Percent
n	27	48.2
N.A.	1	1.8
y	28	50
Total	56	100

Practice Location

	Frequency	Percent
Gleneagles Hospital/Medical Centre	7	12.5
KK Women's & Children's Hospital	20	35.7
Mt Elizabeth Medical Centre	7	12.5
National University Hospital	5	8.9
Private O&G Clinics Central & South Zone	8	14.3
Private O&G Clinics East Zone	1	1.8
Singapore General Hospital	5	8.9
Thomson Medical Centre	3	5.4
Total	56	100

NO OBJECTION

ANIMAL

		Frequency	Percent
Valid	n	3	11.1
	p	2	7.4
	y	22	81.5
	Total	27	100

ADULT

	Frequency	Percent
n	1	3.7
y	26	96.3
Total	27	100

EG

	Frequency	Percent
n	3	11.1
p	4	14.8
y	20	74.1
Total	27	100

ES

	Frequency	Percent
n	7	25.9
p	3	11.1
y	17	63
Total	27	100

therapeutic

	Frequency	Percent
n	5	18.5
p	4	14.8
y	18	66.7
Total	27	100

reproductive

	Frequency	Percent
n	17	63
p	7	25.9
y	3	11.1
Total	27	100

REVIEW

	Frequency	Percent
y	27	100

OBJECTION TO TOP

ANIMAL

	Frequ	Percent
n	7	25
p	2	7.1
y	19	67.9
Total	28	100

ADULT

	Frequ	Percent
n	1	3.6
p	2	7.1
y	25	89.3
Total	28	100

EG

	Frequ	Percent
n	5	17.9
p	6	21.4
y	17	60.7
Total	28	100

ES

	Frequ	Percent
n	15	53.6
p	6	21.4
y	7	25
Total	28	100

therapeutic

	Frequ	Percent
n	11	39.3
p	8	28.6
y	9	32.1
Total	28	100

reproductive

	Frequ	Percent
n	25	89.3
p	3	10.7
Total	28	100

REVIEW

	Frequ	Percent
n	1	3.6
y	27	96.4
Total	28	100

TOPobject

	Frequency	Percent
n	27	100

Practice Location

	Frequency	Percent
Gleneagles Hospital/Medical	2	7.4
KK Women's & Children's Ho	11	40.7
Mt Elizabeth Medical Centre	3	11.1
National University Hospital	2	7.4
Private O&G Clinics Central &	4	14.8
Singapore General Hospital	3	11.1
Thomson Medical Centre	2	7.4
Total	27	100

TOPobject

	Frequ	Percent
y	28	100

Practice Location

	Frequ	Percent
Gleneagles Hospital/M	5	17.9
KK Women's & Childr	9	32.1
Mt Elizabeth Medical C	4	14.3
National University Ho	2	7.1
Private O&G Clinics C	4	14.3
Private O&G Clinics E	1	3.6
Singapore General Ho	2	7.1
Thomson Medical Cen	1	3.6
Total	28	100

B. RELIGIOUS GROUPS/ORGANISATIONS

The Inter-Religious Organisation of Singapore (submitted under the IRO) obtained views from the Roman Catholics, Bahai faith, Jewish faith, Taoists, Hindus and Sikhs.

1. Hindu Endowments Board *(submitted under the IRO)*
2. Taoist Mission (Singapore) *(submitted under the IRO)*
3. St. Anthony's Canossian Convent *(submitted under the IRO)*
4. Sikh Faith view *(submitted under the IRO)*
5. The Spiritual Assembly of the Baha'is of Singapore Ltd *(submitted under the IRO)*
6. The Jewish Welfare Board *(submitted under the IRO)*
7. Singapore Buddhist Federation
8. The Catholic Medical Guild of Singapore
9. National Council of Churches of Singapore
10. Singapore Council of Christian Churches
11. Majlis Ugama Islam Singapura

HINDU ENDOWMENTS BOARD

397 SERANGOON ROAD, SINGAPORE 218123 TEL: 2963469 FAX: 2929766
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Our [redacted]EB/1002-19/(F

19 November 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

1 We refer to your letter dated 8 November 2001.

2 Energy in the form of life is manifested in the living cells including stem cells derived from early embryos (ES cells).

3 It is suggested that in Singapore the embryos created by invitro fertilisation, not more than 14 days old, can be used for research.

4 So also, the ES cells derived from 5 days old frozen embryos can be used to establish the cell lines.

5 According to our Faith (Hinduism) killing a foetus is a sinful act (BHROONA HATHYA). But whether the 14 days old foetus is endowed with all the qualities of life is not well regarded. Therefore, there is no non-acceptance to use these ES cells to protect human life and to advance life by curing diseases.

6 Another point that needs clarification is whether all the cells in the 14 days old foetus will be completely used since they presumably remain in an undifferentiated state. If this is so the question of killing the foetus would not arise and all the cells would continue to live and function.

7 EG cells are not suitable for research since embryogenic germ cells are derived from foetuses and rest of the foetus or living cells would be destroyed or killed.

8 No objection whatsoever for obtaining some cells from bone marrow and umbilical cord since no killing of the foetus is involved. The process is comparable to organ donation. Instead of organ one would be donating cells.

9 However one major ethical question remains largely unanswered. That is the scientist creates a new form of life (embryo) by using two living cells (sperm and egg)of two different morphological categories derived from two different individuals.

10 Diversity establishes uniformity by process of fertilisastion forming embryo, which differentiates again into polymorphic cells. Life is continuing through out this entire process of cell division and differentiation and that is the marvel of life, The risk of damaging life or killing some cells is always there when cells are separated, grown and used again.

11 The implications involved in the process and saving or maintaining the life factor undamaged throughout needs to be fully discussed before arriving at the final decision.

12 I hope that these views would be useful to the committee for discussion.

Yours sincerely

V R NATHAN
CHAIRMAN

Cc Prof A N Rao, HEB-Religious Affairs Committee

feedbackprofrao

新加坡道教协会
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莫以善小無益而不爲 莫以惡小無損而爲之

谨致：生物道德咨询委员会主席
林彬教授　台鉴，

就关于"管制本地胚胎干细胞的研究工作"课题道教的意见书

道教与其他宗教最大的区别之一,就是对于现世生命的热爱、养护和延益.道教把乐生认为是最善,长生认为是大德.这一种乐生贵生的思想,在道教经典中俯拾皆是.教徒们正是在这种思想的指导之下来思考宇宙、社会与人生的,很必然地便将人放在了心的地位.

道教认为日月星辰及天地万物,包括人,均从道中流衍而出.认定道化生了万物,而且万物又将复归于道.

生死是道教教义重要概念.<<性命圭旨>>论生死大概经过以下几个阶段,即一个循环：死 — 投胎 — 成形 — 成人 — 由幼儿到老人 — 死.即虚化神、神化气、气化血、血化形、形化婴、婴化童、童化少、少化壮、壮化老、老化死、死复化为虚、虚复化为神、神复化为气、气复化为物.化化不间,循环无穷.

吕洞宾所传<<钟吕传道集>>之'论真仙'中云："吕曰：人之生也,安而不病,壮而不老,生而不死,何道可致如此?钟曰:人之生,自父母交会而二气相合,即精血为胎胞,于太初之后而有太质,阴承阳生,气随胎化,三百日形圆,灵光入体,与母分离……"

生道合一,是道教基本教义内容之一.道教继承了中国古代仙学传统,特别重视现世生命的长久存在,追求的最高目标是得道成仙,即所谓"深根固蒂,长生久视"之道.其中的生,即是生命、生存的意思.早期道经<<老子想尔注>>中,即将"道"与"生"并列,尊为四大的内容.<<太上老君内观经>>："道不可见,因生以明之;生不可常,用道以守之.若生亡,则道废,道废则生亡.生道合一,则长生不死."认为"天地构精,万物以生","父母和合,人受其生","从道而生谓之命,自一禀形谓之性",从虚无大道中产生了人的生命.而万物之中,人为最灵,"性命合道,当宝爱之",应该至为爱惜生命的存在.生道合一教义是道教仙学的核心内容,以此为准则,道教采摭、造作了诸多炼养方术,如内丹、存思、守一、服气、辟谷、房中等术,以求达到"生道合一"的目标

道教重生、贵生,故注重养生,认为人生活在世界上是一件乐事,死亡才是痛苦的,因此它的教义是乐生、重生和贵术.强调"仙道贵生,无量度人",因而便寻求能够使人长寿的方法.主张"我命在我,不在天地"的理论,认为人的寿命长短,由自己决定,通过修炼能够延年益寿,甚至长生久视.

道教戒律一直为道教徒修道持身之规范,积功累行之径路.益善止恶,皈真舍妄,莫不由此渐进而顿悟.按:<<老君戒经>>曰:"一切众生,含气以上,翱飞蠕动之类,皆不得杀.蠕动之类无不乐生,自蚊蚁蜉蚴咸知避死也.

道教的立场

道教崇尚自然,道教主张要自然无为.要认识自然的规律,并掌握自然,运用自然,反对有为的作为,违反自然,人为地造作.只要是不违反自然的研究,有益于众生,道教是支持的.

道教是科学的,纵观道教的历史,许多道教的道士,方士都是从事科学的研究,道教特别注重各类的身心炼养术研究,如:守一、存思术,服气、胎息术,房中术,内丹术及养生医学...等.

道教非常珍惜生命,有所谓"仙道贵生,无量度人"的说法.在不伤害其他生命,不违反伦理道德及不违背道教教义,而进行有益于延年益寿,造福人类的研究,道教是支持的.

道教反对在违反自然,杀害其他生命及违背道教教义,如采取胚胎之研究.因此,为避免此研究有被滥用的可能性,站在道教的立场来看待此课题,我们坚决认为政府必须设立法定机构,严格管制本地胚胎干细胞的研究工作.希望我们的意见能给
贵会有所帮助.专此奉达,即颂

大安

福生无量天尊　　此致

新加坡道教协会代会长
道末李至旺　　稽首
2001年11月28日

Translation of the letter from the Taoist Mission (Singapore), pages G-3-4 and G-3-5

Respectfully Submitted To:
Bioethics Advisory Committee (BAC) Chairman
Prof. Lim Pin

SUGGESTION PAPER PUT UP BY THE TAOIST MISSION (SINGAPORE)
DISCUSSION TOPIC: REGULATING SINGAPORE'S EMBRYONIC STEM CELLS RESEARCH

One of the key differences between Taoism and other religions is its love for and commitment to prolonging and enriching one's present life. In Taoism, "happy living" is considered the highest level of kindness and longevity, the greatest virtue. This kind of ideology of "valuing life" is very common in the Taoist scriptures. According to this teaching, Taoist believers reflect on the universe, human society and philosophy of life. Naturally, they would put mankind at the centre of their thinking.

Taoism believes that the heavenly bodies – the sun, the moon and the stars, and all things in the universe, including men, all emerge from Tao. It is firmly believed that Tao gives birth to all things on earth and that these things will return to Tao eventually.

Life and Death are important concepts in Taoist doctrines. The *Xing Ming Gui Zhi* talks about life and death in terms of the following stages, forming a cycle: death, reincarnation, formation, becoming human, from infant to the aged, and Death. This involves the transformation of Emptiness to Spirit, Spirit to *qi* energy, *qi* energy to blood, blood to shape/form, form into new born infant, new born into child, child into youth, youth into adult, adult into aged, aged into death. Then death returns to Emptiness, emptiness changes once more into Spirit, Sprit into *qi* energy, *qi* energy into things – the transformation is ceaseless and the cycle goes on without end.

In the chapter entitled "Lun zhen xian" (on true immortals), in the *Zhong Lü Chuan Dao Ji* (Collected writings of Masters Zhong and Lü) by Lü Dong Bin, it is reported that Lü asked Master Zhong: "What is the Way that enables a human being to be healthy and not sick, strong and not grow old, live and not die?" Master Zhong replied, "Life comes from the union of the two parents which leads to the union of ying and yang. The essence and blood then form the embryo and with the interaction of yin and yang, the embryo becomes fully formed after 300 days. At that time the spirit enters the body and the new- born leaves the mother's womb.

The unity of Life and Tao is one of the fundamental teachings of Taoism. Taoism inherited China's ancient beliefs in immortality, and especially emphasizes longevity in one's present life. The highest goal in Taoism is to obtain the Tao and become an immortal. This is what is meant by "the Way of living long and having deep and strong roots." The word "living" here means life, existence. The early Taoist text, the *Laozi xiang er zhu* (The Xiang er Commentary on the *Laozi*) has already placed equal emphasis on "Tao" and "life," listing as the content of what the *Laozi* [chapter 25] describes as the "four great ones." Another Taoist text, the *Taishang Laojun neiguanjing* (The Scripture of Inner Vision of the Supreme High Lord Lao) also says, "The Tao cannot be seen, but through life it can be illuminated. Life is never constant; one must use the Tao to guard it. If life ceases, the Tao is lost. If the Tao is lost, life ceases. If life and Tao merge into one, then immortality can be realized." It also states that "heaven and earth form the essence, from which all beings are born"; and "from the harmony and union of one's father and mother, one receives the gift of life." Further, "what is born of Tao is called destiny; and what is shaped by the One is called nature." From the Great Way that is empty human life is created; and among all things, human beings are the highest in terms of spirituality. "The nature and destiny accord with the Tao and should be carefully treasured." This means that one should cherish to the utmost the presence of life. The union of Tao and life is the key doctrine of Taoism. It provides a standard and gives rise to a host of

practices, such as internal alchemy, preservation of pure thoughts, guarding the One, ingesting energy, avoidance of the five cereals, and the arts of the bedchamber, to realize the goal of the union of life and Tao.

Taoism emphasizes life, values life, and as a result it stresses the preservation of one's health. It considers being alive in this world as a pleasure, and death an agony. Thus the teaching of Taoism is to cultivate and nurture life, to value life and to find techniques that enable one to live longer. It stresses that "the way of immortality is to value life, and the highest virtue is to save others." Thus, it seeks to find ways to enable human beings to live long. It stands by the theory that "My life lies in my hand, not in heaven and earth." Whether one's life is long or short, it is determined by oneself. Through the practice of Tao, life can be prolonged and one can even live forever.

The rules and principles of Taoism have been providing Taoist believers with a standard for self-cultivation and a way to accumulate merit through constant practice. Benefit the good and stop evil, follow the truth and discard lies – this is the way that all can make progress and obtain enlightenment. According to *Laojun jiejing*, "All living creatures that breathe, including those that fly and crawl, should not be killed. Even wriggling creatures also treasure life, even mosquitoes and other insects understand the avoidance of death.

Position of Taoism

Taoism values nature. It advocates being natural and opposes aggressive behavior. Recognize the principles of nature, know nature well, apply what is natural, oppose artificial action that goes against nature. Taoism will support researches that are not against nature and are beneficial to all living beings.

Taoism is scientific. Looking at the history of Taoism, many Taoist masters engaged in scientific research. Taoism especially emphasizes various kinds of

practices that cultivate body and mind – for example, guarding the One, preservation of pure thoughts, ingesting energy, embryonic respiration, the arts of the bedchamber, internal alchemy, medical knowledge that prolongs life, etc.

Taoism treasures life deeply. As indicated by the Taoist saying, "the way of immortality is to value life, and the highest virtue is to save others." Provided that it does not injure life, is not against morality and not against the teachings of Taoism, Taoism supports research that increases longevity and brings benefit to mankind.

Taoism is not supportive of research that goes against the teachings of Taoism, that goes against nature, and that involves the killing of another life, e.g. using embryos for research. Thus, from the perspective of Taoism, in order to prevent such research from being abused, the Taoist Mission strongly believes that it is necessary for the government to set up a legislated body to strictly regulate and control embryonic stem cell research work in Singapore."

Mr. Li Zhi Wang
Acting Chairman
Taoist Mission (Singapore)
28 November 2001

Translated by: Christine Ho, NSTB

St. Anthony's Canossian Convent
1604 Bedok North Avenue 4 Singapore 1646
Tel: 4494319

Mr Harbans Singh
Hon. Secretary, I.R.O.
Blk 173 Woodlands Street 13 #02-397
Singapore 730173

24th November 2001

Dear Mr Harbans,

Re: Stem Cell Research – Catholic view

Please find attached a statement published in the Catholic News dated 28th October 2001concerning the Catholic Church's teaching on the subject mentioned above.

The Archdiocesan Bioethics Committee is a committee composed of professional Catholic doctors and they have been entrusted with the task to study and research into question of the stem cell research particularly the embryonic stem cell. The committee has made a careful study on the subject matter taking into consideration the Church's teaching about the sanctity of human life and human embryonic stem-cell research.

The Church's teaching is clear and we do not compromise on our stand. In responding to the Bioethics Advisory Committee, I request that I.R.O.'s submission to the committee will take into full consideration the view offered by the Church.

Thank you for your kind attention.

Yours faithfully,

Sr. Theresa Seow, F.d.C.C.
Consultor of Pontifical Council for Interreligious Dialogue
Catholic Archdiocesan Representative to I.R.O.

c.c. Venerable Shi Ming Yi, Hon. President

Embryonic stem-cell research kills human beings

In response to the issue of embryonic stem cell research which has drawn much attention of late, the Archdiocesan Bioethics Committee is issuing the following statement to clarify what the Church teaches.

What are stem-cells?

Stem-cells are cells that are present in everyone from the moment of conception. These stem-cells give rise to all our other types of cells and all our tissues and organs as we grow and develop in the womb and after birth.

Some of these stem-cells remain in us as adults and they can then be changed into other types of cells, such as blood cells, under the right conditions. These are called adult stem-cells and they can be found in a number of sites, for example in the umbilical cords of newborn babies and in the bone marrow of adults. Adult stem-cells are already being used in new ways of treating diseases such as thalassemia.

Most important of all, obtaining adult stem-cells for research or treatment does not result in the donor being killed or harmed.

But this is not true in the extraction of stem-cells from the human embryo. When this is done, the embryo is inevitably killed.

What is human embryonic stem-cell research and what are stem-cell lines?

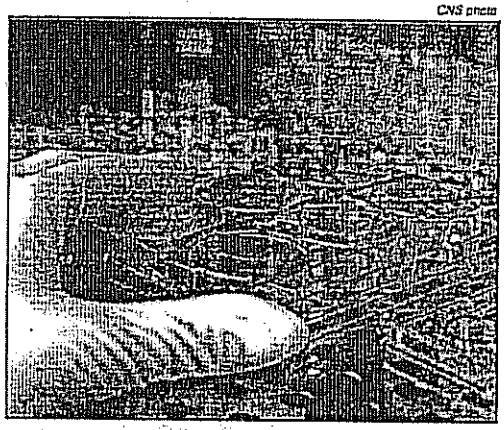
Scientists may extract embryonic stem-cells from either live human embryos produced by artificial reproductive techniques, or specially created by human cloning. After extraction, the cells multiply for prolonged periods in cultures. These are known as cell lines which are then used, sold or exported for further research.

Scientists who do such research hope that products and new methods of treatment may flow from these stem-cell lines. Although the intention of this research may be to find cures for disease, it must be highlighted that live human embryos are killed in the process.

What does the Church teach about the sanctity of human life and human embryonic stem-cell research?

Church teaching regarding human embryonic stem-cell research is consistent with the constant teaching of the Church on the immorality of induced abortion.

CNS photo



A researcher handles culture trays with human embryonic stem cells. A Church document issued last year states it is morally wrong to use human embryos for experimentations.

Since Biblical times, God's divine commandment has been very clear: "You shall not kill" (Ex 20:13, Dt 5:17)

The Church's tradition has always consistently taught the absolute and unchanging value of the commandment, "You shall not kill". It is a known fact that in the first centuries, murder was among the three most serious sins – along with apostasy and adultery. *(Evangelium Vitae, 54)*

Pope John XXIII reaffirmed that human life is sacred because "from its very beginning it directly involves God's creative activity". (*Mater et Magistra*, 1961, 447)

In the encyclical *Evangelium Vitae* (Gospel Of Life), Pope John Paul II said the "evaluation of the morality of abortion is to be applied also to the recent forms of intervention on human embryos which...inevitably involve the killing of those embryos.

"This moral condemnation also regards procedures that exploit living human embryos and foetuses, either to be used as "biological material" or as providers of organs or tissue for transplants in the treatment of certain diseases. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act." (EV 63)

The Church document *Donum Vitae* (The Gift of Life) states that "from the moment of conception, the life of every human being is to be respected in an absolute way.

"God alone is the Lord of life from its beginning to its end: No one can under any circumstance claim for himself the right directly to destroy an innocent human being." (Introduction, 5)

"To use human embryos or foetuses as the object or instrumentation of experimentation constitutes a crime against their dignity as human beings having a right to the same respect that is due to the child already born and to every human person." (I, 4)

On Aug 25 last year, the Church issued a new document entitled, Declaration On The Production And The Scientific And Therapeutic Use Of Human Embryonic Stem-cells which again stated that it is morally wrong to produce or use living human embryos for the preparation of embryonic stem-cells for the following reasons:

1. The human embryo, from the moment of conception, has a right to its own life, and therefore every intervention which is not in favour of the embryo is an act which violates that right.

2. The ablation of the inner cell mass of the blastocyst, which critically and irremediably damages the human embryo, curtailing its development, is a gravely immoral act and consequently is gravely illicit.

3. No end believed to be good, such as the use of stem-cells for the preparation of other differentiated cells to be used in what looks to be promising therapeutic procedures, can justify an intervention of this kind. A good end does not make right an action which in itself is wrong.

The document further declared, "It is morally wrong to use embryonic stem-cells, and the differentiated cells obtained from them, even if supplied by other researchers or are commercially obtainable, because it entails a proximate material cooperation in the production and manipulation of human embryos on the part of those producing or supplying them."

It is morally wrong to benefit from the evil of human embryonic stem-cell research, even if we ourselves have not done this evil.

The document instead urged "using adult stem-cells to attain the same goals as would be sought with embryonic stem-cells. These applications are undoubtedly a source of great hope for a significant number of suffering people."

Finally, *Donum Vitae* makes this observation: "Science and technology are valuable resources for man when placed at his service and when they promote his integral development for the benefit of all, but they cannot of themselves show the meaning of existence and of human progress." (*Donum Vitae*, Introduction, 2).

Those who would like to read the Pontifical Council For Life's Declaration on Embryonic Stem-Cell Research in its entirety may visit http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html

HUMAN STEM CELL RESEARCH
(Sikh Faith View)

The Sikh faith totally respects the sanctity of the Gift of Human Life by God and expects every effort to be made to preserve this stand.

No human being has the right to disturb this natural order or pattern of life's existence. This decision only rests with God. For, it is He who gives life or takes it away as He wills.

> **"By (God's) order, O Nanak! Man comes and goes."**
> **[Adi Granth 13]**

The coming (birth) and going (death) of human beings is at the discretion of God, that is, according to His Will. Any attempt to go against His Divine Will is unethical and also morally wrong.

Human life begins when the male and female living cells unite and God by His word gives life for conception to take place. The human embryo is then formed. Hence, life exists from the very onset.

> ***Placing the soul in the body-cave,***
> ***The Lord began to blow the musical***
> ***Instrument of breath into it.*** ***[Adi Granth 922]***

Therefore, the question of the age of an embryo is merely academic. It does not arise. Any attempt to change this human life pattern is going against Nature and the Will of God. The removal of stem cells from the human embryo kills the embryo in the same way that an abortion does.

Even doctors, when they treat patients cannot claim success unless the God's Grace there.

> ***The assembly of the physicians meets together.***
> ***The medicines become effectual, when the Lord,***
> ***Of Himself, stands amidst them.*** ***[Adi Granth 1363]***

Scientific research may need to continue to prolong life and minimise human suffering. The real danger is in the zeal and enthusiasm of research scientists whose attempt(s) to advance their own study and personal prestige may result in the undesirable cloning of human beings.

> ***Kabir, the physician says, 'I alone am good.***
> ***All medicines are in my power.'***
> ***But, this thing belongs to the Lord***
> ***He takes it away, when He wills.*** ***[Adi Granth 1368]***

There is no objection to the adult AS cells, or EG cells that are derived from human foetuses (due to miscarriage) being used. In regard to ES cells, our view is that human cells are living from the onset of conception and that any form of intervention will kill the embryo in the process.

The destruction of innocent life regardless of the objective of human cell experimentation is not acceptable. It is against the preservation of dignity of human life. Anything that goes against Nature albeit for creation of new life is wrong, both on moral and ethical grounds.

Any attempt or claim to change this natural order by other means is a violation of the sanctity of the Gift of Life, which must always be upheld and respected absolutely.

Gurbaksh Singh Grewal
A Venerable Sikh Devotee
Director Satnam Textiles
B1-19 High Street Centre

Harbans Singh PS
IRO Sikh Faith Representative
Secretary Central Sikh Gurdwara Board

CSGB2001.BAC (Sikh)

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THE SPIRITUAL ASSEMBLY OF THE BAHÁ'ÍS OF SINGAPORE LTD
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Transmitted electronically
30 November 2001

Mr P. Harbans Singh PBM
Hon Secretary
Inter Religious Organisation
Singapore

harbans@singnet.com.sg

Dear Esteemed Sir,

Council Feedback (BAC Request)

We are pleased to attach herewith the reply form and our statement on the question of Human Stem Cell Research in Singapore.

Yours faithfully,
For The Spiritual Assembly of the Bahá'ís of Singapore

William Hui
Secretariat Manager

SIGNED CONFIRMATORY COPY WILL BE SENT BY POST IN DUE COURSE

HUMAN STEM CELL RESEARCH IN SINGAPORE

1. We would like to first express our gratitude to the Inter-Religious Organization in asking us for the Bahá'í perspective on this topic. We have also read the Bioethics Advisory Committee's (BAC) consultation paper regarding human stem cell research locally and the following represent our feedback to the BAC paper.

2. The supreme body of the Bahá'í community worldwide, the Universal House of Justice, has stated that there has been nothing specific in the Bahá'í Writings on subjects such as stem cell research or human cloning. Though the Universal House of Justice has the spiritual authority to make decisions on such previously unaddressed matters, it has in a recent communication stated that it would be premature to currently make judgments on these topics and their spiritual consequences. The House of Justice has thus advised believers who are faced with such questions that they are free to come to their own conclusions based on their knowledge of the Bahá'í teachings on the nature and purpose of life, taking care at the same time not to make dogmatic statements or to offer their individual understandings as standard teaching of the Faith.

3. Below is a brief compilation of pertinent passages from the Bahá'í Writings that indicate the underlying standards that Bahá'ís needs to be mindful of when deciding upon a topic such as human stem cell research.

a) With regard to the soul of man: According to the Bahá'í Teachings the human soul starts with the formation of the human embryo, and continues to develop and pass through endless stages of existence after its separation from the body. Its progress is thus infinite. *(From a letter written on behalf of Shoghi Effendi, 1937)*

b) ... the Bahá'í Writings affirm that the human soul comes into being at the time of conception. However, they do not clearly define the exact biological moment and nature of the event described as "conception" and this may, indeed, be a question that is insoluble by human thought or investigation, since it relates to mysteries of the spiritual world and the nature of the soul itself. *(From a letter written on behalf of the Universal House of Justice, 1997)*

c) The Bahá'í view is very balanced. While appreciating the value of the new medical techniques which enable previously childless couples to enjoy the blessings of a family, the teachings define such limits as are necessary to preserve the dignity of the individual and the sanctity of marriage.

In relation to artificial insemination, the beloved Guardian in a letter written on his behalf to an individual believer states: "... there is no objection to having a baby by means of artificial insemination as long as your husband is the father of it." While artificial insemination is a very different process from in vitro fertilization, the principle enunciated by the Guardian is the same; namely, that to be acceptable to Bahá'ís the egg cell of the wife should be fertilized by the sperm of the husband in the procedure. *(From a letter written on behalf of the Universal House of Justice, 1984)*

d) You have specifically requested information defining the Bahá'í position on the important matter of experimentation with human embryos. It is not practicable for the House of Justice to consider this delicate issue at this time ....*(From a letter written on behalf of the Universal House of Justice, 1990)*

e) Nothing specific has been found in the Bahá'í Writings on genetic engineering. This is therefore a matter on which the House of Justice may have to legislate but the time has not yet come for that. The subject is quite complex, and an informed opinion can be offered only when the scientific understanding is much further advanced than at present and the social implications are clearer. With the emergence of adequate understanding, it will also be opportune to deal with the ethical issues involved. In the meantime, Bahá'ís faced with questions about genetic engineering are free to come to their own conclusions based on their knowledge of the Bahá'í teachings on nature and the purpose of life. However, they should be careful not to make dogmatic statements or offer their own understanding as the teaching of the Faith. *(From a letter written on behalf of the Universal House of Justice, 1997)*

Yours faithfully,
For The Spiritual Assembly of the Bahá'ís of Singapore

Dr. Suresh Sahadevan
Chairman

Notes:

Shoghi Effendi: (1897 – 1957) The Guardian of the Bahá'í Faith after the passing of 'Abdu'l-Bahá in 1921, designated in His Will and Testament as His successor in interpreting Bahá'í writings and as Head of the Faith.

The Universal House of Justice: Head of the Bahá'í Faith after the passing of Shoghi Effendi, and the supreme administrative body ordained by Bahá'u'lláh in the Kitáb-i-Aqdas, His book of laws. The Universal House of Justice is elected every five years by the members of all National Spiritual Assemblies, who gather at an International Convention. The Universal House of Justice was elected for the first time in 1963. It occupied its permanent seat on Mount Carmel in 1983.

'Abdu'l-Bahá: (1844 – 1921) Son of Bahá'u'lláh, designated His successor and authorized interpreter of His writings. 'Abdu'l-Bahá means "Servant of Bahá'u'lláh".

Bahá'u'lláh: Title assumed by Mírzá Husayn-'Alí, Founder of the Bahá'í Faith. Born on 12 November 1817, He declared His mission as the Promised One of All Ages in April 1863 and passed away in Acre ('Akká), Palestine, on 29 May 1892 after forty years of imprisonment, banishment, and house arrest. Bahá'u'lláh's writings are considered by Bahá'ís to be direct revelation from God.

THE JEWISH WELFARE BOARD
SINGAPORE

19 December 2001

Prof. Lim Pin
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof. Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

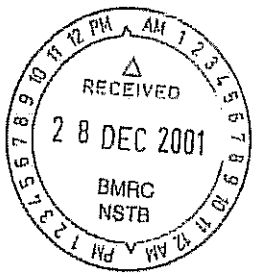
We refer to your letter of 8 November 2001 and reminder of 7 December 2001. Our apologies for not replying earlier as Rabbi M. Abergel is presently on home leave and will return to Singapore in late December. He will revert with his comments.

Thank you.

Yours sincerely

Joseph Benjamin
Honorary Secretary

cc Rabbi M. Abergel



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RABBI MORDECHAI ABERGEL
ORTHODOX JEWISH COMMUNITY OF SINGAPORE

Monday, December 31, 2001

Ms. Lauren Noto
For Prof Lim Pin
BAC Chairman
250 North Bridge Rd.
#15-01/02 Raffles City Tower
Singapore 179101

Dear Ms. Noto,

First and foremost I would like to apologize for the delay in our reply. We very much value your interest in the religious aspect of this important issue.

Herewith enclosed is an article which presents the Jewish religious viewpoint. I hope it will answer your request.

Yours Truly,

Rabbi Mordechai Abergel

19 Oxley Walk, #0
Tel/Fax: (65) 737 9112 e-mail: morueiiai@singnet.com.sg

Stem Cell Research in Jewish Law

by Daniel Eisenberg, MD

Introduction

Stem cell research is among the most promising and controversial technological breakthroughs of our time. Most cells in the human body are differentiated and, if they maintain the abillty to divide at all, have the ability to form only cells similar to themselves. Stem cells have the unique property of being able to divide, while maintaining their totipotent or pluripotent characteristics. Early in mammalian development, stem cells (under the proper conditions) have the ability to differentiate into every cell of the human body (totipotent), potentially forming an entire fetus. Stem cells derived from later stages of mammalian development have the ability to differentiate into multiple cell types, but not into an entire organism. If we were able to manipulate the conditions controlling cellular differentiation, we might be able to create replacement cells and organs, potentially curing illnesses such as diabetes, Alzheimer's disease, and Parkinson's disease.

The ultimate promise of stem cell technology would be to combine it with cloning. Imagine a man dying of liver failure. If we could take a somatic cell from his skin and place the nuclear DNA into a denucleated egg cell, we would have created an almost exact copy[1] of that sick man's cell, capable of differentiating into his clone. Instead of allowing the cloned cell to develop into a fetus, we might place it (or its stem cells alone) into the appropriate environment that would cause it to differentiate into a liver that would be virtually genetically identical to the sick man. If we could "grow" this liver to maturity, we could offer the sick man a liver transplant without the risk of rejection and without the need for anti-rejection drugs.

This sounds like a virtual panacea for many of man's ills. Yet we still do not know if we are able to successfully clone a human, nor are we sure what practical value can be derived from stem cells. We are currently in the realm of fascinating speculation. It will require years of very expensive, labor intensive research to determine the potential that stem cells hold for the treatment, palliation, and cure of human illness. While stem cells have been isolated from adults and aborted fetuses, the best source is the "pre-embryo," the small clump of cells that compose the early zygote only a few days following conception. Therefore, to best investigate the latent possibilities inherent in stem cells, scientists wish to use the approximately 100,000 "excess" frozen pre-embryos that are "left over" from earlier IVF attempts.

What is the *halachic* perspective on such research and what could the possible objections to such research be? There is little argument that the use of stem cells

derived from adult somatic tissue pose few ethical problems. The issues raised by stem cell research involve the use of in vitro fertilized eggs which have not yet been implanted in a woman and the use of tissue from aborted fetuses.

The issues raised by stem cell research may be divided into several questions:
1. Is in vitro fertilization permitted to begin with?
2. What is the Jewish approach to abortion?
3. Are pre-embryos included in the prohibition of abortion?
4. May a very early embryo be sacrificed for stem cells that could save lives or at least cure disease?
5. May we fertilize ova specifically to create an embryo to be sacrificed for stem cells?
6. Need we make "fences" in the form of protective laws to protect fetuses from wanton destruction? May tissue from aborted fetuses be used for research or medical treatment?

In Vitro Fertilization

Artificial insemination has been dealt with a length by a spectrum of *poskim* (rabbis qualified to decide matters of Jewish law). While artificial insemination by a donor is generally strongly condemned, the use of a husband's sperm for artificial insemination in cases of necessity was accepted by most Rabbinical authorities.[2] The question of in vitro fertilization was dealt with later. A significant majority of authorities accepted in vitro fertilization under the same rubric and limitations as artificial insemination,[3] including the fulfillment of the mitzvah of procreation.[4] However, a fundamentally new question arose. What is the status of the "spare" embryos that are not implanted as part of the first cycle of IVF?[5] Must they be implanted in the mother as part of another attempt at pregnancy. May/must they be donated to another women to allow the pre-embryo its chance at life? May they remain frozen indefinitely?[6] Most importantly to our topic, the question arose - may pre-embryos be destroyed? To answer this question, we must first generally examine the Jewish approach to abortion.

Abortion in Jewish Law

The traditional Jewish view of abortion does not fit conveniently into either of the major "camps" in the current American abortion debate. We neither ban abortion completely, nor do we allow indiscriminate abortion "on demand." To gain a clear understanding of when abortion is sanctioned, or even required, and when it is forbidden, requires an appreciation of certain nuances of *halacha* (Jewish law) which govern the status of the fetus.

The easiest way to conceptualize a fetus in *halacha* is to imagine it as a full-fledged human being - but not quite. In most circumstances, the fetus is treated like any other "person." Generally, one may not deliberately harm a fetus, and sanctions are placed upon those who purposefully cause a woman to miscarry. However, when its life comes into direct conflict with an already born person, the

autonomous person's life takes precedence.

It follows from this simple approach that, as a general rule, abortion in Judaism is permitted only if there is a direct threat to the life of the mother by carrying the fetus to term or through the act of childbirth. In such a circumstance, the baby is considered tantamount to a *rodef*, a pursuer after the mother with the intent to kill her. Nevertheless, as explained in the Mishna (Oholos 7:6), if it would be possible to save the mother by maiming the fetus, such as by amputating a limb, abortion would be forbidden. Despite the classification of the fetus as a pursuer, once the baby's head has been delivered, the baby's life is considered equal to the mother's, and we may not choose one life over another, because it is considered as though they are each pursuing the other.

Judaism recognizes psychiatric as well as physical factors in evaluating the potential threat that the fetus poses to the mother. However, the danger posed by the fetus (whether physical or emotional) must be both probable and substantial to justify abortion. The degree of mental illness which must be present to justify termination of a pregnancy is not well established and therefore criteria for permitting abortion in such instances remain controversial.

As a rule, *halacha* does not assign relative values to different lives. Therefore, almost all major *poskim* forbid abortion in cases of abnormalities or deformities found in a fetus. Rabbi Moshe Feinstein, one the greatest *poskim* in this century, rules that even amniocentesis is forbidden if it is performed only to evaluate for birth defects for which the parents might request an abortion. Nevertheless, a test may be performed if a permitted action may result, such as performance of amniocentesis or drawing alpha-fetoprotein levels for improved peripartum or postpartum medical management. While most *poskim* forbid abortion for "defective" fetuses, Rabbi Eliezar Waldenberg (in his *"Tzitz Eliezer,"* vol. 9, chapter 51:3) is a notable exception. Rabbi Waldenberg allows first trimester abortion of a fetus which would be born with a deformity that would cause it to suffer, and termination of a fetus with a lethal fetal defect such as Tay Sachs up to the end of the second trimester of gestation.

The question of abortion in cases of rape, incest, and adultery is a complex one, with various legal justifications propounded on both sides. In cases of rape and incest, a key issue would be the emotional toll exacted from the mother in carrying the fetus to term. The same analysis used in other cases of emotional harm might be applied here. Cases of adultery interject additional considerations into the debate which are beyond the scope of this short article.

In sum, the parameters determining the permissibility of abortion within *halacha* are subtle and complex.

Are Pre-Embryos Included in The Prohibition of Abortion?

While the practical aspects of the Jewish approach to abortion are relatively agreed upon, the exact source and nature of the prohibition is not. Depending on the origin of the prohibition, the application to the pre-embryo will differ. For instance, while most *halachic* authorities consider the prohibition of abortion to be from the Torah, a few consider it to be Rabbinic in nature. It is interesting to note that both the person who performs the abortion as well as the woman who voluntarily allows it to be done are culpable.[7]

The most obvious place to look for the Biblical prohibition would be from the *aseret ha'dibrot* (Ten Commandments), "Thou shalt not murder"[8]. This prohibition, called *retzicha*, usually carries a death penalty for transgression. Nevertheless, it appears the Torah itself teaches that killing a fetus is not equivalent to killing an adult. The Torah specifically states[9] that if in the course of an altercation with a third party, a person causes a woman to miscarry, he pays only monetary damages, while if the woman herself were to die of her injuries, the aggressor would receive a death sentence. Rabbi Yehuda Ashkenazi, in his commentary on the Code of Jewish Law,[10] reasons from here that a fetus is not a full-fledged person, since regarding the one who hits the woman, causing her to miscarry, ". . . he pays the value of the child and we do not label him a murderer, nor do we execute him. . .."

Notwithstanding the statement of Rabbi Ashkenazi, several *poskim* rule that abortion does represent murder, but without the punishment of death.[11] This law is similar to the law of one who kills a *trelfe*[12] (a specific type of terminally ill person), for whom there is a prohibition of murder, but no death penalty.[13] If the pre-embryo is included in this prohibition, then very little short of the pre-embryo posing a threat to someone's life could justify its destruction. An independent threat to the life of a third party would not suffice to allow destroying the pre-embryo.

The argument regarding whether a fetus is included in the prohibition of murder is complicated and fascinating.[14] Both positions garner support from two sides of the same page of the Talmud. Arachin 7a states that the court should strike the abdomen of a pregnant woman to cause a miscarriage prior to her execution.[15] The life of the fetus seems inconsequential in that discussion. On the other hand, Arachin 7b states that the Sabbath may be desecrated for the life of a fetus, something which may only be done to save a life, for *pikuach nefesh*. This apparent contradiction is dealt with at length in the responsic literature.

But is the pre-embryo included in this prohibition? That question is best answered by evaluating the next possible Biblical source for abortion. When Noah and his family exited the ark, G-d commanded them seven laws, which apply to all of humanity. The usual translation of one of these laws is: "Whoever sheds the blood of man, by man shall his blood be shed."[16] The Torah clearly demands capital punishment for murder. While this prohibition appears straightforward, there is a fascinating twist.

The Talmud[17] attempts to prove that non-Jews, who are not obligated by most of the Torah's commandments given at Mount Sinai, are forbidden to perform abortions.[18] The Talmud brings the literal translation of the previously mentioned passage (with slightly altered punctuation), which is: "Whoever sheds the blood of man, within man, his blood shall be shed." It then asks: "What is the meaning of 'man within man'? This can be said to refer to a fetus in its mother's womb." This prohibition, as part of the Noachide laws, would apply to all people, Jew and non-Jew alike, although for technical reasons, the degree of severity would differ.[19]

Once the "standard" prohibition of *retzicha* (murder) is separated from that of killing a fetus, we may investigate how this difference might affect the status of the pre-embryo. From the Talmudic discussion of abortion, we might expect that pre-embryos are not covered by the prohibition of abortion, because they have never been implanted. The rationale for such a decision is based on the concept that a pre-embryo left in its petri dish will die. It is not even potential life until it is implanted in an environment in which it can mature.

Others derive the prohibition of abortion from the Torah's proscription of inflicting damage to one's self or others (*chavala*)[20]. One may not wound one's self without a valid reason (such a medical necessity as in surgery). Obviously, one may not damage someone else.[21] As a result, some claim that the prohibition of abortion arises from the prohibition of the woman wounding herself[22], while others feel that the derivation is from the prohibition of wounding the fetus.[23] Unlike murder, for which only a threat to the mother's life[24] could justify killing the fetus, the rationale of *chavala* allows greater leeway in allowing its abrogation. Particularly, if the wounding of the mother is the prohibition, her consent to being wounded might be considered a determining factor. Whether this prohibition applies to a pre-embryo is open to debate (albeit my personal opinion is that the prohibition of *chavala* does not apply at this level).

The last possible prohibition to consider is the Torah's forbidding of "wasting seed" (*hashchatat zera*).[25] This is the main prohibition involved in questions of male contraception (for example, condoms) as well as the laws governing gathering of sperm for analysis, IVF, or artificial insemination. The prohibition forbids the "useless" emission or destruction of sperm that could create life. Some *halachic* authorities have ruled that excess sperm from fertility treatments may be destroyed. Further, the emission of semen for analysis has been permitted as part of the process of procreation in those suffering from infertility.[26] (Nevertheless, according to most *poskim*, this prohibition does not apply once fertilization has occurred.) Since this ban may be waived for the sake of saving a life,[27] it is conceivable that destroying a pre-embryo to save someone's life (or potentially treat severe illness; this would bring us into the complicated question of "*v'chi omrim lo l'adam chatei bishvil sheyizke chaveirecha*" -- do we allow one to sin in order to save his friend, -- an issue beyond the scope of this article)

would be permitted as part of the mitzvah of *pikuach nefesh*.

Two positive Biblical commandments bear on the obligation to save life (the obligation of *hatzala*). The Torah requires that we "Do not stand idly by as your neighbor's blood is being shed."[28] This *mitzvah* is interpreted by the Talmud[29] to require one to expend positive effort and even money to protect an endangered person. Maimonides learns the whole commandment for a qualified individual to heal his neighbor from the obligation to return lost objects. Regarding a lost object, the Torah commands: ". . . and you should surely restore it to him."[30] From an extra letter in the sentence, Maimonides[31] derives that if one must return a lost object, he must certainly return someone's "lost" health.

Both of these positive commandments may apply regardless of whether there may be any prohibition of abortion for a pre-embryo. But do these positive commandments apply to a pre-embryo? That is, do we have a positive obligation to protect the pre-embryo that is sitting in the freezer?

Forty days

In our analysis, we must also evaluate whether we are more lenient with the destruction of an embryo prior to forty days gestation. There is reason to argue that prior to forty days gestation, the fetus lacks "humanity." The Mishna[32] states that a miscarriage prior to forty days does not cause *tumat leida*.[33] The daughter of a *Cohen* (priest) whose non-Cohen husband has died may continue eating *trumah* (tithes) only if she has no children and is not pregnant. Rav Chisda[34] states that in a case where her non-Cohen husband died soon after marriage, she may continue eating *trumah* for forty days. He reasons that if she is not pregnant, then there is no problem, and that if she is pregnant, that up to forty days the fetus is "*mayim b'alma* (mere water)."

These sources suggest that a fetus prior to forty days gestation is not considered to be an actual person and we might extrapolate that destruction of such a fetus is not forbidden by Jewish law. If we now apply this reasoning to the possible sources for abortion discussed above, we note consistency on the part of the *poskim*.

Rabbi Unterman, former Ashkenazi chief Rabbi of Israel, who ruled that a fetus is protected by the prohibition of murder (*retzicha*), rejects these sources as removing the early embryo from the prohibition of murder. He bolsters his opinion by quoting from Toras Ha'Adam[35], a famous Jewish law book by Nachmanides (Ramban) that discusses medical issues. The Ramban quotes the Ba'al Halachot Gedolot, who asserts that one may desecrate the Sabbath for a fetus because, by desecrating one Sabbath, the fetus will be able to fulfill many Sabbaths in the future.[36] Thus, the Ba'al Halachot Gedolot argues that saving the life a fetus before forty days overrides the Sabbath; therefore, argues Rabbi Unterman, feticide is murder.

Rabbi Yair Bachrach, author of Chavot Yair, does not accept the forty days distinction because he derives the prohibition of feticide from wasting male seed, which is prohibited even before conception.[37]

Rabbi Yosef Trani (author of Responsa Maharit), who argues that abortion is forbidden as *chavala* (wounding) of the mother, does not specifically mention the forty day cutoff. However, Rabbi Yechiel Weinberg (author of the Responsa Seridei Aish), clearly held that there is no prohibition of abortion before forty days according to Rabbi Trani's opinion since there is no "limb" to injure prior to formation of a recognizable fetus at forty days.[38] Rabbi Weinberg himself at first permitted abortion prior to forty days, but later reconsidered his position.[39]

All of the above approaches apply only to Jews who are bound by Torah law. The prohibition of abortion for non-Jews, as discussed above, devolves from the Noachide laws. Of course, non-Jews are forbidden to commit homicide. Yet, according to many commentators, non-Jews are not bound by the commandment in Leviticus 19:16 to protect the lives of their comrades, since it was not commanded to Noah. The scope of their prohibition includes murder and "shedding blood of man within man." These obligations include only actual lives, not potential lives. Therefore, according to Rabbi Unterman,[40] there is no prohibition of abortion for a non-Jew, nor for a Jew to aid in such an abortion, before the fortieth day of gestation.[41]

May a very early embryo be sacrificed for stem cells?

Now that we have analyzed the possible ethical issues in destroying pre-embryos, what is the final outcome? For non-Jews, the issue appears most direct. The combination of the pre-embryo never having existed within a uterus and the generally accepted leniency toward abortion within the first forty days, would strongly argue for a permissive ruling regarding the destruction of pre-embryos for stem cells.

Regarding Jews, the answer is more complicated. Since stem cell research is a new endeavor and cloning of humans has not yet occurred, there are no published responsa on the topic. We must, therefore, look to more practical cases that encompass our question to find an applicable ruling. We find such an issue with respect to the best course of action for couples who wish to avoid having children with Tay Sachs disease when both partners are carriers of the Tay Sachs gene. A similar problem arises in families where the wife carries a gene for a sex-linked disease, such as Fragile-X.[42]

The most promising option for such couples is preimplantation diagnosis, in which a zygote conceived in vitro has a few cells removed to be tested for genetic defects before implantation. Only a zygote that is not homozygous for Tay Sachs or not a male carrier of Fragile-X would be implanted. Rabbi Yosef

Shalom Eliyashuv, possibly the most influention *posek* in Israel today, has permitted preimplantation diagnosis and destruction of affected zygotes to prevent cases of Fragile-X and even in a case of a woman with neurofibromatosis who only had skin lesions.[43] Rabbi Dovid Feinstein has taken a similar view as to the permissibility of discarding "extra" pre-embryos.[44] Pre-implantation diagnosis, which is already accepted by some Rabbinic authorities, is likely to be acceptable to most Jewish legal experts when used to prevent serious diseases in offspring.

Based on these rulings, it would seem that we now have a practical answer to our question of stem cell research. If the pre-embryo may be destroyed, it certainly may be used for research purpose and other life-saving work. In fact, Rabbi Moshe Dovid Tendler, in testimony for the National Bioethics Advisory Commission[45], argued strongly in favor of the use of pre-embryos for stem cell research.[46] Nevertheless, it is important to realize that this conclusion is not unanimous[47] and that all of these rulings are predicated upon the understanding that the pre-embryo is not included in the prohibition of *retzicha* (murder).

May we fertilize ova specifically to create an embryo to be sacrificed for stem cells?

The creation of embryos for the purpose of taking their stem cells is a complex issue. While no responsa yet exist specifically dealing with this question, it is likely that Rabbinic authorities will not favor such a leniency. The mere existence of already created pre-embryos creates a need to decide the *halachic* ramifications of their destruction. We therefore may decide that such research is permitted *bedieved* (*ex post facto*), once the pre-embryos exist. However, since there are *poskim* who forbid abortion even within the first forty days,[48] it is much harder to argue *lichatchila* (*a priori*) that creation of pre-embryos with the intention of destroying them is permitted.

There are additional questions that we as a society must ponder. May we *and should we* deliberately create pre-embryos in order to destroy them?

"Fences" around the law and the use of stem cells and aborted fetal tissue

The Rabbis often create protective edicts (*gezerot*) to prevent the desecration of Torah law. Additionally, the Rabbis may promulgate decrees intended to protect Torah values by preventing untoward behavior that is not already prohibited by the Torah itself. For example, more than 1000 years ago, Rabbenu Gershon enacted *gezerot* banning polygamy and opening the mail of others, despite the absence of actual Torah prohibitions for either of these two actions.

The protection of life is a strongly held Torah ideal. While the destruction of pre-embryos in the course of fertility treatments or to prevent disease may be permitted, this does not mean that pre-embryos may be destroyed without

compunction. To avoid the proverbial "slippery slope," should we ban stem cell research on embryonic stem cells as a dangerous encroachment on the sanctity of life? That is, even if pre-embryos may be destroyed, should we enact preventative laws barring stem cell research that requires the destruction of potential lives to avoid cheapening life by treating the process of creating humans as another scientific process, stripped of its miraculous underpinnings? In his testimony, Rabbi Tendler summed up the issue of protective enactments as follows:

Jewish law consists of biblical and rabbinic legislation. A good deal of rabbinic law consists of erecting fences to protect biblical law. Surely our tradition respects the effort of the Vatican and fundamentalist Christian faiths to erect fences that will protect the biblical prohibition against abortion. But a fence that prevents the cure of fatal diseases must not be erected, for then the loss is greater than the benefit. In the Judeo-biblical legislative tradition, a fence that causes pain and suffering is dismantled. Even biblical law is superseded by the duty to save lives, except for the three cardinal sins of adultery, idolatry, and murder. . . Life saving abortion is a categorical imperative in Jewish biblical law. Mastery of nature for the benefit of those suffering from vital organ failure is an obligation. Human embryonic stem cell research holds that promise. . ..

Human embryonic germ cells may also be derived from gamete ridge tissue removed from first trimester abortuses (at approximately eight-weeks gestation). While abortion of fetuses is a grave offense, it is difficult to justify prohibiting the use of life-saving tissue from these aborted fetuses for fear of encouraging or condoning abortion. This is another case where the cost of a preventative enactment might be the avoidable death of human beings.[49] [50]

Footnotes

[BACK]

* Dr. Eisenberg resides with his wife and children in Bala Cynwyd, Pa. This article was reviewed for *halachic* accuracy by Rabbi Sholom Kaminetsky of the Talmudical Yeshiva of Philadelphia.

If you have any comments or questions about this article or other medical / *halachic* issues, feel free to contact Dr. Eisenberg at eisenber@pol.net.

[BACK]

1. While the nuclear DNA would be identical to the donor skin cell, the mitochondrial DNA would be that of the donor egg.

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2. See "Artificial Insemination in Jewish Law," Maimonides: Health in the Jewish World, Vol 5, No. 1, Winter, 1999.

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3. With the important exceptions of (1) Rabbi Ovadia Yosef, who forbids it and rules that it does not fulfill the obligation of fathering children, (2) Tzitz Eliezer XV, no. 45, and (3) Rabbi Moshe Sternbach who denies paternity to the sperm donor and forbids the procedure.

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4. The use of sperm for IVF once the mitzvah of procreation has been fulfilled is more controversial.

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5. See the article by Rabbi Yitzchok Breitowitz, "The Preembryo in Halacha" posted on JLaw.com at http://www.JLaw.com/Articles/preemb.html

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6. The development of cryogenic techniques to freeze pre-embryos only pushed off the crucial question of whether pre-embryos could be destroyed. Prior to cryogenic techniques, several Rabbinic authorities ruled that all fertilized embryos must be implanted. This severely limited the availability of IVF to Torah observant Jews because of the great expense and low yields of each IVF attempt (necessitating fertilization of many ova), and the inherent risk of implanting many embryos. With the advent of cryogenic techniques, many ova could be fertilized with only a few implanted. Nevertheless, the question of disposition of these "frozen" pre-embryos which now number approximately 100,000 remains.

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7. Nishmat Avraham, Orach Chaim 656:1 (p. 92)

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8. Exodus 20:13

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9. Exodus 21:22-23

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10. Be'er Hetiv, Choshen Mishpat 425:2

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11. See Rabbi I.Y. Unterman, Responsa Shevet M'Yehuda, Vol. I, p. 29 and Noam 6 (1963): 1-11.

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12. A treife is a person with an organic illness that is expected to be fatal within a year.

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13. See Igrot Moshe, Choshen Mishpat II, 69B

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14. For more extensive treatment of this debate, see Jewish Ethics and Halakhah For Our Time, Sources and Commentary, Vol. I, by Rabbi Basil F. Herring.

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15. To spare her the embarrassment of bleeding during her execution.

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16. Genesis 9:6

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17. Sanhedrin 67b: "In the name of Rabbi Yishmael they said: A ben Noach [is liable] even for killing a fetus. What is the reasoning of Rabbi Yishmael? Because it is written [in Genesis 9:6]: 'Whoever sheds the blood of man by man [literally "in man"], his blood shall be shed'. What is the meaning of 'man in man'? This can be said to refer to a fetus in its mother's womb."

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18. Since the Torah was given to the Jews at Mount Sinai, only they are bound by its commands. Nevertheless, all laws given to Noah, the father of all nations, are binding on non-Jews.

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19. Tosofot, Chullin 33a, (d.h. "Echad oveid kochavim"), Tosofot, Sanhedrin 59a (d.h. "Layka")

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20. Bava Kamma 90b based on Genesis 9:5 ("the blood of your lives I will surely require"). See Responsa Maharit 97 & 99. See also Responsa Seridei Aish, vol. 3, no. 127 (originally published in Noam 9: 193-215).

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21. The laws of damage in *halacha* are extensively discussed in the Torah, Talmud, and codes of Jewish law.

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22. See Responsa Seridei Aish, vol. 3, no. 127 (p. 249)

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23. Rabbi J. David Bleich, Contemporary Halakhic Problems, Vol. 1, p. 341

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24. As noted above, the fetus would be classified a *rodef*

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25. See Nida 13b and Responsa Chavot Yair, no. 31. Responsa Sheilot Yaavetz, no. 43 argues that once the sperm has been deposited in the woman, the primary prohibition of *hashchatas zera* no longer applies.

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26. Igrot Moshe Even HaEzer I:70, III:14

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27. Generally, all Torah prohibitions except for murder, idolatry, and forbidden sexual relationships are waived to save a human life.

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28. Leviticus 19:16

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29. Sanhedrin 73a

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30. Deuteronomy 22:1-2

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31. Maimonides, Commentary on the Mishnah, Nedarim 4:4

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32. Nidda 30a

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33. *Tumat leida* is the impurity that is created by the birth process, whether live or by miscarriage.

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34. Yevamot 69b

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35. Torat HaAdam (in Mosad HaRav Kook Kitvei Haramban, Vol. 2, p. 29)

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36. This line of reasoning is brought in Talmud Yoma 85b as one possible reason for why saving a life overrides the Sabbath.

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37. See Responsa Sheilot Yaavetz, no. 43, where Rabbi Yaakov Emden argues that "wasting seed" only bars preventing the semen from reaching the woman's uterus. He nevertheless forbids abortion prior to forty days for other reasons.

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38. Seridei Aish, vol. 3:350, n.7

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39. Seridei Aish, vol. 3, no. 127 (p. 249)

[BACK]
40. Responsa Shevet M'Yehuda, Vol. I, 9 and Noam 6:4.

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41. Rabbi Chaim Ozer Grodzinski (Responsa Achiezer, III, 65:14) even entertains the possibility that there may be no Biblical prohibition of abortion before forty days. See also: Tzofnat Paneach 59; Responsa Bet Shlomah, Choshen Mishpat 162; Torat Chesed, Even Ha'ezer, 42:33 all of whom discuss the decreased stringency of abortion within the first forty days.

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42. Males with a single gene for a sex-linked disease will be affected by the disease.

[BACK]
43. Personal correspondance with Dr. Avraham Steinberg.

[BACK]
44. Personal correspondance with Rabbi Sholom Kamenetsky.

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45. *Stem Cell Research and Therapy: A Judeo-Biblical Perspective*, Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives, September 1999, pp.H-3 to H-5. The full text may be downloaded from the National Bioethics Advisory Commission

website at http://bioethics.gov/pubs.html.

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46. "The Judeo-biblical tradition does not grant moral status to an embryo before forty days of gestation. Such an embryo has the same moral status as male and female gametes, and its destruction prior to implantation is of the same moral import as the 'wasting of human seed.' After forty days-the time of 'quickening' recognized in common law-the implanted embryo is considered to have humanhood, and its destruction is considered an act of homicide. Thus, there are two prerequisites for the moral status of the embryo as a human being: implantation and forty days of gestational development. The proposition that humanhood begins at zygote formation, even in vitro, is without basis in biblical moral theology." Testimony of Rabbi Moshe Dovid Tendler, Ph.D , *Stem Cell Research and Therapy: A Judeo-Biblical Perspective*, Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives, September 1999, p.H-3.

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47. E.g., Rabbi J. David Bleich has voiced opposition to the destruction of pre-embryos and their use in stem cell research.

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48. Responsa Seridei Aish, vol. 3:350, n.7, Responsa Shevet M'Yehuda, 1;50, Responsa Maharash Engel, 7:85, and Rabbi Moshe Yonah Zweig, Noam 7:48.

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49. "In stem cell research and therapy, the moral obligation to save human life, the paramount ethical principle in biblical law, supersedes any concern for lowering the barrier to abortion by making the sin less heinous. Likewise, the expressed concern that this research facilitates human cloning is without merit. First, no reputable research facility is interested in cloning a human, which is not even a distant goal, despite the pluripotency of stem cells. Second, those on the leading edge of stem cell research know that the greater contribution to human welfare will come from replacement of damaged cells and organs by fresh stem cell products, not from cloning. Financial reward and acclaim from the scientific community will come from such therapeutic successes, not from cloning." Testimony of Rabbi Moshe Dovid Tendler, Ph.D., *Stem Cell Research and Therapy: A Judeo-Biblical Perspective* Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives, September 1999, p.H-4.

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50. Other issues applicable to stem cell research are generic and apply equally to all research. Full informed consent, careful risk-benefit analysis, allocation of scarce resources, and the role of financial gain and renumeration in research have all been dealt with in Jewish law, and are beyond the scope of this article.

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26th November, 2001

Messrs. Bioethics Advisory Committee

250, North Bridge Road
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Singapore 179101

Dear Sirs,

FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

The basic precept of Buddhism is against harming and killing all beings. We are taught to have love and compassion for all beings.

Regarding the research on human stem cell, Buddhism will look at it seriously from the point of intention. If the intention of the research is to find cums specifically to human therapeutic. In other words, if the aim of the research is to help and benefit humankind, then we will deem the research as ethical. On the other hand, if the research is something just for the sake of doing or simply to make money out of it, then we will feel it is unethical.

As for human claning, although Buddhism did not state that beings are created by God and the different forms of birth are mentioned in the scriptures, but we are definitely against it. We feel that this will affect the society both morally and socially.

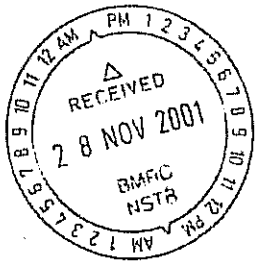
In conclusion, we will support research on human stem cell that will benefit humankind as a result, but are definitely against human claning. We hope the above clarify with the committee the Buddhist stand on human stem cell research in Singapore.

Please feel free to contact us if you have further queries.

Thank you and with best regards,

Yours sincerely,

Venerable Shi Ming Yi
Secretary General---Singapore Buddhist Federation



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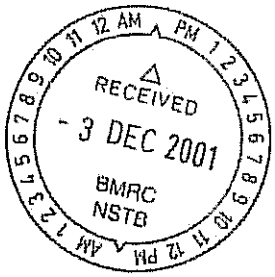

DR LEE HEW MUN
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25th NOVEMBER 2001

Dear Sirs

FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

We refer to Prof Lim Pin's letter dated 8th November 2001, requesting for feedback on the BAC's position on human stem cell research in Singapore.

We would first like to thank the BAC for this invitation for our feedback.

Having read the consultation paper prepared by the Human Stem Cell Research Subcommittee (HSR), we cannot but express our disappointment and disagreement with the HSR's position on research exploiting embryonic stem cells derived from early embryos ('ES cells') and embryonic germ cells obtained from babies killed by induced abortion('EG cells').

We have previously explained our rationale for our opinion in letters to the Deputy Prime Minister, Dr Tony Tan, and the Bioethics Advisory Committee itself, copies of which are enclosed. Together with these, we have also enclosed a copy of the letter sent to the National Medical Ethics Committee by the Archdiocesan Bioethics Commission.

In summary, we would like to put forth the following points:

1. On the basis of a complete biological analysis, the living human embryo is - from the moment of the union of the gametes - a human subject with a well defined identity, which from that point begins its own coordinated, continuous and gradual development, such that at no later stage can it be considered as a simple mass of cells. Jerome Lejeune, who was a professor of fundamental genetics in Paris and a pioneer in detecting chromosomal diseases, once said to a US Senate committee: "Life has a very, very long history but each individual has a very neat beginning, the moment of its conception."

The two moments of real discontinuity in the life of an individual are to be found in the acts of fertilization and of death.

Objections based upon the appearance of the primitive streak and of the nervous system bud, and upon the relevance of the implanting as a decisive event for the continuation of development, do not bear in the least upon the individuality of the embryo or the continuity of development: the appearance of the primitive streak and of the nervous system -- like the whole process of organogenesis -- are the outcome of this active and individualized development. Therefore the objective facts of science tell us that every human being begins life from the moment of conception, or in the case of cloning, when the nucleus of a somatic cell to be cloned is incorporated into an enucleated ovum. It seems painfully apparent that those who have chosen to deny this fact of science have done so in a thinly veiled attempt to justify policies that favour continued experimentation on, and destruction of, our younger and most vulnerable citizens for the sake of material gain.

Put in another way, is it not incoherent to state that a human being begins life only on the fourteenth day after it has already started living (from the moment of conception)?

2. The human being is to be respected and treated as a person from the moment of conception; and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life.

From this it follows that as a human individual it has the right to its own life; and therefore every intervention which is not in favour of the embryo is an act which violates that right. Therefore, the ablation of the inner cell mass (ICM) of the blastocyst, which critically and irremediably damages the human embryo, curtailing its development, is a gravely immoral act.

In the same vein, every type of therapeutic cloning, which implies producing human embryos and then destroying them in order to obtain stem cells, is immoral.

3. No end believed to be good, such as the use of stem cells for the preparation of other differentiated cells to be used in what look to be promising therapeutic

procedures, can justify an intervention of this kind. A good end does not make right an action which in itself is wrong.
We note that the HSR quite rightly banned reproductive cloning of human beings because it "goes against the moral idea that a human being is not to be treated as a means to an end, but only as an end." It is precisely because of this that a human being, whose life begins at conception, should be given absolute respect at all stages. This respect that is accorded to him should not be made relative to the potential benefit his death may reap for others.

We would like to assure you that the Catholic Medical Guild has no intention of waving aside the potential for good, for curing disease and saving in the name of dogma. On the contrary, we encourage such research for the good of humanity, as in research on adult stem cells and cells obtained from babies that have died from natural abortion (provided adequate informed consent has been obtained). We cannot however condone research on cells obtained from the destruction of embryos and babies killed by induced abortion.

We would therefore like to conclude by stating our unequivocal objection to research that entails the destruction of human life at any stage, because we know that at the end of our lives, we will have to account for what we have done to others at the beginning of theirs.

Yours faithfully

Dr John Hui Keem Peng

Master
The Catholic Medical Guild
of Singapore

Dr John Lee Hew Mun

Immediate Past Master
The Catholic Medical Guild
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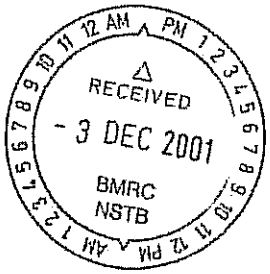

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17th September 2000

Dear Sir,

HUMAN STEM CELL RESEARCH

We are pleased that, in an interview with Channel News Asia on 28th June 2000, you brought up the necessity of a national bio-ethics committee in the future to make sure that our foray into the field of life sciences research is kept within proper ethical boundaries. As health care professionals trained to care for human life from conception to natural death, may we request that such a committee be formed immediately, and that research on human embryonic stem cells be banned, for reasons that follow.

I. **LIFE SCIENCES RESEARCH IS PROGRESSING AT A FAST PACE**
It was first brought to the public's attention in May 2000 that the NUS had been conducting research on stem cells from human embryos less than one week old. On August 11th 2000, it was announced that the EDB, through its investment arm, Life Sciences Investment, would be investing $17 million in a new company, ES Cell International to develop and commercialise a research project on embryonic stem cells by local and foreign scientists.

With this development, research in the life sciences has now gone into full throttle. It is significant to note that it is going on without the existence of a bio-ethics committee to formalise ethical guidelines for such projects. This might undermine your desire to bill Singapore "as a country with practices of high ethical standards in medical research."[1]

II. HUMAN LIFE BEGINS AT CONCEPTION

This is a very important issue, one that will decide our stand on the ethical issues surrounding human embryo research.

Every individual human being begins as a human embryo at fertilisation with the initial fusion of sperm and ovum.[2] In the case of cloning, a new human life begins when genetic material from a somatic cell is fused with an enucleated oocyte.

At fertilisation, the single cell human zygote, in vivo or in vitro, is genetically already a little boy or girl. Immediately, this tiny human being stops his mother's menstrual periods and requiring only shelter and nutrition unilaterally directs his or her own growth and development from a single cell zygote through the 12-16 cell morula and the 5-6 day blastocyst stages until finally setting his own birthday. The blastocyst is never a "pre-human" clump of cells. It is the human embryo, a little human being, that each one of us once was.

III. THE ETHICS OF HUMAN EMBRYONIC STEM CELL RESEARCH

As health professionals, we are convinced that human life must be absolutely respected and protected from the moment of its beginning at conception. In human embryonic stem cell research, pluripotent cells from the inner cell mass of the human embryo at the blastocyst stage are used. In the process the human embryo is destroyed. Such means to achieve the end of excellence in the life sciences can never be justified.

A policy that accords absolute respect to the human embryo is no mere political compromise. It is a reflection of universally accepted ethical principles governing experiments on human subjects – principles reflected in the Nuremberg Code (1947), the World Medical Association's Declaration of Helsinki (1964) and other like documents. Members of the human species who cannot give informed consent for research should not be the subjects of experiments unless they themselves may benefit from it or the experiments carry no significant risk of harm to them. Only by such ethical principles do we avoid treating people as mere means to obtaining knowledge or benefits for others.

IV. WHAT HUMAN EMBRYONIC STEM CELL RESEARCH WILL LEAD TO.

If we accept that there is such a thing as a human life that is not worth protecting at its initial stage of development, it will only be a matter of time before our respect for life at all other stages will be eroded too. If we can experiment with and dispose of a 5-day old embryo, we can do the same with a 2-week, 3-week, or a 5-week old or older embryo.

This is no mere speculation. It has already occurred in Singapore.

At an international symposium on the treatment of Parkinson's Disease held at Singapore General Hospital on 26th August 2000, a local presenter revealed that eight unborn babies had been used at that hospital to treat one patient with Parkinson's Disease. In this procedure, the heads of these babies aborted at six to eight weeks' gestation were taken out whole from their mothers' wombs. Their brains were then dissected and cells were removed from them to be subsequently implanted into the brain of the recipient in a procedure that is still considered experimental.

If unborn children are considered disposable material to be used to treat other "more worthy" human beings or are deemed "useless" or a "burden" to the economy or to the family, there are no further ethical barriers to stop anyone from killing those already born and similarly burdensome, a likely situation in time given the expected increase in the numbers of aged and handicapped.

Again this is no mere conjecture. There is precedent. The Nazi experience and the subsequent Nuremberg medical trials in 1946 revealed previously unthinkable facets of human nature and serve as a chilling reminder of the depths to which even well educated and distinguished men can sink. Starting with the presumption that there is such a thing as a human life not worth living, these doctor-scientists too followed their dream of genetic cleansing by exterminating in turn the mentally handicapped, the physically infirm, the aged and finally the "inferior" ethnic groups.

And this despite the German government being one of the first in the world to install a system of informed consent in human experimentation, after **Albert Neisser** was fined for infecting patients with syphilis without their knowledge or consent in 1898. It is significant that these regulations in 1900 were initiated by government authorities rather than by doctors or research institutions.

In 1931, the Reich government again found it necessary to issue detailed guidelines clearly distinguishing between therapeutic and non-therapeutic research, even setting out some stricter and more detailed precautions than those contained in the much later Nuremberg code and the Declaration of Helsinki.[3]

Notwithstanding these ethically and legally advanced regulations, it is a matter of history how Nazism made it possible from as early as 1933 for about 400 German doctor-scientists, of whom only 23 were indicted, to systematically destroy the fabric of medical decency.[4] Not only did the then Government abrogate its responsibility but it was also guilty of complicity in medical crimes against humanity that the world still finds difficulty in comprehending. In the words of **Hartmut M Hanauske-Abel**, "*In 1933 the convergence of political, scientific, and economic forces dramatically changed the relationship between the medical community and the government. That same convergence is occurring again and must be approached with great caution if medicine is to remain focused on the preservation of physical and medical integrity.*" [4]

Such people and tendencies are not past, never to happen again. They have continued as hitherto low-key threats. For example, the legacies of Nazism and its medical collaborators reached even into the post-war institutions created to prevent recurrence of their crimes - Nazis **Dr Ernst Fromm** and **Professor Dr Hans Joachim Sewering** were members of the World Medical Association which authored the Declaration of Helsinki (1964).

These threats are increasing. According to **Grodin,** the Declaration itself,"*..undermined the primacy of subject consent in the Nuremberg code and replaced it with the paternalistic values of the traditional doctor-patient relationship.*"[5] It was further modified in 1975 and 1983 and even now the USA's FDA is considering allowing placebo trials whether or not it has already approved one or more treatments for the same condition under study, in direct conflict with para II (2) of the Declaration.

As in Germany before the last war, decades of legalised abortion and in-vitro fertilisation and now embryo stem cell research in Singapore and in the world continue to desensitise us to the fact and the inviolability of human life and foreshadow the same outcome. In the USA, despite much talk of human rights, the escalation of abortion to partial birth abortion in 1996 is another stark reminder of how anaesthetised people have become to the baby's humanity.

Not the least consequence of the failure of care and concern for the unborn baby is the crisis of under-population, irremediable by international migration, that the United Nations Population Division predicts will hit first Europe and Japan over the next 50 years, a possibility hitherto denied for decades by most world leaders.[6]

Significantly, the European Parliament voted at Strasbourg on 7 Sep 2000 by a narrow majority against therapeutic cloning, and asked the governments of the European Union "to introduce binding norms that prohibit all forms of research on any type of human cloning in their territory, and provide penal sanctions for any violation." In addition, the document called on the British government to review its stance on the cloning of human embryos.

It is facile to believe that fertility decline is due to development alone. Development removes the economic reasons for having children and leaves only spiritual and other intangible benefits, reasons that have now also been removed by the soul destroying effects of legalised contraception and abortion. Without these reasons, the motivation to have children cannot be restored by a raft of monetary or opportunity incentives. And as physical infertility and infirmity supervene due to the continuation of societal ageing, even the eventual restoration of these values will likely fail to rejuvenate the population. The pressure for euthanasia and human reproductive cloning may then become intolerable.

The possibilities that Science is providing are increasing so rapidly that ethics and laws have not been able to keep up. There is great danger that each and every such additional scientific "success" desensitises us further and makes us more liable and more vulnerable to a cataclysmic end.

With no moral compass, mankind will pay a very high price if it pursues embryo stem cell research claiming that it offers "*great promise to relieve human misery*" without even having a clear understanding or acknowledgement of what it means to be human. Failure to recognise that an individual human being begins at fertilisation or refusal to acknowledge it on the premise that any action is licit if it benefits others opens a Pandora's box of inequity and injustice against those unable to defend themselves.

Concepts such as pragmatism, loosely translated as "what works is good", and democracy or "governance by the majority," despite their undoubted usefulness, are insufficient, even misleading, as moral or ethical surrogates. Since every evil act has some good effects (that's why people do them), the commonly held notion that the moral integrity of an act can be judged solely by its good effects leads to an increasing acceptance of evil acts and to the escalation of evil. Once it is wrongly claimed that harm can be done to a human being in its early existence for the benefit of others, all further barriers to immoral and unethical action can be whittled away just by the further use of reason.

We need instead to actively promote what **Engel** called the scientific-physician, one who espouses and exemplifies humanism in medicine, and on the other hand to identify and neutralise the impostor, the physician-scientist, to whom human beings are mere scientific material whose mysteries are an object of curiosity to be unravelled without flouting those laws of the land, if any, that have kept up with the scientific possibilities. It is as true today as in 1987 when **Engel** observed that "*...there is an elite class of physician-scientist but as yet few fully qualified scientific-physicians.*"[7]

V. VIABLE AND ETHICAL ALTERNATIVES TO HUMAN EMBRYONIC STEM CELL RESEARCH

Recent research suggests that adult stem cells harbour previously unsuspected developmental potential. Adult bone marrow stem cells injected into the circulation of irradiated adult mouse hosts have given rise to new microglia and astroglia in various parts of the brain[8], new skeletal muscle cells[9], and new hepatic oval cells [precursors to differentiated liver cells][10].

More recent research showed that stromal stem cells injected directly into neonatal lateral ventricles could give rise to differentiated astroglia[11], whereas haematopoietic stem cells contributed cells to new muscle fibres, and postnatal muscle stem cells could give rise to blood cells[12,13]. So too work is being done on new growth factors that permit the body to heal itself.

Adult stem cell research is a lot less objectionable from the moral point of view, and appears to offer the same therapeutic possibilities as embryonic stem cell research.

VI. VIABLE AND ETHICAL ALTERNATIVES TO TREATMENT WITH HUMAN EMBRYONIC STEM CELLS

Stem cell transplantation is a generic term covering several different techniques[14]. For example, **allogeneic** transplants of a healthy donor matched for HLA type who may be a family member or an unrelated volunteer were first used to treat congenital immune deficiencies, bone marrow failure, and haematological malignancies and is now used routinely for some non-malignant conditions such as thalassaemia. Haematopoietic stem cells from umbilical cord blood and placental material following delivery or from the bone marrow and peripheral blood are used.

Autologous transplantation of stem cells from the patient's *own* bone marrow or peripheral blood was introduced to rescue the bone marrow of patients due to undergo high dose chemotherapy, and is now increasingly written into protocols for the primary treatment of solid tumours such as breast cancer and neuroblastoma. Autologous transplantation is also used experimentally to treat difficult autoimmune conditions such as systemic sclerosis and as a vehicle for gene therapy.

If we can identify the mechanisms regulating the differentiation of adult stem cells, we would have a viable way to develop many other tissues for autologous transplantation, which does not carry the risk of rejection.

Knowledge of stem cell transplantation techniques and their clinical application is thus becoming essential for increasing numbers of medical specialists. These methods are inherently moral and are what the scientific community needs to make continuous progress in medicine. **They do not need to destroy human embryos.**

The developments in the life sciences, and how we respond to them as a nation, will tell us much about ourselves and the values that we embrace. The argument that the destruction of embryonic human beings is permissible when it provides sufficient promise of "medical and scientific progress" may yet win the day. If it does, our nation will have taken a tragic step down the long and perilous path that subordinates morality and human life to cold and utilitarian technology.

We have been beneficiaries of the far-sighted policies of a government that has sought only the best for our country and her citizens. We strongly urge you to look into this matter of grave concern and to establish or re-establish a bio-ethics committee immediately.

CONSTITUTION OF BIO-ETHICS COMMITTEE

We propose that the National Medical Ethics Committee under the present chairmanship of Prof. Ong Yong Yau be given wider terms of reference and powers to regulate the ethics of the burgeoning life sciences. The Committee's membership and statutes may need to be re-constituted to fulfil this wider responsibility.

Alternatively, a new bio-ethics committee of doctors, lawyers, ethicists, scientists, the public, and representatives from major religious groups in Singapore be formed under the chairmanship of the Director of Medical Services or the Deputy Director of Medical Services (Professional Standards).

The terms of reference would include

1. reviewing any patent applications linked to bio-technological inventions
2. blocking any patenting of the human body, any of its parts, embryonic stem cells, the embryo or of human cloning.
3. blocking the patenting of the use of human embryos for industrial and commercial purposes.
4. preventing the creation of embryos for research
5. preventing reproductive cloning.
6. ensuring that any research on embryos will not harm them.
7. preventing procedures modifying the foundational genetic identity of human beings
8. blocking genetic research that could be influence by political, economic and military interests
9. ensuring that any research in the life sciences will be undertaken with full respect for human life in all its stages.

It is imperative that none of its members has any involvement or vested interest (financial or professional) in life sciences research. This committee can meet in

public session, or at least be open to feedback from interested members of the public. This committee shall then report to the ministerial committee looking into the life sciences industry, chaired by your good self, and comprising the Ministers for Trade and Industry and for Health.

We are in full support of a life sciences programme that will enhance the quality of life and generate more wealth for Singaporeans. But it is also our ardent hope that, in our quest to excel in the life sciences, the dignity of human life will still be upheld in all its stages of development. In concluding, we would like to remember what Dwight D. Eisenhower once said: "A people that values its privileges above its principles soon loses both".

Thank you very much for your kind attention and your dedicated service to the nation.

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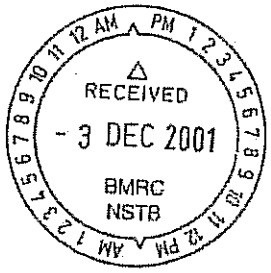

8th October 2001

Dear Sir

Human Embryonic Stem Cell Research

Recent developments in the press and other media on the subject of human embryonic stem cell research have prompted the following further responses from us.

We are highly supportive of the life sciences programme, and are delighted by the government's foresight in developing the "Biopolis", which will certainly help to attract and maintain the top talents in the biomedical sciences. We share in the government's belief that this will help our nation's pursuit of health and wealth. Our support for this includes stem cell research, and the great good for our people that it could result in, with the important exception of research on human embryonic stem cells (HES Cells) and its inseparable killing of human embryos. We have previously focused on this aspect of the life sciences in our letter to Deputy Prime Minister Dr Tony Tan last year.

The following comments are therefore confined to human embryonic stem cell research.

1. **Introduction**
   This is not a debate that we are engaged in but primarily a plea against the unjust taking of innocent human lives, especially among the weak and the voiceless.

Please allow us to elaborate.

2. **The Humanity and Dignity of the Human Embryo.**
First of all, it is a universally accepted fact that the deliberate taking of innocent human life for any reason is beyond debate. The killing of innocent human creatures, even if carried out to help others, constitutes an absolutely unacceptable act.

   The claim that the possible advances in science and medicine are good enough reasons to kill human embryos is seductive, but dangerous as a precedent for future decision making and ethical action.
The question to discuss, if one really exists, is whether or not the human embryo is a human being. And the human embryo is just that.

   He is "human" because he has the human genome and he is a "being" because from the outset he has totipotence, the intrinsic power to develop all his tissues and organs. No cell from human skin or the buccal mucosa fulfils both these criteria. But cloned humans do, which is the primary reason why they may not be created or killed.

3. **On pragmatism as a tool for ethical constructs.**
The principle of pragmatism, loosely translated as "what works is good", is insufficient and misleading, and should not be used as a moral or ethical surrogate.

   In decision making it is first essential to be able to distinguish between acts and their effects. Evil acts are usually committed for their good effects and no sane and free person ever wants an evil result from his evil act. Hence to judge the morality of an act only by its effects is to accept that evil acts are a valid means to an end. Under this principle one may for example try to get rich by any means, fair or foul.

   This is a significant departure from the axiom that crime does not pay and will pave the path to new ways of defining laws and undermine the very core of justice. How for example would a court then treat a plea that there was a good reason for a deliberate murder? In the eyes of the perpetrator there always is.

   A people who believes that good can be obtained through evil are a people who will lose their sense of right from wrong. This degeneration is already obvious in the way that abortion, once a crime, is now a right, and the ease with which the deliberate killing of the human embryo is accepted.

   History is replete with scientists who have done more harm than good, living only for their passion without due regard for the common good. Current scientific literature and the media abound with the exploits of scientists plundering the secrets of unborn humans without concern for their life or welfare and completely disregarding the dignity of babies and ethical concerns of others.

Once we allow the destruction of the human embryo, we will not know when to stop. When we can destroy the embryo at four days for the "greater good" of society, it will be easier to allow the destruction of the embryo at four weeks, then the unborn baby at eight weeks, and so on. One we embark on this path, we will gradually get more and more desensitised to the humanity of our unborn babies. As long as one of us benefits from the death of these babies, it can be justified. It will not be long before this will be extended to the handicapped and aged as our economy in due course feels the strain of looking after the ever-increasing number of aged sick in our midst. Note that pro-euthanasia movements are already very strong in countries that are at the forefront of embryonic stem cell research, namely the United Kingdom and the Netherlands.

Some individuals have tried to justify the destruction of human embryos for research because "they are going to be discarded anyway". The embryo should be treated with as much respect and dignity as any one of us. A convicted murderer who is about to be hanged should not have his organs removed while he is still alive, even if it is for the benefit of others, just because "he is going to die anyway". He is still a human, and deserves respect as such. How we regard embryos perhaps could be extrapolated from how we should regard a child who is found abandoned in the street. We can either try to locate his parents and convince them to take him back, find an adoptive home for him, or if he really is dying, find him a place where he can die with dignity. Any of these solutions sounds plausible. But never dismember him and take out his organs for the benefit of someone else. No one has ever had a right over another's body, but what we do have is a responsibility to care for each other, especially the most vulnerable.

Every embryo destroyed, especially when publicly approved, will weaken our resolve to reduce the already high number of abortions in Singapore. After all, the reasoning is simple: "If the authorities can destroy embryos for society's 'good', why can't I abort my baby for my own 'good' and convenience?"

4. SCIENTIFIC CONCERNS

In a report presented to Congress and the President of the United States in July this year, the NIH conceded that the main problem with embryonic stem cell research was the development of tumours[1]. This fear was well founded, because their scientists found that, when embryonic stem cells were transplanted into mice, some of them turned cancerous. This is not unexpected, given that such stem cells grow almost uncontrollably, and we are far from deciphering the switching on and switching off of cancer genes.

Secondly, the embryonic mouse fibroblast cells that are used as a medium for the growth of embryonic stem cells may be a source of zoonotic infections (infections that are passed from animals to humans), some of

which we may have never encountered, much less been able to diagnose, before. A recent paper presented by a Singapore team involved in such research suggested that they are trying to circumvent this problem by developing a new medium for these cells to grow on. This medium could be of human or synthetic origin. However, this has only been developed in the last six months, is experimental, and is obviously far from perfect. Besides, out of the six cell lines grown so far here, most were developed before the past six months, which means that they have already been exposed to the mouse cells used before. We can never now be too sure if unheard of infections have not already affected these cell lines.

5. **FINANCIAL CONCERNS**

To the extent that financial concerns are tied to ethical concerns over the financial welfare of Singaporeans, we also need to be aware that some problems in embryonic stem cell research might also result in loss of investments.

Among these are the long maturation time of such investments and the risks of therapy such as unknown infections, including zoonotic infections, and the unknown mechanisms involved in the switching on and off of tumour genes.

More important is the increasing opposition to such research in various parts of the world, with the prospect of organisations and governments around the world boycotting products from countries that promote embryonic stem cell research. This cannot be discounted, given the blistering pace at which political structures and events are reshaping the world's political landscape.

Adult stem cell research, which does not involve the destruction of any human being, is progressing at a rapid pace. If a scenario arises whereby a product is developed from adult stem cells at around the same time as one derived from embryonic stem cells, it is almost certain that the former would be preferred.

6. **ON PATIENT CONSENT**

Consent from patients has been offered as a defence to manipulating and destroying human embryonic babies. But to be valid, consent must be **justifiable, informed** and **free**.

"**Justifiable**" means that consent by parents on behalf of their children lacking capacity must be exercised according to the "welfare principle": that the child's "welfare" or "best interests" must be paramount. No parent is ever justified to consent for his child to be given away for prostitution or to be harmed from experimentation. The question is whether consent is in the best interests of the child.

For parents to be "**Informed**" requests need to be transparent. A request like, "Can I have your permission to take your embryo's stem cells? You

should know that he needs these cells to live and will die if I take them" clarifies at least the uncertainty inherent in the current request methods.

Consent must also be **"free."** Vulnerable patients in a dependent physician-patient relationship cannot give valid consent without fearing that their refusal would interfere with this relationship. "Presumed consent" was criticised by the *World Medical Association* at their 52nd General Assembly in Edinburgh in Oct 2000.[2]

Having a system of "informed consent" therefore does not necessarily imply or guarantee a humane or ethically advanced medical service. It is a sobering thought that Germany was one of the first in the world to have a system of informed consent in 1900 but is now remembered as the world's worst experience of man's inhumanity to man.[3]

7. ON THE NBAC'S ROLE

The decisions of the NBAC as expressed in their final document will have far-reaching effects on the moral and ethical fibre of this nation. The recurring assaults on pre-born babies through abortion, and now by stem cell dismemberment, constitute an unjustifiable attack on the defenceless child.

Will Singapore continue to fail the unborn child because he has no voice? If we choose to follow this course, the precedent set may scar our history forever, and set us on a course of a utilitarian and anti-baby mindset that we may never again recover from. Will we fall prey to the temptation of material riches, or will we pride ourselves as a nation in adopting a more humane and just position?

The adoption and legalisation of practices that are considered unethical and immoral will not dissipate, as is hoped by some, but continue to fester and will flare up again and again each time there is a new way that human babies are mistreated.

We believe that the NBAC will have the wisdom and the courage to confront evil and to map Singapore's advance into the era of life sciences without being unduly influenced by big business or the seduction of science for its own sake rather than man's.

8. ADULT STEM CELL RESEARCH – AN ETHICAL AND VIABLE ALTERNATIVE

Resources for research and development could be directed into more acceptable areas such as the presently under-funded **Cord Blood Bank** and **adult stem cell** research programme. Associate Professor Patrick Tan, Director at the Centre for Transfusion Medicine, recently said that public cord blood banks were worth supporting (ST 24 Sep).

Since it was first reported in Jan 1999 that adult neural stem cells can reinvent themselves as haemopoietic precursors[4, 5], cells of the liver, lung,

gastrointestinal tract, skin, heart and muscle have been grown from adult stem cells. Stem cells from the umbilical cord, placenta, bone marrow, fat and skin can now give rise to cell lines that can treat diseases such as strokes, heart attacks, leukaemia, thalassemia, type I diabetes, and systemic sclerosis, and do not pose the risk of tissue rejection or cause tumours as embryonic stem cells do[6-10].

Just last month, a new adult stem cell identifier ABCG2/Bcrp1 that may be much more specific than the old CD34 standard was reported in Nature Medicine.[11] This could lead to greater harvesting of adult stem cells, increasing its availability for research and therapy. All these possibilities can and should increase rapidly in the near future, given adequate funding and resources.

We hope the NBAC will divert the energies of scientists into these and other more ethical and productive activities. This should not be a major hurdle since scientists do not generally pursue their passion with any premeditated attachment to killing human beings or to offend others. These professionals would on the other hand greatly benefit from sound ethical guidelines and just laws, being able to carry on their work with a clear, well formed conscience. Business interests should take their lumps and learn how to make money ethically, as all entrepreneurs should. Let us not be bankrupt of integrity and honour.

If we do not endorse human embryonic stem cell research, we will not be alone. Germany, Austria, Ireland, Hungary, Poland, Norway, Switzerland and Tunisia are among countries that forbid experimentation on the human embryo.

For example, Germany, chastened and wiser after the experience of its Nazi past, has made it an offence since 1990 to experiment on the human embryo and an offence to possess so-called "spare embryos."[12]

The generation that experienced that holocaust understands the need to stop experimenting on human beings as if they are mere human tissue, and formulated the Nuremberg Code (1947)[13] and the Declaration of Helsinki (1964). In addition, the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

9. Conclusion

Our wish for Singapore is that we should not just be rich, but also great. It is our ardent hope, therefore, that the **National Bioethics Advisory Committee** will take a positive role as the moral and ethical compass to the life sciences programme. We do not deny that this role is unenviable, and our prayers and best wishes are with you.

This may be our only hope to prevent yet another threat to Singapore's long-term security, prosperity, and fertility – a deepening loss of respect for

the humanity of the unborn child and a widening ethical divide, both local and regional.[14]

We would like to assure you once again that the Catholic Medical Guild has no intention of waving aside the potential for good in the name of dogma. On the contrary, we encourage research for the good of humanity, as in **adult** stem cell research, as long as it does not seek to save some by destroying others, as in **embryonic** stem cell research. When we defend the right to life of every innocent human being – from conception to natural death – as one of the pillars on which every civil society stands, we are simply promoting a human state, a community in fundamental agreement with human nature.

Finally, we recall what Dwight D. Eisenhower once said: "A people that values its privileges above its principles soon loses both". What kind of a people shall we be? The choice is now yours to consider.

Thank you so much for your kind attention.

Yours faithfully

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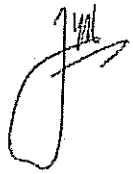

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20 Jun 2001

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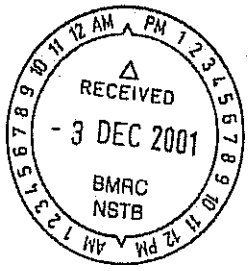

Re: **NMEC Ethical Guidelines for Gene Technology**

1) On behalf of the Catholic Church in Singapore, please allow us to comment on the recent guidelines of the National Medical Ethics Committee (NMEC) entitled, "***Ethical Guidelines for Gene Technology***"

2) The guidelines are a timely reflection of the changing face of medicine and science, and of the increasing needs and wants of the public in this area of medical progress. It is an important area because of the many serious issues effecting researches on the human genome, and the life sciences.

3) It is our opinion that the guidelines are on the whole sufficiently comprehensive and detailed and sufficiently accurate from an ethical perspective to guide the medical and scientific community for the time being, although some amendments and/or clarifications are needed now and in the future as experience is gained.

4) In particular, we have serious reservations to the wording of two entries as presently stated in para 8.2.2(a) and para 9.7 of the guidelines and in para 22 of the summary of recommendations. In our judgement, these are unsatisfactory as they reflect the inadequate practices prevailing with regard to the life of the unborn child.

5) We submit our proposals for changes to these paragraphs for clarity.

6) These important guidelines have been formulated after detailed consideration of the numerous issues relating to the human genome, including important issues such as Human Cloning, and the use of living embryonic stem cells. Thus the guidelines also require the endorsement of the Government of the Republic of Singapore, for if they cannot be enforced, it is as good as not having them. Any professional (e.g. doctors and lawyers) who breaches the professional code of conduct and ethics is subject to disciplinary action. Thus anyone breaching these ethical guidelines must also be subject to disciplinary action.

OUR COMMENTS

7) As stated in the guidelines,
"8 Categories of gene therapy...
8.2.2 We strongly advocate that germ-line therapy with the result of passing on the genetic changes to the offspring should not be contemplated presently for the following reasons:

(a) The ethical issue of whether and when a foetus becomes a patient remains highly controversial. Does the pre-viable foetus have as much an independent right as a patient (subject) as a viable foetus?"

Our comments

7.1 We agree entirely with the NMEC's stand in para 8.2.2 that 'germ-line therapy with the result of passing on the genetic changes to the offspring should not be contemplated'.

7.2 But we are very concerned by the reason given as stated in para 8.2.2(a) which places doubt on the humanness of the baby in-utero. There is no medical or scientific evidence to support the view that the conceptus is at any stage sub-human, pre-human or non-human. As a human being dependent throughout his life in his mother's womb for shelter and nutrition, he is entitled to the care of any patient. Removing this life support is akin to stopping nutrition in an adult who would surely die as a result.

7.3 Worded in the proposed manner in the guidelines, this paragraph is a licence for abortion, foetal experimentation, IVF, trafficking of embryos and embryo spare parts and the sale of human foetal stem cells. Many such abhorrent practices are internationally condemned on ethical and moral grounds.

7.4 For these reasons, the living foetus in the mother's womb is a patient from the time of conception until his birth.

8) As stated in the guidelines,

"9.7 Somatic Gene Therapy in pregnancy.

The introduction of foreign therapeutic gene to the pregnant woman carries a theoretical risk of its inadvertent incorporation into the growing foetus. Such an event, although unlikely with the vector systems used today, is expected to have greater effects on the foetus in the earlier stages of pregnancy, when embryonic organogenesis is actively taking place. *We recommend that somatic gene therapy should be deferred till the last trimester of pregnancy or postpartum unless the perceived benefits of gene therapy to the mother clearly outweigh the risks to the foetus.*"

Our comment

8.1 Introducing foreign therapeutic genes is intended to exert an effect in adult patients who are of course no longer exhibiting organogenesis. Although the very young foetus is at increased risk from these interventions to his mother, the same effects if nor worse may be exerted on him as on the pregnant woman **throughout** intrauterine life, e.g.

8.1.1 When Thalidomide was given to pregnant women (1940s) as a hypnotic drug with no known side effects, it led to the birth of thousands of children without limbs or who had limb defects. This led to considerable suffering for these children and their families for life. Compensation and closure of the company was no expiation for their suffering and for the costs society had to bear for this catastrophe.

8.1.2 Medical Molecular Science is still in its infancy. The functions of many small molecules of proteins, oligonucleosides, and nucleic acids are still unknown. Many of these small protein molecules can cross the placenta and blood brain barrier, and be imbibed and/or endocytosed by totipotential and germinal cells, where intracellular molecular changes may take place. Integration of bacterial proteins are known to take place in the human genome. Natural or synthetic DNA molecules, used for gene or DNA therapy, are often composed of ligands which have bacteria or viral inserts, which can be harmful to the somatic and foetal cells.

One of the major fears of DNA or gene therapy is the induction of carcinogenesis in both somatic tissues and germinal cells in babies in the womb.

For these reasons gene therapy should not be given during ANY stage of pregnancy.

9) The legalisation of abortion and the acceptance of contraception, in particular abortifacient contraceptives, for the last 35 years have dulled the conscience and silenced those who might have sought to protect the unborn child against destruction. And despite the resulting demographic disaster of ageing and death that is surely overtaking the world and the inevitable fate threatening Singapore in about 1-2 decades, no one has yet been able to reverse the decline of fertility for the last 25 years.

10) While the NMEC guidelines cannot adequately counter this threat, they must not propagate further the failure of society to protect the unborn child. The ethic that unborn babies can be killed or maimed to solve social or economic problems must not prevail. In the words of Mr Johannes Rau, President of Germany, "*What is ethically indefensible cannot be permitted for economic reasons.*" He should know. In the aftermath of the world's worst experience of eugenics, euthanasia and selection carried out by a government of an advanced, developed country, Germany banned pre-implantation diagnosis and the use of embryos for research in 1990. This law is still supported by German doctors and by Mr Rau who said, "*Those who begin to instrumentalise human life, to differentiate between worthy of life and unworthy of life are on a runaway train. Nothing may be placed above the dignity of the individual.*"

OUR REASONS

11) Viability assessment is not a philosophical definition for labelling anyone non-human.

The human embryo is capable of independent reproduction and of growing into a developed human form. Viability assessment is a measure of medical management and skill, not a philosophical definition for labelling anyone pre-human, sub-human or non-human. An illustration of the receding frontiers of foetal medicine is the recent example of *Christopher Williams*, who was 16 weeks premature and weighed only 604 grams when he was born in November but who is now, 6 months later, a healthy 4kg in weight.

Furthermore, *Gray's Anatomy*, an internationally acceptable textbook of Human Anatomy and Embryology, has demonstrated that the conceptus has human features at 4 weeks old and that human embryogenesis begins from the time of conception. This definition is accepted by all Human Anatomy Textbooks.

12) Human DNA

Since the time Watson and Crick discovered the structure of human DNA until the present when the structure of the human genome has been unravelled, much information on the human code has accumulated. Yet though the numerous disease associated genes have been identified, much of the functions of the 3 billion oligonucleotides in the genome are still unknown.

13) The human genome is formed in the human zygote

The human genome makes our bodies human bodies and distinguishes a human being from a chimpanzee, a puffer fish and a fruit fly. Each creature has its own distinctive genome that **from the moment it exists** orchestrates its growth and development, determines its structure and function and characterises its status.

14) The totipotent human zygote with its human genome is a living human being

Our human genome formed when each of us originated as a totipotent human zygote co-ordinates our growth and development until we are what we are today. Like the producer and the director, both unfold the story of life **from the moment the covenant is sealed.** From that moment then must the totipotent human embryo with its human genome be accorded the scientific and ethically significant quality of personhood. Hence the dignity of the human person is automatically accorded from the moment of conception.

15) Destroying a zygote that is destined to twin destroys more than one human being

A second arbitrary contention that personhood is absent before the 14th day because of the possibility of twinning before that day is a failure to acknowledge the power of that totipotent human zygote with its human genome to produce not just one but two individuals. Destruction of such a zygote kills more than one human life.

16) The totipotent human embryo is no more a mere collection of cells than we are.

Still others believe that the human embryo is no more than a collection of human cells. If that is true then so is everyone else merely a collection of cells. If we are persons at all, we have been persons since our genome was formed in the totipotent embryo. Whether pearls are in a pile or in a necklace, they are nonetheless pearls. Any seed has the same intrinsic worth as the plant it will grow into - and not because the seed has been genetically modified and patented for profit. To suggest that the embryo has less value than the adult is not to acknowledge the central meaning of embryonic totipotence and the human genome.

17) The totipotent human embryo is a human being and not a *potential* human being.

The human zygote is thus an embryonic human being, possessing all the qualities and power to grow and develop in its natural environment with the addition of only shelter and nutrition until adulthood. Calling the totipotent human embryo with its human genome a potential human person makes as much sense as calling a new motor car under wraps a potential motor car.

18) The sperm cell and the ovum are not potential persons.

On the other hand, it is the human genome that also distinguishes the embryonic human being from a sperm cell and an ovum. The sperm cell and the ovum each has a haploid number of chromosomes and half the DNA complement of somatic cells. Sperm cells deposited in the female genital tract have a maximum life span of about 3 days; an ovum after ovulation a life span of about 24 hours.

After the sperm cell fertilises the ovum, the resulting zygote attains totipotence and a unique complement of human DNA, and when he is placed in his natural environment and his changing needs for growth and development are met, has an expected life span of 75 years until ageing and death. Calling the sperm cell or the ovum a potential human being makes as much sense as calling the hydrogen in the latest zero-emission vehicle potential water, a new entity that has no semblance to it.

OUR PROPOSALS

For all these reasons we therefore propose that para 8.2.2(a) and para 9.7 in the guidelines and para 22 in the summary of recommendations be changed as follows.

19)"8 Categories of gene therapy...

8.2.2 We strongly advocate that germ-line therapy with the result of passing on the genetic changes to the offspring should not be contemplated presently for the following reasons:

(a) All human cells formed from the time of of conception of human parents' sperm and ovum and growing naturally, and sustained in the mother's womb, are living human beings, whose life is sacred from the time of conception. This conceptus shall be accorded the dignity and sanctity of human life. No experiments or procedures whatsoever shall be performed which would be detrimental to the dignity and to the life of the conceptus, which uninterrupted, would result in the birth of the child.

20)"**9.7 Somatic Gene Therapy in pregnancy.**

The introduction of foreign therapeutic genes to the pregnant woman carries a theoretical risk of its inadvertent incorporation into the growing foetus. *We recommend that somatic gene therapy should be deferred till the postpartum period.*"

21)Accompanying the proposal in 8.2.2(a), we propose that para 22 in the summary of recommendations be changed to :

"Summary of recommendations
Recommendations on Somatic Gene Marking and Therapy
22 Somatic gene therapy should be deferred till postpartum."

ALLIED ISSUES

22)**DANGERS OF HUMAN CLONING**

After *Dolly* the first sheep was cloned from the mammary cell of an adult ewe in 1997, scientists cloned other animals within the same breed and also by cross breeding into different species. These successes have emboldened some scientists and clinicians to attempt human cloning now that the procedure has been simplified in animals. What are the dangers of human cloning?

(1) For every *Dolly* that is created there are hundreds of defectives who die or who are aborted, or if they survive have many congenital defects of the heart, lungs and other organs due to DNA damage. Such DNA-damaged persons will pose serious medical and social problems and place a heavy burden on the existing health system. We can also expect that just as foetuses under twenty four weeks are aborted as disposable rubbish, these "less than perfect" human clones could also be thrown into the trash can!!

(2) There have been other serious set backs as *Dolly* did not have the life expectancy of a newborn lamb but died of premature ageing due to unusual telomere shortening that was not present in the normal sheep. Telomere shortening is associated with cell death or premature death.

(3) Even if a human clone survives normally, he would likely be marginalised from a damaged psyche. Although he is a human being like any naturally conceived person, the gods of the human clone will be the machines, incubators and chemicals that gave him life. He can say, "I have no accountability as I am made from a machine or a DNA or the cell of somebody." The desire to help childless couples have their own child or for people to reproduce a dead loved one or for organ transplantation cannot justify the enormous damage to society from thousands of such clones that may be produced in the future. Call to mind also, despite its promise of unlimited energy for the world, how nuclear fission has instead created weapons of mass destruction and caused the expenditure of millions of dollars, leaving less than 10% available for the world's energy needs and for the relief of poverty and famine.
(4) Many international experts, nations, *UNESCO, European Parliament, President Clinton* and now *President Bush*, and Scientists at the Roslin Institute, Edinburgh, have condemned human cloning and have called for a ban on it.

23) LAW ENFORCEMENT & MONITORING.

Without the enforcement of law, there are no penalties for non-compliance. As such, these NMEC guidelines can be flouted with impunity e.g.

Following the NMEC publication (in Feb 2001), several researchers, from the departments of Obstetrics and Gynaecology at the SGH and NUH presented papers at a meeting on the 6 Jun 2001 in the National Cancer Centre on their Stem Cell Research Programme. The presentation was part of a joint proposal for an Institutional Block Grant from the National Medical Research Council to develop the techniques for:

(1) cloning human beings
(2) culturing large quantities of embryonic stem cells
(3) differentiation for tissue engineering (gene therapy)
(4) in-vitro maturation techniques (oocyte maturation & cloning tissue engineering project.)

We are reminded of a lecture at an international symposium on the treatment of *Parkinson's Disease* held at Singapore General Hospital on 26 Aug 2000, where it was revealed that the live brains (embryonic stem cells) of eight aborted babies were used in that hospital to treat a patient with *Parkinson's Disease*. This was subsequently heralded as a great success in the Straits Times on 11 Oct 2000. But reliable studies in the United States since have shown that the condition of some patients who had received these embryonic implants has considerably worsened.

OUR PROPOSAL

(1) Any research grant proposal that incorporates an application to conduct the germ-line research listed above (1-4), which is against the NMEC guidelines, should be rejected by the NMRC and by any other government or government linked funding and regulating body.
(2) Any foreign donation or grant that stipulates the germ-line research listed above (1-4), which is against the NMEC guidelines, should be rejected.

(3) There should be regular (annual, if not more often) inspection of facilities that are conducting research on obstetrical and gynaecological materials to ensure that these guidelines are adhered to. The inspectorate should be given the legal powers to terminate the research there and to withdraw the funding.
(4) These guidelines should be endorsed by the Government of Singapore, and appropriate disciplinary action must be taken against any person(s) who breaches them.

24) We need to actively promote what *Engel* called the scientific-physician, one who espouses and exemplifies humanism in medicine, and on the other hand to identify and neutralise the impostor, the physician-scientist, to whom human beings are mere scientific material whose mysteries are an object of curiosity to be unravelled without flouting those laws of the land, if any, that have kept up with the scientific possibilities. It is as true today as in 1987 when *Engel* observed that "*.there is an elite class of physician-scientist but as yet few fully qualified scientific-physicians.*"

25) The relevant terms of reference of the NMEC and the National Bioethics Committee should therefore include the following:

(1) reviewing any patent applications linked to bio-technological inventions effecting the human genome.
(2) blocking any patenting, and sales of the human body, any of its parts, embryonic stem cells, the embryo, and the human clone.
(3) blocking any funding for the creation of human embryos.
(4) preventing reproductive human cloning
(5) ensuring that any research on embryos will not harm them.
(6) preventing procedures modifying the foundational genetic identity of human beings
(7) blocking genetic research that could be influenced by political, economic and military interests
(8) ensuring that any research in the life sciences will be undertaken with full respect for human life in all its stages.

There should be appropriate penalties for non-compliance.

CONCLUSION

26) Science is at the disposal of Mankind and will give him the power to do immense good or evil. History is replete with examples of both. The seduction of power corrupts and truth itself has become a victim - medical technology is being used equally to save lives and to kill. *Albert Einstein* (1879-1955), himself a scientific giant of the last century, did not mince his words. "*Technological progress*," he said, "*is like an axe in the hands of a pathological criminal.*" Deadly weapons are in the hands of children. If not controlled, science will make victims of us all.

27) It is not that we should become less scientific - we should become more. We must include within medical science the other human sciences and the humanities, such as social science, psychology, philosophy, culture and religion. We have to keep in mind that the purpose of medicine is not only to cure but always to care. Medicine is healing and comforting the sick and doctors have to use their scientific knowledge for the benefit of their patients.

28) We must also have more effective controls. Science needs ethics and a potent NMEC. In the words of *Einstein, "Religion without science is lame; science without religion is blind."* It is within the power of the government to provide the moral medical compass and thus regulate the life sciences so that the promise of Science to relieve human misery and have at the same time a clear understanding of what it means to be human is realisable.

29) We sincerely hope that you will consider our constructive criticisms favourably. These were made in the spirit of Humanism and Science and we are guided by the knowledge that all wonderful gifts given to Mankind are for the benefit and the well being of humanity.

DR.JOHN LEE
CHAIRMAN,
ARCHDIOCESE BIOETHICS COUNCIL
SINGAPORE

DR. GABRIEL OON CHONG JIN
MEMBER

cc
DPM (Dr. Tony Tan)
Minister for Health (Mr Lim Hng Kiang)
Minister for Trade & Industry (BG George Yeo)
Director of Medical Services (Prof Tan Chorh Chuan)
Chairman, Biomedical Research Council (Prof. Louis Lim)
Administrator of the Archdiocese of Singapore

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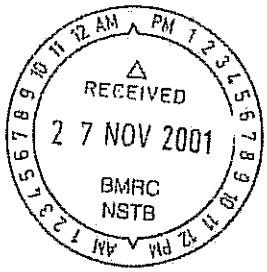

27 November 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof Lim

We refer to your letter dated 8 November to some of us inviting us to send responses to the attached document on Human Stem Cell Research in Singapore.

We wish to thank you for asking for our feedback.

Our denominations are members of the National Council of Churches in Singapore (NCCS). NCCS appointed a Life Sciences Study Group earlier this year to study the ethical issues related to the life sciences. This group comprises scientists, medical doctors, theologians, and ethicists. It has helped us prepare the attached document which is our joint feedback to you.

Besides the denominations we represent, many other churches and Christian organisations are also members of NCCS. The attached response represents our position. We trust that it will receive careful and serious consideration.

Thank you.

Yours sincerely

Bishop John Tan (Lutheran)
NCCS President

Bishop Robert Solomon (Methodist)
1st Vice President (NCCS)

Bishop John Chew (Anglican)

Rt. Rev. Tan Kheng Hock (Presbyterian)
2nd Vice President (NCCS)

Feedback On Human Stem Cell Research in Singapore

presented by the National Council of Churches, Singapore
to the Bioethics Advisory Committee

Introduction

This document, prepared by the National Council of Churches, Singapore (NCCS), serves as a response to the request for feedback made by the Bioethics Advisory Committee (BAC) on the issue of human stem cell research in Singapore. While there are other related ethical issues not dealt with by the BAC document, our comments focus on matters covered in that document. The NCCS would like to express our appreciation to the BAC for requesting feedback from us.

The NCCS represents the mainline Protestant denominations and other member churches and Christian organisations in Singapore.

Science and the Christian Faith

It must be said at the outset that the best of Christian Tradition supports the development of science in general, and medical science in particular. The scientific enterprise can be seen as an exercise of stewardship, which is a responsibility that is entrusted upon humankind by its Creator. Scientific knowledge and advancement may be seen as instantiations of the divine grace. Furthermore, the healing of the sick and the alleviation of human suffering have always been an integral part of the Christian tradition. The Christian ethic of love compels the Church to engage thus with the world. Medical science, insofar as it is directed towards compassionate healing and treatment, is understood as God's gift to humankind.

The theology of grace that shaped the Christian tradition's attitude towards science is always tempered by a theology of sin. Like all other aspects of human culture, the scientific enterprise can either be an instantiation of divine grace or the vehicle for the expression of human sinfulness. Science has undoubtedly contributed to the betterment of humankind. But history tells us that science has also been used to harm humans as well. The scientific enterprise is tainted by sinful aspirations for glory and economic gain. Science can be conducted in an inhumane manner, even when its goals are noble. For this reason, the Christian tradition has always insisted on the need for ethical parameters to govern scientific activity. For the Christian Tradition, these ethical boundaries must be established on theological grounds, and not just on 'humanitarian' ones.

Embryonic Stem Cell Research

The statements in the previous section are extremely important, for they provide the basis for our comments on specific topics addressed in the BAC document. We agree that much mileage can be achieved through research in AS cells, and that stem cell research should focus on this and other sources. We applaud the BAC's view that 'reproductive cloning of human beings should not be permitted', and agree with the moral view there expressed that the 'human being is not to be treated as a means to an end, but only as an end'. While we share the view that the possible benefit of reproductive cloning for the treatment of infertility 'is greatly outweighed by ethical concerns and safety issues', we maintain that cloning of human beings should be banned unequivocally and not merely on account of the 'high risk of foetal abnormalities'. The latter suggests that human cloning might be envisaged if and when health risks are removed through further refinement in the science of cloning. We applaud the BAC for working on the principle that ethical considerations be placed above therapeutic potentials. We shall urge that the same principle be applied to embryonic stem (ES) cell research.

The ethical concerns surrounding ES cell or EG cell research centres on the status of the embryo. The question is : Is the embryo a human being? And if it is a human being, is it also a person? Our reply to these questions, based on Scripture and tradition, is as follows:

1. Although the Bible does not answer this question directly, the overall thrust of its testimony is that God is the Author and Creator of life and that the beginning of human life cannot be reduced to merely a biological process. God is involved. Every human beginning is part of the divine plan and the result of divine agency. We affirm with the Bible that from its earliest beginning, the human person is valued by God and stands in relation to him.
2. The doctrine of the Incarnation tells us that the Second Person of the Trinity was incarnated in human flesh at conception. At conception, the zygote is already the incarnation of the Eternal Son of God, thereby giving credence to the view that human life begins at conception.
3. The Bible and Christian tradition also make it very clear that the embryo or fetus is a human being – and because it is a human being, it is also a bearer of God's image. The Bible does not make a distinction between a 'human being' and a 'person' in the sense that it is possible for a being to be human but not a person. The human being *is* a person.
4. Both science and philosophy may be said to support this view of the human being. From the standpoint of science, the zygote is already endowed with its own genetic code, and its human nature. We affirm that the embryo from conception is already a human person and are not persuaded that it undergoes any metaphysical change after the fourteenth day that renders a non-human pre-embryo into a human embryo. From a philosophical standpoint, it must be argued that the zygote of human parentage cannot articulate itself into another animal. This is because the zygote of human parentage is already a human being sharing in the nature of its parents.

The BAC's position regarding EG cell research is established on the supposition that it introduces 'no new ethical issues' so long as 'the decision to abort is taken separately and independently from the decision and consent to extract the EG cells'. The issues of abortion and EG cell research are inseparable, and this response must deal with the former in order to address the latter. Because the embryo or fetus is a human being, made in the image of God, its destruction is tantamount to the killing of innocent lives. We cannot countenance the destruction of a fetus even in the context of legalised elective abortion. By implication we do not countenance the use of abortuses for EG cell research, except in the case of fetuses that have been spontaneously aborted, in which case, human intentionality does not come into play. The same logic applies to the use of excess embryos that were created *in vitro*. The fact that we are not responsible for their creation does not give us the liberty to use them for scientific research.

In the same vein, we must voice our objection to what the BAC has termed as human 'therapeutic cloning'. The United Kingdom's Human Fertilisation and Embryology Authority (HFEA) holds that the embryo becomes a human being only at day 14 when 'individuation' occurs. Suffice to say that this opinion is not without detractors even among embryologists. For reasons already discussed, we do not subscribe to this view, but maintain that animation or hominization is immediate rather than delayed, and that there is no window between fertilisation and human conception such that an embryo may be said to be a potential rather than an actual human being. For this reason, we cannot agree to 'therapeutic cloning' which involves the deliberate creation of embryos by nuclear transfer for the purpose of harvesting stem cells, which necessarily entails their destruction. The question of human dignity becomes pressing here. Human beings should not be 'created' merely for use in scientific experiments and disposed. To quote the words of the BAC document – which in our view can be applied here with equal forcefulness and relevance – this procedure 'goes against the moral idea that the human being is not to be treated as a means to an end, but only as an end'.

As far as experimentation with embryo that necessitates their destruction is concerned, it is our considered opinion that the ethical concerns far outweigh the therapeutic potentials. On this matter, we urge the BAC to apply the principle it has articulated so clearly with respect to reproductive cloning, vis-à-vis that human beings must never be treated as means to an end, even if the rationale is scientific progress. The refusal to allow scientific progress to overshadow concerns for human life is found not only in the Christian community, but also in the collective wisdom of humankind as a whole, a wisdom born out of immense struggles in history. In the shadow of Nazism, The Nuremberg Code declared that 'no experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur'. In 1975, the Helsinki Declaration of the World Medical Association maintains that 'concern for the interest of the subject must always prevail over the interest of science and society'.

Recommendations

Based on the above considerations, the NCCS wishes to recommend that the BAC advise the Government to permit and invest only in those Stem Cell Research strategies that do not involve the destruction of human embryos. Cell lines developed from adult marrow and from umbilical cord blood can provide ample material for stem cell research without destroying human life. Stem cells taken from dead fetuses that result from miscarriages can also be used to benefit research. Granted that adult stem cells and stem cells derived from spontaneous miscarriages are not as 'highly proliferative' and malleable as embryonic stem cells, they nevertheless represent a viable alternative to the destruction of human embryos. The refusal to use embryonic stem cell may delay or render more difficult the realisation of the full therapeutic potential of human stem cell research, but it would be a price worth paying since it leads us away from the quagmire of doing harm to innocent lives. By so doing, one is to uphold the two ethical commitments articulated in the BAC statement: 'to protect human life and to advance human life by curing disease'. It should be clear from this statement that the NCCS supports and encourages all stem cell research so long as they do not result in the killing of human embryos. The therapeutic potentials of ES cell research can never outweigh the ethical concerns.

Prepared by
The Life Sciences Study Group
National Council of Churches in Singapore

SINGAPORE COUNCIL OF CHRISTIAN CHURCHES

新加坡基督教联合会

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19 November 2001

Professor Lim Pin
Chairman, Bioethics Advisory Committee
via www.bioethics-singapore.org

Dear Professor Lim

BIOMEDICAL RESEARCH

In response to your invitation to the public to voice their views on the subject above (November 18, 2001 : THE SUNDAY TIMES page 5 "Govt Biomedical Watchdog Body May Be Set Up"), may I submit a statement on "STEM CELL RESEARCH" adopted by our church council – the "Singapore Council of Christian Churches" in its 45th Annual General Meeting held on 27 October 2001.

2 The Singapore Council of Christian Church (SCCC) registered under the Societies Act in 1956 bearing registration number R of S REL No 259/56, was the first public body to testify before the Parliamentary Select Committee in 1990 in support of the Maintenance of Religious Harmony Bill (full recordings in the Singapore Parliament HANSARD).

3 SCCC President is Dr Lee Soon Tai, Orthopaedic Specialist, MchOrth (Livp), MBBS (Singapore), FRCS (Glasgow), FRCS (Edin.) FAMS, Med (Surgery). In his voluntary work, he has been serving for many years as Medical Director of Ling Kwang Home for Senior Citizens, Bishan Home for the Intellectually Disabled, Christian Home for the Aged and Ju Eng Home for Senior Citizens. In the event of his personal attendance being needed in any meeting you may be calling to gather feedbacks from the public, Dr Lee will represent our Council.

Thank you.

Yours sincerely

Rev Dr Quek Kiok Chiang, PBM
Vice- President

SINGAPORE COUNCIL OF CHRISTIAN CHURCHES

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STATEMENT NO. 3
ON STEM CELL RESEARCH

The Singapore Council of Christian Churches, meeting on 27th October on the occasion of Reformation Rally 2001 in commemoration of the 484th Anniversary of the 16th Century Reformation, maintains that life begins at the time of conception when the spermatozoan fuses with the ovum. We believe that when Scripture mentions the unborn, the context is almost always one of God's protection for them and His vision for their lives (Psalm 139:13-17 "...Thou hast covered me in my mother's womb"; "Thine eyes did see my substance, yet being unperfect..."; Isalah 44:1-2 "Thus saith the Lord that made thee, and formed thee from the womb..."; Jeremiah 1:5 "Before I formed thee in the belly, I knew thee; and before thou camest forth out of the womb I sanctified thee..."). Human dignity arises from our being created in the image of God.

Whereas, stem cell research is a new frontier in medical science where scientists have succeeded in isolating and culturing stem cells from human embryos, from which body organs are developed and have the ability to grow into the 250 types of tissue in the human body and may hold tremendous promise for treating such conditions as heart disease, cancer and diabetes;

The Singapore Council of Christian Churches opposes stem cell research using human embryos. In order for scientists to isolate and culture embryonic stem cells, a living, human embryo must be killed. It is never morally or ethically justified to kill one human being in order to help benefit another. By requiring the destruction of embryos, the tiniest human beings, embryonic stem cell research violates the Scriptural teaching to preserve life. (Exodus 20:13)

However, opposing the wilful destruction of human embryos for medical research does not mean that stem cell research cannot proceed. The Singapore Council of Christian Churches encourages scientists to continue to explore stem cells found in adult tissues, bone marrow and umbilical cord blood. Initial research using these sources are considered to be very promising, even more promising in some instances than embryonic stem cell sources. (See Appendix on Page 6)

As Christians, we should wholly affirm the desire to develop new treatments for diseases and should vigorously support research into adult stem cells and other non-embryonic sources.

APPENDIX
TO SCCC STATEMENT NO. 3 ON
STEM CELL RESEARCH

An excerpt from the article below gave evidence of the distinct advantages of using adult bone marrow stem cells instead of embryonic stem cell.

A Center for Bioethics and Human Dignity Paper

Cloning and Stem Cell Research Wrong Motives on Both Sides of the Atlantic

"The area of stem cell research has been marked by many unprecedented advances. Ironically, the day before the Donaldson Report was released, the Journal of Neuroscience Research published a study demonstrating that stem cells taken from adult bone marrow had been transformed into nerve cells. This was previously believed to be impossible. Other long-held beliefs, such as the idea that the brain was incapable of regeneration, are being overturned because of research on stem cells derived from non-embryonic sources. With each passing month, research with these stem cells is revealing the huge potential of this area. The hopes of alleviating many devastating illnesses may be achieved via methods which are not dependent upon embryonic stem cells and which therefore do not require the destruction of embryos. As Christians, we should wholly affirm the desire to develop new treatments for diseases and should vigorously support research into adult stem cells and other non-embryonic sources."

Donal O'Mathuna – Mount Carmel College of Nursing

Published in Dignity. Fall, 2000

The national body in Singapore of the International Council
of Christian Churches "for the Word of God and for the testimony of Jesus Christ"

مجلس اكام اسلام سنغافورا
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28 Nov 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPOE

We refer to your letter of 8 November 2001 on the above.

2 The issue had been discussed by the Legal (*Fatwa*) Committee of the Majlis Ugama Islam Singapura which issues *fatwa* (ruling) in matters pertaining to Islamic Law.

3 The Fatwa Committee rules that the opinion of the Bioethics Advisory Committee to use stem cells from embryos below 14 days old for the purpose of research, which will benefit mankind, is allowed in Islam. This is with the condition that it is not misused for the purpose of human reproductive cloning, which would result in contamination of progeny and the loss of human dignity.

4 The full text of the said ruling and its English Translation are attached.

Yours sincerely

HJ MAAROF SALLEH
PRESIDENT
MAJLIS UGAMA ISLAM SINGAPURA

MAJLIS UGAMA ISLAM SINGAPURA
MESYUARAT KHAS
JAWATANKUASA FATWA 2001 – 2004
KHAMIS 22, NOVENBER 2001

- **Pendahuluan**

Jawatankuasa Penasihat Bioetika (BAC) telah mengeluarkan pendapat menerima penggunaan embryo (janin) yang telah disemai di luar rahim wanita mengikut kaedah *in-vitro fertilisation* (penyemaian benih) yang berusia tidak lebih daripada 14 hari, bagi tujuan kerja-kerja penyelidikan berhubung sel induk yang dapat memanfaatkan manusia.

Berdasar kajian saintifik yang telah dilakukan, embryo yang belum mencapai 14 hari tidak dapat merasa sakit kerana hanya pada hari ke 14 satu jalur asli muncul dan berkembang untuk menjadi sistem urat saraf.

Jawatankuasa Fatwa telah diminta memberikan fatwanya dalam isu ini dan hal yang berkaitan dengannya.

Sebelum ini, Muis telah mengadakan ceramah pada 8 September 2001 mengenai Sel Induk dan genom (Stem cell and genome) yang disampaikan Professor Madya Tusqa Too Heng Poon. Ceramah ini dihadiri oleh anggota Majlis Tertinggi Muis dan anggota Jawatankuasa Fatwa Muis.

- **Garis pandu Syarak**

Daripada penerangan tersebut dan pengkajian dalam isu ini, Jawatankuasa Fatwa berpendapat bahawa dasar agama Islam mengalu-alukan penyelidikan ilmiah termasuk yang bersangkut-paut dengan genom manusia, kejuruteraan baka dan seumpamanya. Apa yang diharapkan ialah penyelidikan tersebut dapat digunakan untuk maslahah (kepentingan) manusia bagi merawat penyakit-penyakit yang dihadapi manusia. Sejauh mana penyelidikan dan perlaksanaannya dilakukan hendaklah berlandaskan kaedah fiqh yang muktabar seperti :

a) "لا ضرر ولا ضرار"
Ertinya :
" Tidak ada kemudaratan dan tidak boleh berbuat hal yang memudaratkan".

Maksud kaedah ini ialah :

i. Jangan melakukan kemudaratan kepada diri sendiri dan kepada orang lain, atau

ii. Jangan melakukan sesuatu yang berguna pada diri sendiri, tetapi mendatang kemudaratan atau kesusahan kepada orang lain.

b) " الضرر يزال "
Ertinya : *"Kemudaratan hendaklah dihindarkan"*
Maksud kaedah ini ialah : Sesuatu mudarat jika yakin akan berlaku, hendaklah dihindari sama ada sebelum atau sesudah berlaku.

- **Kedudukan Janin Menurut Syarak**

Apakah pandangan Syarak mengenai janin yang disenyawakan sama ada di dalam atau luar rahim?

Jawatankuasa Fatwa berpendapat bahawa Syarak tidak menetapkan apa jua hukum ke atas janin yang belum terbentuk, lebih-lebih lagi jika ia masih lagi di peringkat embryo. Janin pada hakikatnya dikira bernyawa setelah ditiup roh padanya, iaitu setelah ia berusia empat bulan. Inilah pendapat yang dipegang oleh kebanyakan fuqaha, berpandukan hadis Abdullah bin Mas'ud :

"إن أحدكم يجمع خلقه في بطن أمه أربعين يوما ثم يكون في ذلك علقة مثل ذلك ثم يكون في ذلك مضغة مثل ذلك ثم يرسل الملك فينفخ فيه الروح ويؤمر بأربع كلمات بكتب رزقه وأجله وعمله وشقي أو سعيد"

Ertinya : *"Sesungguhnya setiap kamu diciptakan kejadiannya dalam perut ibunya selama 40 hari air mani, kemudian menjadi segumpal darah seperti demikian itu, kemudian jadi seketul daging seperti yang demikian juga, iaitu 40 hari, kemudian diutuskan kepadanya malaikat lalu diitup roh padanya dan diperintahkannya menulis empat kalimat, iaitu rezekinya, umurnya, amalnya dan celaka atau bahagia."* Muttafaqun 'Alaihi.

Oleh yang demikian, janin yang berusia kurang empat bulan tidak kira sama ada di dalam atau di luar rahim, dianggap hidup berdasarkan keadaannya dalam peringkat proses pembenihan atau pembudidayaan. Ia belum lagi dianggap sebagai suatu permulaan kehidupan yang diukur dengan wujudnya roh.

Pandangan serupa ini telah pun diutarakan oleh para fuqaha dahulu dan masa kini, antara mereka ialah Dr Muhammad Sulaiman Al-Asyqar yang memberikan pandangan bahawa embryo atau janin yang belum terbentuk atau belum lagi berada di dalam rahim wanita tidak sabit hukum ke atasnya atau tidak ada hukum ke atasnya. Beliau menjelaskan :

"فلم يجعل الشرع للجنين قبل التخلق أي اعتبار ، ولا بنى عليه أي حكم شرعي... وقد أبديت رأيي في هذا بإسهاب في مناقشات ندوة الإنجاب. وحتى في القرار الذي اتخذ في ندوة الإنجاب لم يجعل للبييضة الملقحة أية حرمة إلا بعد العلوق بجدار الرحم، أما قبل العلوق فلم يجعل القرار له أي حرمة."

Maksudnya : *"Syarak tidak menetapkan apa jua hukum ke atas janin yang belum terbentuk. Sesungguhnya saya telah menerangkan pandangan saya dengan terperinci dalam perbincangan forum mengenai kelahiran. Dalam forum tersebut keputusan telah dikeluarkan bahawa syariat Islam tidak menetapkan hukum pengharaman ke atas telur wanita yang sudah disenyawa kecuali selepas ianya berada di dalam rahim. Adapun sebelum berada di dalam rahim tidak sabit hukum ke atasnya."*

Pandangan sedemikian juga telah dikeluarkan oleh Institusi Fatwa (Darul Ifta') Arab Saudi di mana selagi belum ditiupkan roh pada janin tersebut, air mani dan telur tersebut dihukum hidup bersesuaian dengan keadaan masing-masing. Ia sebagai zat pembudidayaan atau pembenihan. Ia belum sampai ke tahap zat yang sempurna hidup. Berikut adalah teks fatwa Darul Ifta'tersebut:

لكل من الحيوان المنوي وبويضة المرأة حياة تناسبه إذا سلم من الآفات, تهيئ كلاً منهما بإذن الله وتقديره للاتحاد بالآخر , وعند ذلك يتكون الجنين إن شاء الله ذلك, ويكون حياً أيضاً حياة تناسبه حياة النمو والتنقل في الأطوار المعروفة , فإذا نفخ فيه الروح سرت فيه حياة أخرى بإذن الله اللطيف الخبير .

Yang bermaksud : "*Jika ditakdirkan air mani dan telur wanita tidak mati, kedua-duanya akan hidup sesuai dengan keadaan kedua-duanya (seperti yang diciptakan). Dengan izin Allah dan takdir-Nya kedua-duanya akan bersatu. Ketika itu akan terbentuklah janin dengan izin Allah. Dan janin itu hidup sesuai dengan perkembangannya dan peningkatannya mengikut tahap yang sudah ditetapkan. Apabila ditiup roh padanya akan berputik satu kehidupan dengan izin Allah yang Maha Lembut dan Maha Mengetahui*".

- **Kesimpulan**

Sehubungan dengan ini, Jawatankuasa Fatwa memfatwakan bahawa pandangan Jawatankuasa Penasihat Bioetika untuk menggunakan sel induk daripada embryo yang berusia tidak lebih daripada 14 hari, bagi tujuan penyelidikan untuk kebaikan manusia adalah dibenarkan dari segi syarak selagi ianya tidak disalahgunakan sama ada untuk tujuan pengklonan manusia, atau mencampur-adukkan nasab keturunan, atau pun yang boleh menyebabkan penghinaan atas kemuliaan manusia.

MAJLIS UGAMA ISLAM SINGAPURA
FATWA COMMITTEE SPECIAL MEETING
THURSDAY, 22nd November 2001

INTRODUCTION

The Bioethics Advisory Committee (BAC) is of the view that it accepts the use of embryos created from in-vitro fertilisation, which are less than 14 days old, for the purpose of serious research involving stem cells for the benefit of mankind.

Based on scientific research, human embryos, which are less than 14 days old, have no pain or sentience since only at the 14th day does a primitive streak appear and develop into the nervous system.

The *Fatwa* (Legal) Committee was requested to give a *fatwa* on this issue.

Prior to this, Muis had organised a talk on 8 Sep 2001 on Stem Cells and Genome, which was delivered by Assoc Prof Tusqa Too Heng Poon. The talk was attended by the Muis Council and the *Fatwa* Committee.

ISLAMIC LEGAL GUIDELINES

Based on the explanation and research on the issue, the *Fatwa* Committee is of the view that Islam welcomes academic research on human genome, genetic engineering and other related fields. However, such research must be utilised for the benefit of mankind in areas like the treatment of illnesses. The research has to be within the boundaries of principles in Islamic Jurisprudence, which include :

a) **There should not be any harm and nothing should be done to cause harm**

The principle means :-

- Do not cause harm to one's self and to others.
- Do not do something that will benefit one's self but will harm or cause difficulty to others.

b) **Harm should be avoided.**

The principle means :-

- Harm, which is sure to occur, should be avoided whether before or after it occurs.

POSITION OF EMBRYO IN ISLAMIC LAW

What is Islam's view on the fertilisation of an embryo within or outside the womb ?

The *Fatwa* Committee is of the view that Islam does not place any judgement on an embryo, which is not fully formed. An embryo is only considered as a human life after it is 4 months old as in Islam, it is believed that a soul is introduced into the embryo when it is 4 months old. This is the view of most jurists based on the *hadith* (Tradition) narrated by Abdullah bin Mas'ud which means :

"Verily the creation of each one of you is brought together in his mother's belly for forty days in the form of seed, then he is a clot of blood for a like period, then a morsel of flesh for a like period, then there is sent to him the angel who blows the breath of life into him and who is commanded about four matters: to write down his means of livelihood, his life span, his actions, and whether happy or unhappy..."

Related by Bukhari and Muslim.

Thus, an embryo below 4 months whether within or outside the womb, is considered as a living thing undergoing the growth process. However, it is not yet considered as the beginning of human life with the existence of a soul.

Past and present jurists have given a similar view. Among them include Dr Muhammad Sulaiman Al-Asyqar who is of the view that an embryo which is not formed or is not in a woman's womb, will not be placed any judgement on it. He explained :

"Islamic law does place any form of judgement on an embryo which is not formed. Verily, I have explained in detail my opinion during my forum discussion on birth. In that forum, decision had been made that Islamic law does not place any judgement on a woman's fertlised egg except after it is in the womb. There is no judgement on it before it is in the womb."

A similar opinion was also given by the Fatwa Institution of Darul Ifta', Saudi Arabia where, for as long as there is no soul in an embryo, the sperm and the egg are judged to be living things adapting to their specific conditions. They are considered as components of the fertilization process. The have not reached the stage of a complete human being. The following is the text from the fatwa of Darul Ifta' which means :

"If it is destined that the sperm and a woman's egg do not die, both will live adapting their respective conditions as created. With Allah's will and predestination, both will fuse. At that point, an embryo will be formed. The embryo will live according to its own growth and development following the

defined stages. When a soul is introduced, a human life will be created based on the will of Allah, who is the Subtle one and the All-Knowing".

CONCLUSION

In relation to this, the Fatwa Committee rules that the opinion of the Bioethics Advisory Committee to use stem cells from embryos below 14 days old for the purpose of research, which will benefit mankind, is allowed in Islam. This is with the condition that it is not misused for the purpose of human reproductive cloning, which would result in contamination of progeny and the loss of human dignity.

C. PROFESSIONAL GROUPS

1. Law Reform Committee, Singapore Academy of Law
2. The Law Society of Singapore
3. Singapore Hospice Council
4. Singapore Medical Association
5. Singapore Medical Council
6. Singapore Nurses Association
7. Singapore Nursing Board

S I N G A P O R E A C A D E M Y O F L A W

30 November, 2001

Professor Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179 101

Dear Prof Lim

Feedback Regarding Human Stem Cell Research in Singapore

Thank you for your letter dated 8 November 2001 and the enclosures.

2. The Law Reform Committee specially met to consider the consultation paper of the Human Stem Cell Research Subcommittee ('HSR'). In considering the paper, a couple of the members have also carried out some research on the matters raised, and provided the Committee with some helpful insights. We set out below our views on the various matters raised in the consultation paper.

Use of human embryos of less than 14 days old

3. At page 4 of the consultation paper, the HSR stated that human embryos of less than 14 days have no pain or sentience. We have two observations on this. First, this cut-off age of 14 days was presumably derived from research carried out many years ago, and was adopted in the United Kingdom for the purpose of certain legislation. We were given to understand that some researchers in the 1970s referred to embryos of less than 14 days as "pre-embryos", but that the term has since been discarded. It seems to us that closer investigation and research should be carried out now to determine the safest cut-off period. In this connection, we should point out that President George W Bush has authorised federal funding in the United States for embryonic stem cell lines cultivated from the inner cell mass of a *week-old* embryo (White House Statement, August 9, 2001). With the progress made in scientific and medical research, it is probably timely that the 14-day cut-off period should now be reviewed.

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4. Secondly, as we understand it, the 14-day cut-off period is adopted, presumably because an embryo in its first 14 days does not have any pain or sentience, its nervous system not having been developed. If our understanding is correct, some members question whether this is an appropriate way of determining the cut-off period. It might be argued that the question whether or not it is proper to do research on an embryo less than 14 days old should not be determined on the basis that the embryo does not feel any pain, just as the law does not require that a victim must feel pain before the crime or tort of assault is made out: the experience of pain is not an element which is required to be satisfied. To the extent that the 14-day cut-off period is based on the embryo's failure to feel pain, it is potentially inconsistent with the law.

Class of ES cells to be permitted in research

5. We note that a distinction is made in other reports between various classes of ES cells. For example, the United States has approved federal funding for research using ES Cells from embryos remaining after the conclusion of infertility treatments, which are intended to be discarded, because they are unsuitable or no longer needed for treatment. This is not the position with ES Cells derived from research embryos (created through IVF with gametes provided solely for research purposes); and ES Cells from embryos made using somatic cell nuclear transfer in oocytes (as this has the potential of creating a human embryo).

Ensuring independent donor consent

6. We note that in Singapore human embryos of less than 14 days, which are created through in-vitro (or in-vivo) fertilisation techniques but not used in assisted reproduction treatments, can be used for research, subject to observance of certain stringent guidelines. We understand that one of the requirements of such guidelines is that consent must be obtained from the donors of the gametes. In this respect, BAC is urged to consider seeking ***informed*** consent from donors, especially the consent from the gestational mothers, free from any inappropriate influences and without any financial or other inducements.

Consent at enrolment and at research process

7. Turning to international practice, we think that consent should be obtained not only at the stage when the in-vitro or in-vivo fertilisation process is to be performed, but also at the stage when the embryos would be used for research purposes. It is not difficult to envisage that consent would be readily given at the beginning prior to the in-vitro or in-vivo fertilisation process; however, subsequent experience may alter the position. As we see it, a material factor may well be the success or otherwise of the fertilisation process. Our view is that separate consent should be obtained from the donors, particularly the gestational mother, after the success or failure of fertilisation process, once it is determined that the "unwanted" embryos will be used for research.

Disclosure by Researchers

8. We would highlight that the United States Bioethics Advisory Committee recommended that researchers should fully reveal to the donors the potential use for research purposes of the embryos which would otherwise be discarded, by, among other things, the following:

- disclosing that the ES Cell research is not intended to provide medical benefit to embryo donors;
- ensuring that consent or refusal will not affect the quality of future care to prospective donors;
- describing the general area of research to be carried out;
- disclosing the potential commercial benefits, if known;
- affirming that the embryos used in research will not be transferred to any woman's uterus; and
- confirming that the research will involve the destruction of the uterus.

Legal Process

9. If research on the broad terms set out in the consultation paper is to be permitted, the process should be strictly regulated by legislation. As such research involves human life or potential human life (depending on which perspective is adopted), a breach of the conditions under which it can be performed should be criminalised and be made punishable by an appropriate penalty. Some guidance may be taken from the United Kingdom's latest Human Reproductive Cloning Bill passed by the House of Lords and sent down to the House of Commons on 26 November 2001.

Protections to extend across private and public sectors

10. Any regulations recommended should apply to both publicly-funded and privately-financed research projects in Singapore. We note that the 'oversight system' in the United States has historically resulted in ethically indefensible differences between protection given to participants in federally sponsored research and those outside the jurisdiction of the Food and Drug Administration's jurisdiction.

11. I hope our comments would be some assistance to BAC.

Yours sincerely

L P Thean

L P Thean
Chairman
Law Reform Committee

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Our Ref: LS/66/01/IP/csy

18 December 2001

F R O M T H E P R E S I D E N T

Professor Lim Pin
Chairman
The Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Dear Prof. Lim Pin

Request for Feedback Regarding Human Stem Cell Research in Singapore

I refer to your request for feedback from the Law Society regarding human stem cell research in Singapore. Your Committee has sought the views of various interest groups, and I am confident that moral and ethical issues have been extensively explored and discussed; our feedback herein will thus not dwell on such issues.

I shall deal with the legal position in Singapore – as it now stands.

Stem cell lines are evidently protectable under Patent Law. Inventions relating to this matter are capable of patent protection in USA, and numerous other countries. There appears to be no impediment to its registration as patents in Singapore as long as the steps taken are new, inventive and industrially applicable; such matters are not excluded under section 13(3) of the Patents Act 1994.

However, numerous issues do arise. One issue concerns the ownership of the cells developed from the stem cell lines. Another issue is the ownership of the intellectual property rights for the medical discoveries resulting from research using those stem cells.

Another issue is consent. The necessity for informed consent from the biological parent should be enshrined for stem cell research in the same way as consent for clinical trials, which is set out exhaustively in section 14 of the Medicines Act, Cap 176. The present law on stem cells are inadequate. As the law now stands, embryos removed during medical procedure, may be used without the knowledge or consent of the woman undergoing the procedure. Also, the Termination of Pregnancy Act, Cap 234, does not contain any guidelines on the treatment of aborted foetuses.

The informed consent should therefore be sufficiently detailed and ought to include a statement that the embryos or foetal tissues may be used to derive human pluripotent stem cells for research that may include transplantation research, that the derived cells may be kept for many years, that the research is not intended to provide direct medical benefit to the donor, and that the donated embryos will not be transferred to a woman's uterus and will not survive the stem cell derivation process. It must also state the possibility that the results of the research may have commercial potential, and that the donor will not receive any benefits from any such future commercial development.

There is need for guidelines to govern research using pluripotent stem cells. I would suggest your Committee study and adopt the US National Institute of Health (NIH) Guidelines on such research. However, unlike USA, where the Guidelines applies to NIH funded research, I request the Committee to apply the Guidelines to all research on stem cell lines conducted in Singapore. I seek to suggest, too, that the Committee studies the Human Fertilisation and Embryology Act 1990 when considering and deciding on guidelines for Singapore.

The solutions to these issues should be carefully deliberated before a decision is taken to enshrine it in legislation, and the accompanying Guidelines or Rules. The Law Society will be pleased to participate in further discussions.

Yours

Palakrishnan, SC
President

cc Council

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24 December 2001

F R O M T H E P R E S I D E N T

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Attn: Ms Lauren Noto

Dear Prof

STEM CELL RESEARCH

I have your letter of the 18th instant.

Aside from the proposed Meeting in January 2002, I enclose a copy of a Discussion Paper produced by the Law Institute of Victoria, Australia, for your information and retention.

Yours sincerely

Palakrishnan, SC
President

Enc

The Ownership of Genetic Information and Genetic Material

March, 2000

Law Institute Victoria

Discussion Paper

Contents

Part A - The Ownership of Genetic Information

1. Introduction

Biotechnology is a burgeoning industry. In 1998 the total revenue earned by Australia's 120 core biotechnology companies exceeded 965 million dollars and employed about 4,000 people.[1] It is predicted that this industry will continue to be a driving force in economic and employment growth over the next thirty years, based on Australia's strong fundamentals in research science. Patent grants are important as they encourage financial investment in this area. Genetic information and material are patentable under Australian law and thousands of biological patent applications have already been lodged with the Australian Patent Office. Some are for DNA, genes, genetic sequences and the like. Others are for whole plants and animals.

1.1 Potential uses of biological inventions

Many biological inventions have significant uses in medicine and science, agriculture, the food industry, and environmental uses.

Medicine and science: Diagnostic tests have been developed to detect genetic and other conditions in humans and animals. Insulin, antibiotics, vaccines and new drugs manufactured using genetic manipulation techniques are already being used in human and animal health care. Human diseases that may be treated in future include cancer and multiple sclerosis. An important aspect of the development of new pharmaceuticals is that they can be extracted from the milk of animals genetically manipulated to produce biological substances. This makes the products cheaper to manufacture and also safer. In the future, specially bred animals may become donors of organs and tissue for human patients. Another innovation of particular promise is gene therapy. The ability to replace defective genes with functional genes may one day eliminate genetic disease.

Agriculture: Genetically manipulated crops and animals are being produced that grow faster and are more productive (eg rice with vitamins added for third countries; animals with a higher meat to fat ratio). Crops that are more resistant to disease and pests are already coming onto the market in Australia. Others that are resistant to particular herbicides and pesticides allow a larger quantity of those products to be used early in the growing season to kill weeds and pests, reducing the need for more frequent applications and reducing the overall use of herbicides and pesticides.

Food industry: Fungi, such as yeast for bread making and enzymes used in fermentation processes, have been patented and used in the food industry for many years. More recent advances in biotechnology show promise in generating new food preservatives. New plant varieties developed from traditional breeding methods have also been patented.

Environmental uses: Pollution control, toxic waste management, hydrocarbon breakdown ("oil eating bacteria") have been suggested as potential environmental uses of genetically manipulated organisms.

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[1] Ernst & Young, *Australian Biotechnology Report* (October 1999), 11.

1.2 This paper

This part of the paper analyses the Australian law and experience to date concerning biological patents, as well as the law in the United States and Europe. It then sets out arguments for and against patents on genes and genetic sequences.[2] It outlines a number of proposals in Australia and other countries to change the law together with options for regulating biological patents in Australia.

2. Current Law in Australia

2.1 What is patentable?

As of March 1997, the Patent Office had received some 8,100 applications for gene or gene sequences and granted some 2,100 patents.[3] They include patents on micro-organisms such as bacteria, fungi and viruses; DNA, genes and chromosomes; synthetic genes or DNA sequences and the DNA coding for a gene; plants; and non-human animals.[4] DNA or genes in the human body are not patentable but "a DNA or gene sequence which has been separated from the human body and manufactured synthetically for reintroduction into the human body for therapeutic purposes is patentable".[5] "Products of such living patented matter, eg food supplements, drugs and processes for synthesising the material or making the products" are also patentable.[6] So are other applications of patentable inventions – probes for a particular gene; higher plants/animals carrying the gene; and methods for using a gene or genetic technology.[7] "Human beings, and the biological processes for their generation" are not patentable as they are specifically excluded under section (s) 18(2) of the Patents Act 1900 (Cth).

2.2 Patents Act 1990 (Cth)

In order to be patentable, a biological invention must meet the requirements of section 18 of the *Patents Act* 1990 (Cth). Section 18 provides:

> "18(1) Subject to subsection (2), a patentable invention is an invention that, so far as claimed in any claim:
>
> (a) is a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*; and
>
> (b) when compared with the prior art base as it existed before the priority date of that claim:
>
> (i) is novel; and

---

[2] Although other forms of intellectual property may be relevant to genetic information and material (eg plant variety legislation, trade marks, copyright), patents are by far the most important and are thus the focus of this paper.

[3] Senate Question on Notice 449, 24 March 1997. See also C Lawson, 'Patenting Genes and Gene Sequences in Australia' 1998 (5) *Journal of Law and Medicine* 364, 366.

[4] IP Australia Pamphlet, *Australian Patents for Microorganisms, Cell Lines, Hybridomas, Related Biological Materials and Their Use, Genetically Manipulated Organisms* (Nov, 1998) 1.

[5] Ibid.

[6] Ibid.

[7] Ibid.

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim....."

Subsection (2) provides:

"(2) Human beings, and the biological processes for their generation, are not patentable inventions".

There are thus four main requirements that must be satisfied for a patent to be granted. (i) It must be a manner of manufacture. (ii) It must be novel and involve an inventive step. (iii) It must be useful. (iv) It must not have been secretly used prior to the application of the patent. Although there is an extensive body of case law on the elements of patentability,[8] the following discussion focuses principally on these criteria.

2.2.1 It must be a manner of manufacture

The requirement that an invention must be a "manner of manufacture" means that it must be possible to reproduce the product or process for which the patent is sought by following the specifications in the patent application. (Under the Budapest Treaty, to which Australia acceded in July 1987, this requirement can be also met by depositing a sample of a biological substance instead of a description of how to produce it. However, the fact that the sample is then available to researchers to use directly is an obvious disincentive to follow this procedure, which is optional.) The product must also be useful, have some material advantage, have some economic advantage and have an industrial application - an innovative idea that provides a practical solution to a technical problem.[9] It may be a new product, a new method of producing an existing product, or a new use for an existing product.

Furthermore, an invention is not patentable subject matter if it is a mere discovery. The observation of certain physical properties of an existing substance, or the finding of a previously unknown but naturally occurring substance, is not something that is patentable.[10] For instance the laws of physics are not patentable subject matter. However, the distinction between a discovery and an invention is not precise, as was noted by the High Court of Australia in *National Research Development Corporation v Commissioner of Patents*.[11] In that case, the court insisted that the whole process must be looked at and one inventive step in the process might justify a patent.[12] Therefore although the identification of a naturally occurring gene sequence may be a discovery,

[8] See,eg: S Ricketson, *Intellectual Property Cases Materials and Commentary* (Butterworths, 1994) chs 13 and 14.

[9] IP Australia Phamplet, above n 4, 2.

[10] J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed. 1997) 290.

[11] (1959) 102 CLR 252, 264.

[12] Ibid.

the isolation and characterisation of the gene and utilisation of that knowledge to make a synthetic gene and gene products, will be patentable inventions.[13]

The distinction between discoveries and inventions is also illustrated by another Australian case, *Kiren-Ambgen Inc v Board of Regents of the University of Washington*.[14] That case involved a patent application for the purified or isolated DNA sequence encoding the human protein erythropoietin. The Deputy Commissioner of Patents stated that a claim directed to a naturally occurring DNA sequence would be claiming no more than a discovery per se and not be a manner of manufacture.[15] However, because the claim specified a purified and isolated DNA sequence, the claim related to "an artificially created state of affairs", and thus was a manner of manufacture.[16]

2.2.2 It must be novel

The assessment of novelty basically requires an investigation to establish whether the alleged invention has been anticipated, judged at the time of the patent application. Anticipation principally occurs through prior publication or prior use.[17] The Australian Patent Office has specified that the requirement of novelty with respect to gene sequences and related biological materials is satisfied if the subject matter is new in the sense of not previously being available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials that have previously been made publicly available.[18]

2.2.3 It must be inventive

In addition to being novel, the invention must involve a degree of inventiveness. To establish an inventive step one must ask the question: Was it, for practical purposes, obvious to a person skilled in the particular art, armed with all the common general knowledge of his or her art, that he or she could do what the patent proposes?[19] In most instances this requirement is easily met as there need be only a "scintilla of invention".[20] Academic commentators in Australia have argued that the cloning and sequencing of a gene is unlikely to amount to an inventive step. Once information about an amino acid sequence is known, then to a person skilled in the art of molecular biology, with common general knowledge, the cloning and sequencing of a gene is the obvious next step.[21] However the Patent Office does not seem to hold this opinion and the

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[13] D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law' (1996) 3 *Journal of Law and Medicine* 231, 238, citing the Australian Patent Office, *Manual of Practice and Procedures* ss 8.1.15.2(c), 8.1.15.3.
[14] (1995) 33 IPR 557.
[15] Ibid 569.
[16] Ibid.
[17] *Griffin v Isaacs* (1938) 12 AOJP 739. See also McKeough, above n 9, 297.
[18] IP Australia Pamphlet, above n 4, 2.
[19] *Patents Act* 1900 (Cth) s 7(2).
[20] *Samuel Parks & Co Ltd v Cocker Bros Ltd* (1929) 46 RPC 241, 248.
[21] See comment by C Lawson, 'Patenting Genetic Materials: Old Rules May be Restricting the Exploitation of a New Technology' 1999 (6) *Journal of Law and Medicine* 373, 379.

requirement of inventiveness has not proved an obstacle to the patenting of genetic sequences in Australia.[22]

2.2.4 It must be useful

The requirement that the invention must be useful means that there must be an actual use for the invention rather than speculation as to future uses;[23] and the Australian Patent Office has specified that the use must be fully described. For example, it may be used to treat human diseases such as cancer or multiple sclerosis. However, a genetic sequence on its own which lacks some function, component or application is not patentable for lack of utility.

2.2.5 Human beings are not patentable

Section 18(2) of the *Patents Act* (Cth) provides that human beings, and the biological processes for their generation, are not patentable inventions. The Patent Office has stated that the only limitation that this exclusion creates in the area of genetic research is that DNA or genes in the human body are not patentable as such.[24]

3. Law in other countries

3.1 United States

Since 1980, it has been well settled law in the United States that nucleic acid sequences, isolated genes, isolated proteins and organisms are patentable.[25] In that year, the United States Supreme Court held that a genetically engineered bacterium capable of breaking down oil spills was patentable (*Diamond v Chakrabarty*[26]). Since then, the United States Patent Office has granted some 12,000 patents on inventions related to DNA sequences.[27] Patents have also been granted for plants and animals. An example of the latter is the Harvard oncomouse, genetically manipulated to develop tumours and so useful in cancer research on diagnosing and treating tumours.

Patent law in the United States requires three technical requirements; novelty, utility and non-obviousness.[28] Novelty involves a judgment whether the invention is truly something new and original.[29] Utility requires that the invention has some articulated use.[30] Non-obviousness requires a hypothetical judgment by a person with ordinary skill

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[22] This is illustrated by the cases of *Hoffmann-La Roche AG v Bresagen Ltd* (1997) 40 IPR 53, and *Kiren-Amhgen Incorporated v Board of Regents of University of Washington* (1995) 33 IPR 557.
[23] IP Australia Pamphlet, above n 4, 2.
[24] Nicol, above n 13, 241.
[25] Committee no 1001, Chaired by H L Baker, Section of Intellectual Property Law, Annual Report 1995-96, American Bar Association, Chicago, Illinois.
[26] 447 US 303 (1980)
[27] As of October 1999 - determined using IBM Intellectual Property Network database.
[28] See 35 USC 100-12
[29] 35 USC 101-102. With respect to genetic sequences it was held in the case of *Amgen, Inc v Chughai Pharmaceutical Co Ltd* 927 F2d 1200, 1203. that the requirement of novelty is satisfied if the sequences are "purified and isolated".
[30] 35 USC 101.

in a particular field to determine whether the invention is more than an obvious progression in the field.[31]

The requirement of utility in respect of gene sequences has caused considerable debate in the United States. The grounds required to establish utility were discussed in the case of *Brenner v Manson*.[32] The Supreme Court said that "unless and until a process is refined and developed to the point of a substantial utility - where a specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."[33] The court expressly recognised that an invention "which either has no known use or is useful only in the sense that it may be an object of scientific research"[34] is not patentable. It was because of this requirement that an application by the United States National Institutes of Health (NIH) in 1991 for a patent on some 2,000 gene sequences (ESTs[35]) failed. The function of the genes was unknown, and mere use of the sequences as probes was unacceptable. There was not the requisite degree of specific benefit - they were mere research tools. However in 1995 the United States Patent Office issued guidelines on assessing utility which are far more generous. According to these guidelines one need only establish a "credible utility". "Credible utility" is defined as "whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided".[36] Academic commentators have argued that this broader test makes a utility rejection highly unlikely.[37] It has been suggested that they are of such breadth that the use of ESTs as probes satisfies the utility requirement, and are therefore patentable.[38] This has been confirmed by the United States Patent Office which has stated that ESTs, in principle, are patentable.[39] This has caused considerable concern among researchers - that their basic tools might be subject to patent rights.

With respect to obviousness, the United States Court of Appeals has found that genes and gene sequences for proteins of known function are patentable (*Re Duel*[40] and *Re Bell*[41]). This is because the sequence would not have been known without cloning and sequencing, which is sufficient for it to be non obvious.[42] In both cases the court accepted that degeneracy in the genetic code meant that a number of different nucleotide sequences might code for a specific protein, and therefore the nucleotide sequence

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[31] 35 USC 103.
[32] 383 US 519 (1966)
[33] Ibid 534-535.
[34] Ibid 535.
[35] Expression Sequence Tags, are segments of DNA, of unknown function which are routinely used by researchers in gene discovery.
[36] 'PTO Examination guidelines on Utility Requirements', 50 *Patent, Trademark and Copyright Journal* 295, 303.
[37] A Kight, 'Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of *Brenner*' (1998) 73 *Indiana Law Journal* 997, 1015.
[38] Ibid 1019.
[39] C O'Brien, 'US Decision Will Not Limit Gene Patents' (1997) 385 *Nature* 755. See also S Bent and P Booth, 'Genomics Races Raises Ownership Boundary Issue' Foley and Lardner <http://www.foleylardner.com/PG/IP_BIOT/genomics.html>
[40] 51 F 3d 1552, 1558 (1995)
[41] 999 F 2d 781, 784 (1993)
[42] The court in coming to this conclusion focused on the non-obviousness of the sequence itself, as opposed to the nonobviousness of the method of sequencing.

claimed was not obvious.[43] A result of these decisions is that prior disclosure of an amino acid sequence does not necessarily render obvious the DNA molecules that encode the protein, further widening the scope for patenting DNA sequences. More recently the legislature in the United States passed the *Biotechnological Process Patent Act* 1995, which strips biotechnological processes of the presumption of unobviousness. As a result, an applicant applying for a patent over a biotechnological process has the option of waiving the requirement that the process itself be found unobvious.[44]

3.2 Europe

Patent law in Europe is governed largely by the European Patent Convention. Article 52 provides that for an invention to be patentable it must be an invention; novel; present an inventive activity; and have an industrial application. As in the United States and Australia, there was initially some dispute as to whether a gene or genetic sequence met these criteria. There were also concerns about the morality of patenting larger organisms.

In relation to genes and genetic sequences, the European Parliament and European Commission passed a directive on the legal protection of biotechnological inventions in order to make it clear that these could be patented. The preamble to the directive recognises that biotechnological inventions are playing an increasingly important role in a broad range of industries.[45] Research and development in the field of genetic engineering is a high risk investment and therefore requires adequate legal protection.[46] Developing biotechnology should be encouraged by the patent system as it is important in combating disease and hunger.[47] The human body and its elements are unpatenable in their natural state because patent law should respect the fundamental principles safeguarding the dignity and integrity of a person.[48] Yet the directive clearly makes provision for the patenting of human DNA sequences. Article 3 states that inventions that are new, involve an inventive step and are susceptible of industrial application will be patentable even if they concern a product consisting of biological material. Article 5 provides that an element isolated from the human body, including the sequence of a gene, may constitute a patentable invention.[49] However, a mere DNA sequence without indication of a function is not a patentable invention.[50] The two key requirements are an isolated gene sequence and knowledge of the gene's function.

An additional limiting factor is that, in Europe, inventions must not be contrary to ordre public or morality. Article 6 provides that such inventions are unpatentable.[51] The

[43] *Re Duel* 51 F 3d 1552, 1558 (1995); *Re Bell* 999 F 2d 781, 784 (1993). See also Lawson, above n 21, 380.
[44] S Maeblus, 'Biotechnological Process Patent Act: Legislative Relief for Process Claims' Foley and Lardner <http://www.foleylardner.com/PG/IP_BIOT/pate20_biot.html>
[45] *Directive of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, 6 July 1998, 98/44/EC, recital 1.
[46] Ibid, recital 2.
[47] Ibid, recital 11.
[48] Ibid, recital 16.
[49] Ibid, article 5(2).
[50] Ibid, recital 23 and article 5(1).
[51] Ibid, article 6(1).

directive specifies that the cloning of human beings and the use of human embryos for industrial or commercial purposes fall within this category.[52]

4. Arguments in favour of biological patents

Sections 4, 5 and 6 below set out the arguments for and against biological patents and then evaluate those arguments.

4.1. Patents encourage research and development

Patents provide an incentive for research and development. They encourage investment in biotechnology, a risky and financially unrewarding endeavour. Without this investment, new drugs and treatment will not be developed. Denying patent protection would lead to increased secrecy and delay research and the release of new drugs, to the detriment of the community.[53]

4.2 Patents encourage dissemination of information

Patents inform the public about the results of scientific research because a patent will not be granted without full disclosure. Other researchers will learn about the invention and not undertake unnecessary duplication of research.[54]

5. Arguments against biological patents

5.1 Religious objections: usurping God's province

Humans and animals are creations of God, not humans, and as such should not be patented as human inventions.[55] Patenting of genomic sequences "represents the usurpation of the ownership rights of the sovereign of the universe".[56] A coalition representing more than eighty faiths and denominations, including Catholics, Evangelicals, Protestants, Jews, Muslims and Buddhists have declared their opposition to the patenting of genetically engineered animals, human genes, cells and organs.[57]

5.2 Genetic information is commonly owned

The human genome is a common, universal possession, representative of humankind's collective heritage.[58] The genome is thus not a proper subject matter for intellectual

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[52] Ibid, article 6(2).
[53] See comments in G Poste, 'The case for genomic Patenting' 1995 (378) *Nature* 536.
[54] Nicol, above n 13, 232.
[55] Foundation for Economic trends and General Board of Church and Society of the United Methodist Church, statement issued at press conference, 18th May 1995, Washington DC. See also, K Woodward, 'Thou Shalt Not Patent!' (1995) May 29 *Newsweek* 68.
[56] R Stone, 'Religious Leaders Oppose Patenting Genes and Animals' (1995) 268 *Science* 1126.
[57] Ibid.
[58] Note the comments made by H Curien, 'The Human genome Project and Patents' (1991) 254 *Science* 1710.

property rights.[59] Everyone is entitled to share any economic benefit from genetic research. Also, biological patents would inevitably benefit wealthy countries and corporations more than poor ones, when all humans should enjoy such benefits.[60]

5.3 Biocolonialism

Allowing wealthy countries to patent genetic material from poorer countries encourages biocolonialism (ie the exploitation of the biological resources of other countries). Examples include a patent obtained by the United States National Institutes of Health for an unusual variant of HIV obtained from the Hagahai people of Papua New Guinea; and a genetically engineered variant of South East Asian Basmati rice which may put small Asian farmers out of business.[61] Australia as a mega diverse nation should protect its genetic diversity by banning the patenting of DNA sequences.

5.4 Collective and individual privacy

Genes are the building blocks of human life. They are part of everyone's body, as well as their intellectual and emotional constitution. Allowing genes to be patented by a third party without a person's consent infringes that person's right to privacy;[62] or the privacy rights of the group or race to which the person belongs.

5.5 Patenting genes and genetic sequences increases costs for other researchers and the community

Patents on genes and genetic sequences impose an extra cost on researchers who want to use them in more extensive research. For example, the pharmaceutical giant Merck has argued that restricting access to basic structural and descriptive information about the genome through patents will prevent the human genome being extensively exploited.[63]

Multiple patents also increase the cost of genetic testing. If the research was initially government-sponsored, the public pays twice – first, for the project that ultimately results in a patent and later, for using the patented product.

5.6 Patents may delay research and product development

Some commentators have questioned the assumption that companies will not undertake research without the incentive of patent protection. Indeed, if a competitor holds a patent that covers part of the area in question, that may be a disincentive to others to

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[59] B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' 1994 (26) *Law and Policy in International Business* 231, 234. Cf Universal Declaration on Human Rights Article 27: each person in the world should share in the benefits of scientific advancement and particularly in the "moral and material interests resulting from any scientific, literary or artistic production of which he is an author".

[60] Looney, above n 59, 240.

[61] D Wertz, 'Controversial Attempts at Patenting' 1999 3(2) *The Gene Letter* <http://www.geneletter.org>

[62] Looney, above n 59, 238.

[63] D Dickson, 'Open Access to Sequence Data will Boost Hunt for Breast Cancer Gene' (1995) 378 *Nature* 425. One should add after exploited: "until after the patent period".

undertake research. An example cited by Charles Lawson is the case of *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc.*[64] Lawson argues that, if the patent claimed by Chiron on Hepatitis C strain 1a had been upheld, that would have precluded Murex offering a more extensive test for other Hepatitis C strains not covered by the Chiron test. Australian blood suppliers would then have been able to test only for Hepatitis C strain 1a and not for the more prevalent strains 2, 3 and 5, causing increased anguish to those affected and increased costs to the community.[65] The conflicting parties might reach agreement through cross-licensing but the cost of that negotiation and the reduction in profitability of its potential product are still a disincentive to pursue the research.[66]

6. Evaluation of arguments concerning biological patents

It seems clear that patents generally do encourage research, disclosure of information and the development of new products. Those who say that patents promote secrecy often do not understand the requirement of patent law that the details of an invention must be revealed, together with instructions for reproducing it, before the patent will be granted. Also, if the patent holder refuses to allow others to use the patented invention, the Patents Act 1900 (Cth) contains provisions allowing a court application for a compulsory licence to be granted to someone who wants to use the invention. As a general principle, patents do not restrict or delay research.

They do, however, add to the cost of research and may affect the type of research that is undertaken. This is especially so with patents on the basis "tools" of research in biotechnology, such as genes and genetic sequences. Although it seems fair to reward the finder of a new gene or genetic sequence, it must be remembered that one person's product is another person's tool[67] and that that person will have to pay each time the tool is used. Being required to pay for the basic material for biological research is a disincentive, especially in the straitened circumstances facing universities and other research centres today. And naturally, researchers funded by the private sector will use biological tools that their sponsor has already developed and patented – because they do not have to pay for access to it – and also, because they may develop further profitable uses for it. Yet, those tools may not be the most appropriate for the task.

These factors have influenced opponents of biological patents to argue that patents on at least genes and sequences should not be permitted, even if patents are allowed on whole

[64] unreported, Federal Court, (NG380/1996).

[65] C Lawson, "Patenting Genes and Gene Sequences in Australia" (1998) 5 *Journal of Law and Medicine* 363, 364-5. Lawson argues that the grant of patents of genes and gene sequences "fails to take account of s 6 of the Statute of Monopolies. That section requires that the invention should 'be not contrary to the law or mischievous to the state by raising process of commodities at home, or hurt trade, or generally inconvenient'": ibid at 364. He advocates legislation (*semble* to prevent or restrict patents and genetic sequences) first because the powers of the Patent Office are limited in looking at the broader implications of a patent (p 365-6); and judges have declined to consider policy arguments concerning patents as those are a matter for Parliament (p 370).

[66] Lawson, ibid at 369, citing *Kirin-Ambgen Inc v Board of Regents of University of Washington and Genetics Institute Inc* [1995] 64 AIPO (19 Oct 1995).

[67] This was discussed at the First International Conference on DNA Sampling in Montreal, reported by Loane Skene and Donald Chalmers, (1997) 4 *Journal of Law and Medicine* 229-234.

organisms. However, the issue is not clear cut. Even if patents are granted, they are only for a limited period and the patented tool can still be used in research, though at a cost. More importantly, a patent holder can waive patent rights and that often occurs where there is a request from a university or private researcher who will not profit financially from using the invention. Finally, in future as it becomes easier and cheaper to isolate genes, more emphasis may be placed on their "utility" and fewer may be granted. Other technologies have gone through a similar stage with numerous patents, including "tools"; for example, in information technology.

In relation to the patenting of organisms, the objections to what some people see as the commodification of the basic elements of life – or the usurping of God's role – are met to some degree by the fact that a patent is not the same as ownership. With third world countries or collectivities, it is true that their biological material may be used in research, or even commercialised, but there are also potential benefits for those people from the research (new drugs and other medical treatments; genealogical knowledge; more productive agricultural animals and crops etc). Countries with strong economies gain greatest financial benefit in the early stages of a patent but later, patent-holders may choose not to register their patent in many countries or not to defend apparent breaches of the patent. It must be emphasised again that they do not own the product; they have an intellectual property interest in it for a limited period.

7. Recent Recommendations and Proposals for Change

7.1 Two Bills that would have prevented gene patents

Two Australian Bills that would have prevented gene patents were not pursued.

In 1990, Senator Coulter proposed an amendment to section 18 of the *Patents Bill* 1990 (Cth) (1990) that "A patentable invention should not include a gene or genes, whether derived from cells or chemically synthesised".[68] The amendment failed to win Senate support.

In 1996, Senator Stott-Despoja proposed the *Patents Amendment Bill* 1996 (Cth) (1996). It provided that naturally occurring genes, gene sequences and descriptions of the base sequence of naturally occurring genes do not possess the quality of novelty and inventiveness and should not be patentable.[69] The debate was adjourned, and the bill subsequently lapsed.

7.2 AMA concerns

The Australian Medical Association (AMA) said in its *Position Statement on Genetic Issues* (1988) that the holding of patents should not infringe the principle that the human genome is the common heritage of humanity and should not prevent an obstacle to the prevention, management and treatment of disease.[70]

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[68] Senate, *Hansard*, 17th September 1990, p 2478.
[69] *Patents Amendment Bill* 1996 (Cth) Schedule 1, 1. Senate, *Hansard*, 27th June, p2332.
[70] AMA 'Genetic Issues - 1998', Australian Medical Association, 1.

7.3 Later proposals in Australia and the UK would not prevent gene patents

There have been a number of policy recommendations that have supported the grant of biological patents, in some cases with limits. These are noted in paragraphs 7.3 and 7.4. The limits suggested are noted especially in paragraph 7.4.

7.3.1 ***Genetic Privacy and Non-Discrimination Bill 1998 (Cth).*** The most recent proposal relevant to patents of human biological material is the Genetic Privacy and Non-Discrimination Bill 1998 (Cth), introduced in the Australian Senate by Senator Stott Despoja. The scheme of the Bill would not prevent the patenting of human genetic material but samples could not be obtained or patents sought without the full consent of the person concerned. The Bill is based on the principle that people have dominion over their bodies and that they should therefore have sole right to decide who should have access to their genetic information and material. Under the Bill, DNA could not be collected, stored or analysed without the written authorisation of the person concerned after specified information and a specified notice of rights and assurances has been provided. The person would have the right to require that the sample be destroyed at any time and to share in the proceeds of any commercial exploitation of the tissue.

7.3.2 House of Representatives Standing Committee on Industry, Science and Technology, ***Genetic Manipulation: The Threat or the Glory*** **(1992).** This Committee concluded in 1992 that there is no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort.[71] Denying the right to patent, allowed in other countries, would probably adversely affect the biotechnology industry in Australia.[72]

7.3.3 House of Commons Science and Technology Committee, ***Human Genetics: The Science and its Consequences*** **(1995).** The House of Commons Science and Technology Committee took a similar view in England in 1995. It said that patenting of genetic sequences should be permitted provided the application displays the requisite degree of novelty and utility.[73] Patent exclusion on the ground of morality should remain, given the increased importance of the concept of human dignity[74] but patents of DNA sequences do not fall within that exclusion.

7.4 Calls for limits on gene patents

However, some reports, while supporting biological patents, have called for limits. The need to obtain full consent from human donors has been noted above (para 7.2.1). Also, the English concern about morality (para 7.2.3). Two other reports suggest other limits.

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[71] House of Representative Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory* (February 1992), 7.113.
[72] Ibid 7.112.
[73] House of Commons Science and Technology Committee, Third Report, *Human Genetics: The Science and its Consequences* (1995), xix, para 205.
[74] Ibid xvii, para 195.

7.4.1 Prime Minister's Science, Engineering and Innovation Council (PMSEIC), *Profiting from the Biotechnology Revolution* (1998).[75] In 1998, the PMSEIC stated that the international patent system should be changed to be far less supportive of monopolies in genetics.[76] In some cases, it said, broader than necessary patent protection had been given, particularly for naturally occurring genes.[77] However, limiting the coverage of a patent, compared with coverage in many other countries would probably adversely affect the biotechnology industry in Australia. An international initiative should therefore be encouraged to influence World Trade Organisation forums such as the Trade Related Intellectual Property agreement (TRIPS) to narrow the scope of patents for naturally occurring genes.

7.4.2 Advocates of a Human Genome Trust. A number of academics have proposed the creation of a world genome trust. Such a trust would oversee human genome research, holding gene sequences in trust for humanity. Its board would license researchers to protect rights prior to the development of patentable inventions.[78] It could check unethical development, alleviating some of the fear and mistrust associated with genetic research.[79] Advocates of the Human Genome Trust argue that it recognises the ethical reasons not to patent genes, but preserves the economic incentive of a patent system, finding a compromise between the competing ethical positions of the gene patenting controversy.[80]

8. Options for Legal Regulation in the Future

8.1 Continue to apply existing patent legislation

The first option is to continue to apply the existing principles of patent law. This will facilitate the exploitation of the emerging biotechnology industry. Investment will continue, encouraged by the monopoly protection of a patent. Although it is likely that genetic patents will be concentrated in a number of transnational companies and developed countries, the products will be available for everyone to use. Broad patent applications will probably be accepted under existing law and may limit the fullest exploitation of genetic material;[81] but the patents will eventually lapse, and the information and use of the invention will be freely available.

8.2 Ban the patenting of genes and genetic sequences

The second option is to allow biological patents to continue as at present but to ban or restrict patents on genes or genetic sequences. This would make genetic tools more readily available for researchers wanting to use them in other research. However, there

[75] Independent Working Group chaired by Chief Executive of the CSIRO Dr Malcolm McIntosh, '*Profiting From the Biotechnology Revolution*' Prime Minister's Science, Engineering and Innovation Council, (29th May 1998)
[76] Ibid 8.
[77] Ibid.
[78] Looney, above n 59, 268.
[79] Ibid, 270.
[80] Ibid, 272.
[81] Lawson, above n 21, 373.

would be less incentive for research to isolate and identify new genes and sequences. This would then have an adverse effect on scientific research in Australia. In addition, Australia may be in breach of international agreements, specifically the Trade Related Aspects of Intellectual Property Rights agreement. Article 27(1) of this agreement provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

8.3 Lobby at an international level for more stringent patents

A third option for people concerned about biological patents is to lobby international trade organisations such as the World Trade Organisation and the World International Property Office to limit the scope of gene patents, while maintaining the existing patent framework. This would still maintain an economic incentive for research in biotechnology, while preventing broad monopolies, which may restrict future research.

8.4 Creation of a Human Genome Trust

Finally, people concerned about biological patents might support the concept of international projects such as a human genome trust. This might enable ethical concerns to be considered at a global level. However, this would require a major collaborative effort, especially by the leading developed countries. One is likely to encounter political tension, imbalances of power and bureaucratic waste.[82] It would raise difficult issues with existing patents on the human genome, and it fails to consider patents on gene sequences from other organisms.

9. Conclusion

Australia has much to gain from the emerging biotechnology industry that is already producing major financial returns in the United States and the United Kingdom, where biological patents are allowed, as they are in Australia. The Australian Patent Office has a clear policy for granting biological patents. Many have already been granted and there are many more applications awaiting consideration. Australia also has international treaty obligations that prevent the refusal of patent protection in Australia. A number of policy committees have considered whether biological patents should be restricted and have recommended that they should be allowed.

Although concerns have been expressed about biological patents, many of these are ill informed. They can often be met by explaining that patents apply only for a limited period, are not ownership and do not promote secrecy. However, some objections do need to be considered more closely, especially the effect of patenting genetic tools – genes and genetic sequences. The incentive to work on finding new genetic tools must be balanced against the increased cost to other researchers wanting to use those tools. This balance may be achieved by applying a more stringent test for utility, requiring a specific application for the gene sequence beyond mere use as a research tool. By

[82] Looney, above n 59, 269.

focusing on the function and application of a genetic sequence, as well as limiting broad patent grants, the patent system will encourage investment, but not hinder research.

Part B: Ownership of Genetic Material and Human Tissue

10. Introduction

Tissue is routinely stored in hospitals or laboratories after surgery or pathology tests have been completed. Tissue may also be taken from participants in experimental trials in hospitals, universities, academic institutions and pharmaceutical companies. Who owns this tissue? Can it be used in research or in different research projects than those for which it was first collected? Can it be bought and sold; or stolen? Who can get access to it? Whose consent is required? Who should share in the proceeds if a profitable discovery is made from research on the tissue? Do the same rules apply to tissue collected for genetic registers to assist families to establish their genetic pedigree and assess risks for genetic conditions? These questions raise complex issues of property in genetic material and human tissue. Many are discussed below.[83]

This part of the paper commences with an outline of the Australian law, then describes the law in the United States and Europe. It sets out and evaluates the arguments for and against recognising a property interest in tissue and information derived from it. It explains some recent recommendations of professional bodies concerning the procedures to be followed in genetic testing (they require information and consent but stop short of recognising a property interest). Finally, the paper describes some recent Australian proposals to regulate genetic testing (especially the Genetic Privacy and Non Discrimination Bill 1998 (Cth)); and lists some legal options for regulation.

10.1 An example - *Moore v Regents of the University of California*[84]

In 1976, John Moore was suffering from hairy cell leukemia. His physician, Dr David Golde, recommended that Moore's enlarged spleen should be removed to slow down the disease. Without telling Mr Moore, Dr Golde retained parts of the spleen for research purposes and developed from them a valuable cell line that was subsequently patented. The cell line contained Moore's DNA. Did he own it? Did he have other property rights in it? Is he entitled to share in the proceeds of its distribution and use?

11. Law in Australia

11.1 Legislation

There is no Australian legislation specifically on ownership of biological material and tissue samples but all jurisdictions have human tissue legislation that is indirectly relevant.[85] This legislation deals with the donation of tissue for specified purposes,

[83] Issues of ownership arise in many other areas, such as forensic DNA banks, and IVF technology. These are not considered in this paper.

[84] *Moore v Regents of the University of California* 793 P 2d 479 Cal (1990).

[85] *Human Tissue Act 1982* (Vic), *Human Tissue Act 1983* (NSW), *Transplantation and Anatomy Act 1979* (Qld), *Human Tissue Act 1985* (Tas), *Human Tissue and Transplant Act 1982* (WA), *Transplantation and Anatomy Act 1983* (SA), *Transplantation and Anatomy Act 1978* (ACT), and the *Human Tissue Transplant Act 1979* (NT).

including medical and scientific purposes. It does not state that donated tissue is property but it recognises the value of tissue and facilitates an arrangement where tissue can be the subject of a gift or bailment.[86] The Acts provide for consent to donations and they prohibit people from buying and selling tissue, including blood.[87] The ban on sale protects tissue supplies from contamination by samples from impoverished or unhealthy donors and reduces risk to recipients.[88]

11.2 Common Law

The common law has come to recognise that body parts may constitute property but there is no case law directly on the ownership of body parts. Initially, a long line of English cases[89] concerning the legal status of human corpses established that there was no property in a dead body. That rule prevented the recognition of proprietary rights in body parts, as parts removed from a body are similar to a corpse. However, in 1906 the High Court of Australia accepted in principle that a human body could be the subject of property (*Doodeward v Spence* (Griffith CJ)); [90] and that approach gained momentum in later cases. In *R v Rothery*,[91] a defendant who removed a blood sample after a blood alcohol test was found guilty of theft. In *PQ v Australian Red Cross Society*[92] the Supreme Court of Victoria accepted that blood products were goods under the *Trade Practices Act* 1974. But the question of ownership remains untested.

In the situation illustrated by *Moore's* case above, where a doctor removes tissue without telling a patient and later develops a profitable product from it, it is conceivable that a court might acknowledge the patient's interest on the principle that the doctor breached a fiduciary obligation to the patient. Although the High Court of Australia said in *Breen v Williams*[93] that the doctor-patient relationship is not a fiduciary one, the court recognised that a doctor owes a patient certain fiduciary obligations. One such obligation is that the doctor should not gain a financial benefit from the relationship with the patient without telling the patient first. That principle might lead to a similar outcome to that in *Moore* (see below), if such a case were litigated in Australia.

11.3 Guidelines

11.3.1 The *National Statement on Ethical Conduct in Research Involving Humans* (1999) published by the National Health and Medical and Research Council (NHMRC) requires that genetic information or material must not be used without the consent of the person concerned, after full information about what is proposed has been

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[86] R Magnusson, 'Proprietary Rights in Human Tissue' in NE Palmer and E McKendrick (eds), *Interests in Goods* (2nd ed, 1998) 43.
[87] *Human Tissue Act 1982* (Vic) s38, *Human Tissue Act 1983* (NSW) s 32, *Transplantation and Anatomy Act 1979* (Qld) s 40-44, *Human Tissue Act 1985* (Tas) s 27, *Human Tissue and Transplant Act 1982* (WA) s29, *Transplantation and Anatomy Act 1983* (SA) s35, *Transplantation and Anatomy Act 1978* (ACT) s44, and the *Human Tissue Transplant Act 1979* (NT) s24.
[88] Magnusson, above n 86, 67.
[89] Originating from *Hayne's case* (1614) 12 Cp. Rep 113; 77 E.R 1389.
[90] (1908) 6 CLR 406.
[91] [1976] Crim L. R 691.
[92] [1992] 1 VR 19.
[93] (1996) 186 CLR 71.

given.[94] However, there are provisions for some research to be undertaken without consent if a Human Research Ethics Committee approves the project and the data is de-identified. It is significant that the NHMRC guidelines do not address the issue of ownership, but nonetheless recognise the interest that an individual has in his/her genetic sample and the importance of privacy and confidentiality.

11.3.2 The NHMRC's *Guidelines for the Use of Genetic Registers in Medical Research* (1991)[95] take a similar approach in requiring prior information and consent before tissue or data are used. The guidelines recommend procedures for collecting data, use of data and release of data. There is no direct reference to the ownership of biological samples stored in genetic registers. Researchers may use stored tissue in certain circumstances with the approval of the keeper of the register and consent from the person concerned. They must ensure security and confidentiality of the information.[96] The guidelines do not explicitly discuss ownership but acknowledge that there is a unique position of trust between the subjects and the keeper of the register, and that special care must be taken to ensure that research does not endanger or exploit that special relationship. In addition, the guidelines set out a number of considerations which should be considered in determining whether consent should be waived.[97]

11.3.3 Anti-Cancer Council of Victoria Guidelines - *Lovell Report*.[98] A different approach was taken by the Cancer Genetics Ethics Committee of the Anti-Cancer Council of Victoria in its report, *Ethics and Familial Cancers*, 1996. It sees tissue as adjunct to the patient's medical records[99] (which are the property of the person who prepared them, not the patient); and tissue specimens, which also, like other laboratory materials, belong to the body holding the material, and not the person concerned. Thus in state public hospital laboratories, property in the tissue would vest in the government of the state or territory. In private laboratories, it would vest in the body under whose auspice the laboratory functions.[100] The guidelines thus state that "inquirers should understand that records, including tissue specimens sent for DNA testing, are the property of the bodies that make the records or hold the tissues".[101]

11.3.4 Contractual arrangements: Human Genetics Society of Australia. Whatever the general law concerning ownership of genetic material, that can presumably be clarified or altered by contract between the parties. The Human Genetics Society of Australia has a generic consent form for a presymptomatic genetic test in its *Guidelines for DNA Predictive Testing*. The consent form includes a statement that the

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[94] Chapter 15. These Guidelines are available on the NHMRC web site <http://www.health.gov.au/nhmrc>

[95] These guidelines are currently being updated. The 1991 version and the new draft are on the NHMRC's web site.

[96] NHMRC, *Guidelines for the Use of Genetic Registers in Medical Research* (1991), 5.

[97] Ibid paragraph 15.8.

[98] Anti-Cancer Council of Victoria - Cancer Genetics Ethics Committee, *Ethics and Familial Cancers* (1996), later referred to as the Lovell report. The underlying philosophy of the report is described by L Skene 'Patients' rights or family responsibilities? Two Approaches to Genetic Testing' (1998) 6(1) *Medical Law Review* 1-41.

[99] Lovell report, above n 98, para 7.28.

[100] Ibid para 7.23.

[101] Ibid 59.

blood or tissue tested has been voluntarily given to the testing laboratory and that DNA remaining after the test is done will be the property of the testing laboratory and will be stored in good faith. In addition, the guidelines provide that the testing laboratory will not use DNA samples for purposes other than those agreed in the consent form. The contractual transfer of rights in relation to the tissue avoids the issue of whether it is property and all the legal difficulties that arise from so characterising it.[102]

12. Law in other countries

12.1 United States

In the United States, the notion of property rights in cells removed from the body has been rejected at common law, but several states have legislated to provide for property interests in tissue.

12.1.1 Common law. The facts of the principal case, *Moore v Regents of the University of California*[103] have been mentioned above. Moore's claim was rejected on a preliminary motion at trial but, on appeal, the California Court of Appeal found that he had retained a proprietary interest in his cells, and so was entitled to compensation for conversion. On further appeal, the Supreme Court of California overturned the decision of the Court of Appeal, ruling that Moore had no proprietary interest in his removed cells and thus could not sustain his action for conversion.[104] The court held that the removal of a person's cells and bodily tissues extinguishes a patient's property interest in his cells and genetic material.[105] The court, in justifying its decision, argued that to hold otherwise would restrict access to the raw materials that are needed for research, both legally and as a practical matter, having a detrimental effect on the emerging biotechnology industry.[106] The majority in this case drew on the patent grant stating that the fact that a patent had been issued showed that the tissue in question could not possibly belong to Moore.[107] The majority found that patients' rights are best protected by imposing fiduciary obligations on surgeons towards patients, the result being, in American law, that removed tissues cannot be used without the patient's consent.[108] In acknowledging the complexity of the issue, the California Supreme Court left the final disposition of such complex policy matters to the legislature.[109]

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[102] L Skene 'Patients' rights or family responsibilities? Two approaches to genetic testing' (1998) 6(1) *Medical Law Review* 1,40.

[103] *Moore*, above n 84.

[104] Moore's claim against Dr Golde and the University of California had 13 causes of action, including conversion of bodily property, lack of informed consent, breach of fiduciary duty, fraud, unjust enrichment, and negligent misrepresentation.

[105] *Moore*, above n 84, 488-89.

[106] M Lin, 'Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy' 1996(2) *American Journal of Law and Medicine* 109, 118.

[107] *Moore*, above n 84, 492-93. Note that there is an inherent problem in the court's argument as the patent granted was for the process or procedure for creating some new, useful invention, not the cells themselves.

[108] S Huynen, 'Biotechnology - A Challenge for Hippocrates' 1991(6) *Auckland University Law Review* 534, 535.

[109] *Moore*, above n 84, 496. See also Lin, above n 106, 109.

12.1.2 Legislation. Some states have legislated to regulate the accessibility and use of genetic information and genetic discrimination.[110] The legislation is in the form of model Genetic Privacy and Non-Discrimination Bills developed at a federal level.[111] However there is no legislation that specifically addresses the issue of property rights in biological material.

12.1.3 Practice in DNA Banking. The number of DNA samples banked in the United States is rapidly increasing;[112] but the banks often have no written agreement concerning rights over the tissue.[113] Where such agreements exist, they do not state that individuals retain ownership interests in the samples or provide for monetary compensation in the event that research results in the development of commercially valuable products.[114]

12.1.4 Recent federal proposals for legislation. There have been a number of proposals for legislation in the United States in addition to the model Bill mentioned above. These have emanated from concerns about the privacy of genetic information and the potential misuse of that information. Some contain provisions about ownership.

The *Genetic Privacy Bill* 1995 (US), for example, has been presented to the United States Congress but not passed. It not only prohibits the collection of an individually identifiable DNA sample without the written authorisation of the sample source,[115] but it also states that an individually identifiable DNA sample is the *property* of the sample source.[116] This is a major reason why the bill has not been passed.

The *Genetic Confidentiality and Nondiscrimination Bill* 1997 (US) has also been presented to the United States Congress but not passed. It does not confer a proprietary right to genetic material, but still legislates extensively to protect an individual's interest in his/her genetic material. For example, a tissue sample may not be collected unless, prior to collection, the donor is given a written notice of rights and assurances which states, amongst other things that:

- the DNA sample will be used only as authorised in the written authorisation
- the individual has the right to order the destruction of an identifiable DNA sample at any time

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[110] Lin, above n 106, 130.

[111] The underlying philosophy of these Bills is described by L Skene, above n 102.

[112] A study as early as 1994 revealed that 90% of the 148 DNA diagnostic labs surveyed had begun to bank DNA. Over half of these had already accumulated 500 samples or more: J McEwan and P Reilly, 'A Survey of DNA Diagnostic Laboratories Regarding DNA Banking' (1995) 57 *American Journal of Human Genetics* 1477.

[113] The study above (note 112) found that 35% of the laboratories holding tissue had no written internal policies regarding any aspects of DNA storage, and more than half were without any type of written depositor's agreement.

[114] Ibid.

[115] *Genetic Privacy Bill* 1995 (US) s101(a). This is similar to other regulatory instruments and guidelines. It also states that the written authorisation must satisfy specific requirements to remain valid, such as identifying the collector, containing instructions for the sample after analysis, and stating the authorised uses for the sample: s 103.

[116] Ibid, s 104(a).

- the DNA sample will be destroyed upon the completion of the genetic analysis or the genetic test, unless the individual has consent in writing to further use of the sample
- researchers may be granted access to a DNA sample only as specified in the written authorisation
- the collection, storage, and analysis of the DNA sample and the genetic information characterised from the sample are protected by the Act
- an individual whose rights under the Act are violated may seek civil remedies.[117]

12.2 Europe

Most countries in Europe have legislation on organ transplantation[118] but very few have legislated with respect to human tissue.[119] Those that have legislated on human tissue include Belgium, France, Spain, Macedonia and Austria. Most countries prohibit tissue collection for commercial purposes. A report funded by the European Commission in 1992 found that in no European country was a citizen granted full ownership of his/her genetic material.[120] This report further noted that the concept of ownership is not often used in Europe with regard to body material. Nonetheless there is support for varying degrees of control by the individual over the body and bodily parts.[121] This is illustrated by the Council of Europe's Committee of Ministers Statement on Genetic Testing and for Health Care. Principle 13 states that:

"Samples collected for a specific medical or scientific purpose may not, without permission of the persons concerned or the persons legally entitled to give permission on their behalf, be used in ways which could be harmful to the persons concerned."

Furthermore Principle 8 provides that:

"The collection and storage of substances and samples ... must be in conformity with the Council of Europe's basic principles on data protection laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data."

In general, it can be observed that European countries have avoided recognising proprietary rights in genetic material. Nonetheless, it is clear that the Council of Europe has considered it important that individuals should retain limited control over their samples, and that the collection and storage of samples be regulated.

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[117] *Genetic Privacy and Nondiscrimination Bill 1997(US)*, sec 101.
[118] With the notable exceptions of Germany, Holland, and Switzerland.
[119] O Quintanta, 'Human Tissue Banks in Europe' in B Knoppers (ed) *Human DNA: Law and Policy* (1997) 423.
[120] J de Witte, *Human Genome, Body, Identity and Property: Philosophical Issues* (EC Project PL 9101027, 1992).
[121] R Chadwick, 'The Status of Human Genetic Material - European Approaches' in B Knoppers (ed) *Human DNA: Law and Policy* (1997) 55, 57.

13. Arguments in favour of a proprietary right in human tissue

Sections 2, 3 and 4 below set out the arguments for and against the acknowledgement of a proprietary right in human tissue and then evaluate those arguments.

13.1 Owning one's body is a basic human right and this extends to removed tissue

It is self-evident that people own their own bodies in the sense that no one can lawfully remove anything from a person's body without consent or some other lawful justification. There is no logical reason why the ownership of the body should not extend to tissue samples taken from the body. The recognition of a property right in human tissue is essential if individuals are to maintain sufficient control over their bodies, and be accorded human dignity (see *Moore*[122]).

13.2 Proprietary rights protect autonomy

The ethical principle of autonomy is paramount in medical ethics and law today. This has been acknowledged in many judgments in Australia and other common law countries. It is the basis of legislation such as the Medical Treatment Act 1988 (Vic). People are entitled to make their own decisions about medical procedures and to be provided with information to enable them to make an informed choice. This right to control and decide about their bodies extends to deciding what may be done with their tissue. Genetic testing allows access to private medical information about an individual. People are concerned about this information being used by insurers and employers to discriminate against individuals. Recognising a proprietary right in human tissue is the best way to protect people's autonomy, privacy and confidentiality.

13.3 Human biological material is already property

Stating categorically that human tissue cannot be subject to proprietary rights suggests that it could not be gifted, bought, sold, stolen, converted, bailed or patented, in the absence of specific empowering legislation.[123] That is contrary to current practice. Physicians, researchers, and pharmaceutical companies already exchange such material, increasingly for a fee, and apply for, and receive patents for such material.[124] There are therefore ample grounds for concluding that human tissue, like other commercial goods, can be the subject of proprietary rights.

13.4 Proprietary rights will encourage scientific research

Acknowledging property rights in biological material will advance, not hinder, the biotechnology industry. It will promote future investment and scientific research. The reason is that proprietary rights provide an incentive for people to supply biological

[122] This argument was advanced by Justice Mosk in his dissent in *Moore*, above n 84.
[123] Magnusson, above n 86, 25.
[124] Moore, above n 84, 160.

material. Without the inducement of a property right, they may be reluctant to allow their tissue (or themselves) to be used for laboratory or clinical research purposes. Having more samples increases a researcher's chance of success because the best samples can be selected.

14. Arguments against proprietary rights in human tissue

14.1 Proprietary rights will restrict research

Recognising proprietary rights in human tissue will impede scientific research and development.[125] Every researcher who uses tissue samples in research could be held liable in conversion unless the donor previously agreed to that use. Although donors can be "revisited" for their specific consent, that can be difficult in practice.[126] Researchers will naturally be reluctant to use tissue if there is a risk of liability. This will deter investment and the development of new pharmaceutical products.

14.2 Proprietary rights will prejudice health care

If genetic registers and the tissue associated with them are not freely available to all blood relatives, some may be deprived of information they need for their health care. If people have a property right in stored tissue, their consent will be required before access to tissue or information can be granted. Providing adequate information and obtaining consent in every case will be cumbersome and expensive.[127] Also people could veto access. For this reason, one major policy committee recommended that a person whose tissue is taken and tested for familial cancer should not be entitled to prevent access when that is necessary for the health of another relative.[128]

14.3 Proprietary rights will encourage trade in tissue

Recognising property rights in human tissue will make tissue nothing more than a tradeable commodity. Trading in human flesh takes us back to the days of slavery. The poor and disadvantaged will be further victimised by being forced to sell their organs.[129] Tissue supplies will then be contaminated by diseased and unhealthy samples. Also, selling body parts to the highest bidder is unjust. All people have an equal right to treatment, irrespective of their wealth.[130]

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[125] R Gold, *Body Parts Property Rights and Ownership of Human Biological Materials* (1996) 26. Citing the majorities reasoning in *Moore*.
[126] L Skene, above n 102, 33.
[127] Ibid 26.
[128] Ibid 27.
[129] S Mortinger, 'Spleen for Sale: *Moore v Regents of the University of California* and the Right to Sell Parts of Your Body' (1990) 51 *Ohio State Law Journal* 499, 508-509.
[130] Huynen, above n 108, 541.

15. Evaluation of arguments concerning ownership of tissue samples

Most policy committees have stopped short of recommending, as a general proposition, that a property interest should be recognised in human tissue. There is good sense in this. Imagine the complex issues that may arise if tissue is legally regarded as always being owned by the person from whom it was taken. If the person dies and the tissue is still stored in the hospital laboratory, will it pass to the person's heir under a will or on intestacy? And under what legal principle does the hospital acquire the tissue in the first place? Is it a bailment? Can the person demand that the tissue be returned after "use"? Can it be sold? If it is stolen or destroyed in a laboratory fire, can the person claim compensation on the hospital's insurance policy? What financial value could be placed on tissue (say a test tube filled with oesophageal tumour cells) in such circumstances? These are lawyers' questions arising from the basic principles of property law but the mere statement of them indicates the oddity of a general rule that tissue is the property of the donor.

Also, such a principle seems undesirable from a policy perspective, at least in relation to tissue held in hospitals after diagnostic tests. The intention of the parties in this case is surely that the tissue should be used for the patient's diagnosis and treatment. This obviously covers its use in the initial diagnostic test and perhaps for repeat testing soon afterwards. It may even be argued to extend to later tests by the hospital; for example, quality assurance measures to check the accuracy of testing procedures, since that testing may also be for the patient's benefit, albeit longer term. (If the test is shown to be faulty, the patient can be contacted and re-tested). However, use of the tissue in research is more difficult to justify on the basis of the original intention or an implied consent, since the benefit to the patient is less evident and immediate. But, even if the person obtains no benefit from the research, what harm is there if the tissue is used in a codified or anonymised form? Could one not apply a utilitarian approach and say that on a risk-benefit analysis, the limited invasion of the donor's privacy right is outweighed by the potential benefit of the research?

Civil libertarians certainly place a high value on the mere use of tissue without specific consent, even in the absence of any demonstrable harm to the person concerned. Does the public at large take the same view? Could one not take a communitarian perspective and argue that, as members of a community, we have an obligation to contribute to the general good where that involves no harm to us personally?

The effect on research if property rights are - or are not - recognised in tissue seems moot. On the one hand, it may encourage donors to come forward, or to consent to the use of stored samples. On the other, it imposes additional costs in gaining approval from ethics committees, informing donors, obtaining and documenting consent, reporting back to institutional and central ethics committees and the like. When the impact of the latter requirements is considered in more detail (the various steps, the number of people involved, the bureaucracy), it seems that research would be better encouraged by non-recognition of a property right in the tissue.

Even if a general property right is not acknowledged, there remains the issue of tissue (like blood products) that are already bought and sold, for example by the Australian Red Cross. There are good therapeutic and humanitarian reasons for allowing this type of sale. How is this different from a general principle that there can be no property in tissue? Could one argue simply that this is an exceptional case? Or that property rights can be acquired when tissue is "processed" in some way? Does it make a difference that the donor has consented to the use – or that the use is directly therapeutic?

Throughout any policy analysis, one should remember the concerns that people have about the use of tissue without consent. They are worried about being exploited – or about possible repercussions for them if personal information is wrongly used or revealed in the public domain. There are other responses to these concerns. First, doctors and researchers have common law duties in trespass and negligence to obtain consent for medical procedures and to provide information about what is proposed before the patient agrees. Secondly, the High Court of Australia has recognised the existence of fiduciary obligations on the part of doctors which prevent them obtaining a financial reward for themselves without informing the patient (*Breen v Williams, supra* although there is little Australian law to date on that aspect). Thirdly, ethical guidelines of bodies like the National Health and Medical Research Council recommend that tissue should not be used without consent unless that is coded or anonymised; and the research is approved and overseen by Human Research Ethics Committees. If necessary, other methods could be developed to protect patients' interests and assuage doubts about doctors or researchers gaining an unfair advantage from using patients' tissue without consent. (These might include fuller information requirements; or an "opting out" facility.)

Finally, one should distinguish between the use of tissue for therapeutic and research purposes. The former includes procedures such as establishing an index case for genetic diagnosis; conducting genetic linkage within a family; preparing a family pedigree; and running a genetic register. In all of these circumstances, there is a stronger argument for denying a right of veto over the use of tissue where that can directly benefit other blood relatives. The reason is that one has greater obligations to one's family than to the world at large; and the benefit of knowing about the genetic risk is more immediate and direct than the potential benefits of research.

For reasons such as these, commentators have generally focussed on the right of donors to autonomy – not to have things done to them without being properly informed and without their consent. This right to autonomy has been emphasised, rather than a right to privacy (not to have their tissue secretly used); or a right to property in the tissue (a right to control its use; or to buy and sell it). The right to autonomy could be supported by fuller disclosure requirements before the tissue is taken, perhaps with a general statement that stored tissue may be used in research without further reference to the donor on an anonymised basis and subject to the supervision of a Human Research Ethics Committee. Although it is conceivable that living DNA might be preserved and reproduced indefinitely in a therapeutic form such as a cell line that encodes personal details of the particular donor, it would be of little significance since that person could not be identified.

16. Recommendations by Professional Bodies

Many professional bodies have published guidelines recommending procedures to be followed in taking tissue for genetic testing and for the storage of tissue and genetic information. These guidelines focus on the need to provide information to the person concerned and to obtain consent to the taking, storage and use of tissue and information. Although some approve the use without consent for research in limited circumstances, that can only be done if the information is de-identified (ie coded but the donor can be traced if necessary); or anonymous (all identification severed). The guidelines that are specifically directed to research are more stringent in restricting access than those dealing with genetic registers, which are more concerned with sharing information among family members for health reasons. The guidelines include the following.

16.1 The American College of Medical Genetics, *Statement on the Storage of Genetics Materials* (1995)[131] does not refer to the ownership of genetic material. It recommends that certain matters should be clarified when samples are obtained for clinical tests. These include:

- the anticipated use of samples
- the scope of permission to use samples or results in counselling and testing relatives and if so, which relatives
- the permission to use samples in research if identifiers have been removed including the type of research
- the duration of storage of genetic materials.

16.2 The American Society of Human Genetics, *DNA Banking and DNA Analysis: Points to Consider* (1996)[132] states that:

- banked DNA is the property of the depositor unless otherwise stipulated
- deposited DNA may be used for purposes unrelated to the original request of the depositor only with his/her express consent
- DNA banks should only disclose the result of a DNA test to a third party with the express consent of the individual.

16.3 The Human Genome Organisation (HUGO) Ethics Committee, *Statement on DNA Sampling: Control and Access*[133] did not acknowledge an express right of ownership. It said that:

- tissue taken and stored for medical care may be used for research if there is general notification of such a policy, the patient has not objected, and the sample has been coded or anonymised
- tissue taken before notification of the policy may be used for research if the sample is anonymised

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[131] American College of Medical Genetics, 'Statement on Storage and Use of Genetic Materials' (1995) 57, *American Journal of Human Genetics* 1499-1500.

[132] American Society of Human Genetics, 'Statement on Informed Consent for Genetic Research' (1996) 59 *American Journal of Human Genetics* 471-474.

[133] Human Genome Organisation Ethics Committee, *Statement on DNA Sampling Control and Access* (Feb 1998). Available on the web at <http://www.gene.ucl.ac.uk/hug/sampling.html>

- tissue taken for research (and its information) can be used if people consent, either to identified use, de-identified use or anonymous use
- research samples obtained with consent and stored may be used for other research if there is general notification of such a policy, the participant has not yet objected, and the sample is coded or anonymised.

16.4 The World Health Organisation, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* (Dec 1997)[134] state that the most efficient approach to consent for genetic registers is a blanket informed consent that allows the use of samples in future projects. The guidelines say that:

- control of DNA may be familial, not only individual
- blood relatives should have access to stored DNA to learn their genetic status, but not to learn the donor's genetic status
- DNA should be stored as long as it can be of benefit to living or future relatives or foetuses
- no one should have access without the donor's consent, except for forensic purposes or where the information is directly relevant to public safety
- insurance companies, employers, schools, government agencies and other institutional third parties (who may be able to coerce consent) should not be allowed access, even with the individual's consent.

16.5 The Australian National Health and Medical Research Council (NHMRC), *Draft Guidelines for Genetic Registers and Associated Genetic Material* (1999) comprehensively cover the operation of genetic registers in Australia. They replace earlier guidelines that were amended following criticism by the Privacy Commissioner in his report entitled *The Privacy Implications of Genetic Testing* (1991).[135] The guidelines cover the establishment of registers, recruitment of registrants, consent and confidentiality, security of registers, and amalgamation and winding up of registers. There is no express right of ownership but the following information must be given before consent to the taking and storage of tissue, or the inclusion of the person on the register:

- what information and genetic material is collected and stored[136]
- the intended duration of storage (consent should include consent to dispose of the material at the end of that time;[137] and register staff should check to see if the registrant still agrees before disposing of the material)[138]
- what should be done with identified information and stored genetic material after death[139]
- the register's guidelines for ensuring confidentiality of information and protection of registrants' privacy[140]

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[134] Available on the internet at <http://www.who.int/ncd/hgn/hgnethic.htm>

[135] Privacy Commissioner, *The Privacy Implications of Genetic Testing: Information Paper number Five* (1996).

[136] NHMRC, *Draft Guidelines for Genetic Registers and Associated Genetic Material* (1999), 12.

[137] Ibid 5.2.1.(b)

[138] Ibid 5.2.1 (b)

[139] Ibid 5.2.1 (c)

[140] Ibid 5.1 (viii).

- who is denied access to identified information and genetic material eg. insurers, employers, family members who do not have the registrant's permission for access.

17. Recent Australian developments

17.1 Genetic Privacy and Non Discrimination Bill 1998 (Cth)

Senator Stott-Despoja (Dem) introduced this Bill into the Senate in 1998. As she said in the Second Reading speech, "The provisions are a balance between the interests of complete ownership and promoting the opportunity of researchers to derive a commercial benefit from their endeavours". The Bill is similar to the US model *Genetic Confidentiality and Nondiscrimination Bill* 1997 (and also to the recommendations of the professional bodies described above) in requiring information and consent before tissue is collected, stored or used.[141] But it goes further by envisaging that people may be entitled to share in the proceeds if their tissue or information is used to develop a commercial product. This is not exactly a property interest but it does have financial value. Yet the Bill also provides for research on tissue without consent in certain circumstances (see below), if the use is anonymous. That would not be possible if the donor owned it.

The Bill requires that tissue must not be taken, tested or stored without prior written authorisation from the donor[142] and that the donor must also be given a notice of rights and assurances. There are specific requirements for each of these.

The *written authorisation* must state:
- all authorised uses of the DNA sample[143]
- whether it may be used in research
- whether it may be used commercially, with a waiver of, or provision for, economic benefit to the individual[144]
- the option of supplying the sample in a de-identified format.[145]

The *notice of rights and assurances* must state:
- the DNA sample will be used only as authorised[146]
- the donor may order the sample to be destroyed[147]
- the sample will be destroyed after the test unless the donor gives written consent for further research[148]
- the donor may appoint someone else to decide about disposing of the sample[149]
- the donor has the right to examine records[150]

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[141] *Genetic Privacy and Non-discrimination Bill* 1998, Part 3, clause 12.
[142] Ibid clause 16(1)(a)
[143] Ibid clause 16(1)(d)
[144] Ibid clause 16(1)(f)
[145] Ibid clause 16(1)(f)(iii)
[146] Ibid clause 14(a)
[147] Ibid clause 14(b)
[148] Ibid clause 14(c)
[149] Ibid clause 14(d)
[150] Ibid clause 14(e)

- researchers may get access only as permitted by the written authorisation[151]
- storage and analysis of the DNA sample and the genetic information characterised from the sample are protected
- an individual whose rights are violated may seek redress.[152]

DNA samples may be used in research without consent in limited circumstances; ie if:
- the sample is essential to the project
- the potential benefit of the research to society outweighs the potential risk to research subjects[153]
- the research protocol provides adequate safeguards to protect privacy;[154] at a minimum this means satisfying any guidelines issued by the NHMRC, and approved by the Privacy Commissioner[155]
- it ensures that research subjects are not identifiable in any report or publication[156]
- it has procedures to remove or destroy any individual identifiers at the earliest opportunity.[157]

17.2 Senate Report on the Genetic Privacy and Non Discrimination Bill 1998 (1999)

The Genetic Privacy and Non Discrimination Bill 1998 was referred to the Senate Legal and Constitutional Legislation Committee, which reported in March 1999. This Committee said that the Bill dealt with the relevant issues but some required further consideration and consultation, particularly ownership of genetic material; and ownership of information derived from such material.[158]

The Committee said that there are legitimate interests on all sides in medical research – researchers, pharmaceutical companies, indigenous groups and individuals. Regulation is needed to clearly enunciate the policy position that is to be adopted and to ensure that justice is done to individuals and groups of people who may otherwise be commercially exploited. Also, from the perspective of public policy, it is desirable that a lack of regulation does not prompt people and groups of persons to refuse to participate in research because their interests are not recognised by the law.[159]

In general, the Committee said, medical research in Australia is well regulated. There are adequate safeguards to ensure that research is conducted appropriately. However, there is some doubt about whether research funded in the private sector is covered by the NHMRC guidelines.[160]

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[151] Ibid clause 14(f)
[152] Ibid clause 14(g)
[153] Ibid clause 20(1)(a) and (b).
[154] Ibid clause 20(c)(i).
[155] Ibid clause 20(2)(a)
[156] Ibid clause 20(2)(b)
[157] Ibid clause 20(2)(c)
[158] Senate Legal and Constitutional Legislation Committee, *Report on the Genetic Privacy and Non Discrimination Bill 1998* (1999), para 4.41
[159] Ibid para 4.39
[160] Ibid para 4.40

18. Policy Options

18.1 Legislate to recognise a proprietary right in human tissue

If it is decided that a proprietary right should be recognised in human tissue, one could legislate to establish such a right with provisions similar to the Genetic Privacy Bill in the United States (para 3.1.4 above). People would then be able to capitalise on commercial enterprises resulting from scientific research on cells they provide. Also, it would provide additional protection from genetic discrimination resulting from unauthorised use of their samples.

This would need to be balanced against added costs and practical difficulties for scientists undertaking research and the impact for the community as a whole. The issues raised above concerning the legal implications of recognising a property interest (para 15) must also be considered. Also, are property interests appropriate when tissue is collected for therapeutic purposes, such as genetic registers, rather than for research from which the donor – or the donor's family - will obtain no special benefit?

18.2 Legislate to regulate the area, but do not recognise a proprietary right in tissue

A second option to protect the interests of tissue donors is to legislate to regulate the use of genetic samples, without expressly recognising a proprietary right in human tissue. This is similar to the recommendations of the various professional bodies concerning tissue used in research (paras 7.1-7.3 above), focussing on the need for full information and consent. It could be achieved by enacting legislation like the Genetic Privacy and Non-Discrimination Bill 1998 (Cth) (para 8.1 above), excluding the provision for sharing in profits of use of tissue.

This option has the advantage of not commercialising organ or tissue donation, while at the same time protecting people from potential exploitation. Laws restricting disclosure of information and access to samples will protect an individual's privacy and confidentiality. Legislation, of course, has the advantage of direct enforceability. It can establish regulatory bodies to oversee compliance and impose penalties. This would meet the concern that the NHMRC guidelines may not apply to private agencies.

But is legislation really necessary when the present system of guidelines administered by the NHMRC seems to be working well? And, if legislation is desirable, would it not be better restricted to anti-discrimination or privacy legislation directed to the wrongful *use* of the information, rather than legislation that imposes burdensome bureaucratic requirements every time tissue is taken for health purposes?

18.3 The status quo: regulation by guidelines of NHMRC and professional bodies

Currently most hospitals and academic institutions which bank human tissue samples are regulated by Human Research Ethics Committees (HRECs), which are in turn bound

by NHMRC guidelines. The Australian Health Ethics Committee (AHEC), one of the principal committees of the NHMRC, oversees the guidelines and the activities of HRECs. AHEC is a diverse body with representatives from all sectors of the community. HRECs are also widely based, with representatives from outside the institution. In addition, there are professional guidelines that recommend procedures for genetic testing and there are similar indirect legal inducements to comply with them.

Although these guidelines do not have legislative backing, they are likely to be observed. Compliance is a condition of funding in NHMRC funded projects. The guidelines are an indication of accepted practice in proceedings for negligence or breach of contract. Breach might be unprofessional conduct in disciplinary proceedings. Even if the guidelines are not directly incorporated in a contract of employment, it is expected that they will be observed and a breach might impede career advancement or publication prospects. In short, non-statutory guidelines do have teeth! This applies even if the research is not funded by the NHMRC so that it is not covered by the guidelines. The guidelines are still an indication of accepted practice and could be taken into account in litigation or disciplinary proceedings. Guidelines also have the advantage of flexibility. Given the accelerating pace of biotechnological innovation this is a substantial advantage.

On the other hand, guidelines cannot compensate someone whose tissue is used in a profitable enterprise without the person's consent. A further concern is the possibility of future litigation based on alleged property rights. The legal uncertainty may deter investors from investing in scientific research. However, if anonymity is preserved in using tissue commercially, there seems little scope for this.

18.4 Establishment of a Royalty-Based Clearinghouse system

A proposal that has arisen in the United States is a royalty based system similar to that of the Performers Rights Association, which privately calculates and distributes royalties to the music industry. With respect to biological raw materials, a similar system could be set up wherein patient-donors sign up with a "clearinghouse" that would distribute the cells, tissues, and other biological materials. The clearinghouse could then charge the industry for access to these raw materials. It has been argued that such a system would be a feasible alternative to the legislative or judicial recognition of proprietary rights in genetic material.[161] An advantage of this system is that it would provide a central point for sample collection, and would also compensate individuals for commercial exploitation of their genetic material. However, it would not cover the whole field of stored tissue, including genetic registers.

18.5 Regulation by Contract

It has been proposed that the issue of whether a research institution owns a DNA sample should be regulated by a contract between the donor and the institution. An individual contracting with an institution could, for example, transfer all rights concerning the tissue subject to an undertaking by the storage facility that it will provide information,

[161] Lin, above n 106, 121.

or make samples available for testing by blood relatives. Furthermore a contract could bind an institution to conduct research according to established ethical practices, supervised by an ethics committee.[162] It has been noted that the contractual transfer of rights in relation to the tissue avoids the issue of whether it is property and all the legal difficulties that arise from so characterising it.[163] Critics argue that such a system promotes standardised contracts that do not recognise an individual's rights with respect to a tissue sample.

19. Conclusion

Recognising a general property right in tissue raises difficult legal issues. Some are abstract or technical, such as the legal basis on which a hospital or laboratory acquires tissue for testing; and the donor's subsequent rights in relation to its use and disposition. Others are more significant from a commercial perspective, such as the donor's right to share in the proceeds if a valuable product is developed from the donor's tissue, cells or DNA.

Most government instruments, guidelines, policy recommendations and commentators, both in Australia and other countries, have not recommended recognising a general property right in tissue. Instead, they have focussed on the autonomy rights of the donor, sometimes advocating fuller disclosure of information, or the provision of a statement of rights and responsibilities, before the initial removal of tissue.

If tissue is later used in research without the donor's consent, ethical guidelines in Australia and other countries recommend that information derived from the tissue should be coded or anonymised; and that approval should be sought from institutional ethics committees which must supervise on an ongoing basis. In Australia, these committees are Human Research Ethics Committees under the aegis of the National Health and Medical Research Council (NHMRC). For research funded by the NHMRC, there are direct and indirect inducements to comply with the guidelines. For research funded from other sources, the guidelines provide a guide to accepted practice and might have indirect legal effect. This form of non-statutory regulation is in line with that for other types of medical and scientific research and there is no reason to believe that it is not working well.

It is true that there are anomalies in the current law, such as the judicial recognition that blood and blood products are goods under the Trade Practices Act and may be bought and sold – obviously suggesting a property interest. However, those anomalies would not seem to justify major amendment of the existing law to categorise tissue as property in all circumstances. Concerns about potential misuse of tissue and genetic information derived from it can largely be met by requiring that research undertaken without the donor's consent must be coded or anonmyised; and that it is part of a doctor's fiduciary obligations towards the donor to ensure that that occurs.

[162] Skene, above n 102, 39.
[163] Ibid.

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Part C: Position of the Law Institute of Victoria

Biological patents

Australian law should continue to permit patents of human genetic material and applications of that material provided the basic requirements of utility and novelty are met. If any change is made, it should be limited to a more stringent test for utility, requiring a specific application for the gene sequence beyond mere use as a research tool.

The reasons for this recommendation are as follows:

1. Patents encourage research and the development of new products.
2. Australia has much to gain from the emerging biotechnology industry that is already producing major financial returns in the United States and the United Kingdom. Biological patents are allowed in those countries, as they are in Australia.
3. The Australian Patent Office has a clear policy for granting biological patents. Many have already been granted and there are many more applications awaiting consideration.
4. Australia has international treaty obligations that prevent the refusal of patent protection in Australia.
5. A number of policy committees have considered whether biological patents should be restricted and have recommended that they should be allowed.
6. Patents are not ownership. They apply only for a limited period.
7. A patent holder is not permitted to refuse to allow others to use the patented invention. If that occurs, the Patents Act 1900 (Cth) contains provisions allowing a court application for a compulsory licence to be granted to someone who wants to use the invention.
8. Patents do not encourage secrecy. Patent holders must reveal the details of the invention, together with instructions for reproducing it, before the patent will be granted.
9. Concerns have been expressed about the effect of patenting genetic tools (eg genes and genetic sequences) because paying to use these tools increases research costs for others. However, denying patents for genetic tools reduces the incentive to work on finding new ones. A balance is needed between the interests of researchers working on new genetic tools and researchers wanting to use those tools in their research. This may be achieved by applying a more stringent test for utility, requiring a specific application for the gene sequence beyond mere use as a research tool. By focussing on the function and application of a genetic sequence, as well as limiting broad patent grants, the patent system will encourage investment, but not hinder research.

Use of human tissue for research and patenting

The law should not recognise a general property interest in human tissue (ie that tissue is always being owned by the person from whom it was taken).

If there is legal intervention, it should be similar to the National Health and Medical Research Council's guidelines. That is, tissue taken with consent after full information about the immediate purpose for which it will be used, may be used in research without further reference to the donor on an anonymised basis and subject to the supervision of a Human Research Ethics Committee.

The reasons for these recommendations are as follows:

1. Although the law currently recognises property rights in tissue in limited circumstances, complex legal issues will arise if that is extended to a general right.
2. The current law is adequate to protect people from having their tissue taken, used in research or exploited for commercial purposes:
   - Doctors and researchers have common law duties in trespass and negligence to obtain consent for medical procedures and to provide information about what is proposed before the patient agrees.
   - The High Court of Australia has recognised the existence of fiduciary obligations on the part of doctors which prevent them obtaining a financial reward for themselves without informing the patient (*Breen v Williams*, *supra* - although there is little Australian law to date on that aspect).
3. Ethical guidelines of bodies like the National Health and Medical Research Council also recommend that tissue should not be used without consent unless the research is approved and overseen by Human Research Ethics Committees; and the samples are coded or anonymised. Although these guidelines do not have legislative backing, they are likely to be observed:
   - Compliance is a condition of funding in NHMRC funded projects.
   - The guidelines are an indication of accepted practice in proceedings for negligence or breach of contract.
   - Breach might be unprofessional conduct in disciplinary proceedings.
   - Even if the guidelines are not directly incorporated in a contract of employment, it is expected that they will be observed and a breach might impede career advancement or publication prospects.
   - This applies even if the research is not funded by the NHMRC so that it is not covered by the guidelines. The guidelines are an indication of accepted practice and could be taken into account in litigation or disciplinary proceedings.
4. Guidelines have the advantage of flexibility. Given the accelerating pace of biotechnological innovation this is a substantial advantage.
5. If legal intervention is considered, it should be similar to the guidelines. That is, tissue taken with consent after full information about its immediate use could lawfully be used in research if anonymised and overseen by a Human Research

Ethics Committee. This would provide additional legal protection for researchers. However, litigation is unlikely if tissue is used anonymously.

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SINGAPORE HOSPICE COUNCIL

13 December 2001

Prof. Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
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Singapore 179101

Dear Prof Lim Pin

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

Firstly, please accept my apologies for the delay in replying to the request for feedback.

I had actually given the principal members of the Council time to consider and respond to me individually. To my pleasant surprise we are unanimous in opinion.

The points made are:

1. **Source**

   Concern is expressed over the extraction of stem cells from embryos or feotuses. We would find this most unacceptable. We are pro-life and believe that life begins with fertilization.
   We have less reservation over adult stem cells obtained from tissues such as bone marrow, umbilical cords and brain.

2. **Acceptable uses of stem cells**

   We do not find any ethical issue behind using stem cells as Cells and EG Cells – basically to support life.

3. **Unacceptable uses**

   We are all against the use of stem cells for reproductive cloning of human beings or even therapeutic cloning. We are against cloning or other similar work.

Cont'd /2

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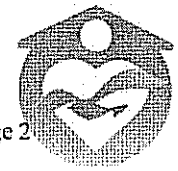

Prof. Lim Pin
Chairman
Bioethics Advisory Committee

13 December 2001

Working on the basic principles above we are concerned over the source for obtaining the stem cells. We would favour existing and new uses of stem cells for supporting life. We are definitely against any form of cloining.

I hope that our response is useful for the deliberations of the Committee.

Thank you.

Yours sincerely,

Gerard Ee
Chairman

GE:sw

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Our Ref: SMA/LCH/cge/BAC/2001

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Singapore 179101

Dear Prof Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

Thank you for your letter of 8 November.

The SMA Council is grateful for the opportunity to review the consultation paper prepared by the Human Stem Cell Research Subcommittee.

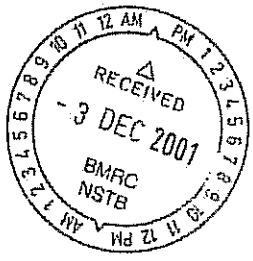
We are pleased to submit our feedback in Appendix 1 from member.

We appreciate the opportunity to present our feedback.

Yours sincerely

LOW CHENG HOCK
President
Singapore Medical Association

Enc:



SUBMISSION FROM SINGAPORE MEDICAL ASSOCIATION ON THE CONSULTATION PAPER BY THE BIOETHICS ADVISORY COMMITTEE REGARDING HUMAN CELL RESEARCH IN SINGAPORE

Like most cutting edge research, human stem cell research raises a number of difficult and important ethical issues and concerns, requiring the potential benefits to be balanced against the need to protect the rights and welfare of citizens. Based on our limited knowledge and experience, we would like to offer the following comments for the BAC to consider.

1. The view of the Bioethics Advisory Committee (BAC) on embryonic germ (EG) cells echoes those held by in UK and the USA, i.e. that there should be a clear separation between decisions and actions relating to the termination of pregnancy and decisions and actions relating to the use of the foetal material made available. However, it is our humble opinion that explicitly spelt out guidelines, like the Polkinghorne guidelines in UK, should be drawn up to govern the use of foetuses and foetal materials in treatment and research. This should, in particular, include:

    a) the prohibition of directed donation of cadaveric foetal tissue for EG cell derivation. This is necessary to ensure that inappropriate incentives and coercions are not introduced into a woman's decision to have an abortion.
    b) the prohibition of sale of foetal tissue for research purposes. The potential for coercive pressure is greatest when financial incentives are present, and the respect for the moral status of the embryo may be significantly undermined by commercial motive introduced into donation or solicitation of foetal tissue for research purposes.
    c) referral of any research proposal involving the use of foetal materials to a research ethics committee or institutional review board.

2. Much of the debate on the research involving embryonic stem (ES) cells revolves around the moral status of the human embryo, and the level of respect and protection that should be accorded. This is an especially sensitive issue in pluralistic society like Singapore, where different cultural and religious groups may have very contrasting views. The position taken by the BAC parallels the Human Fertilisation and Embryology Act 1990 of UK; the embryo is recognised as a potential rather than a full human being, where the potential benefits of the proposed research can be weighed against the respect due to the embryo. We believe that the key issue here is the public acceptability of such a position, and we are confident that an public policy on stem cell research can be achieved based on widely shared values in our society, carefully weighing the benefits of stem cell research against the need to protect human life. We support therefore the BAC's view that:
    a) the eventual guidelines will need to take into account as wide as possible a spectrum of views and opinion from the community, especially those with medical, religious, scientific, ethical and legal interests.
    b) the need for careful regulation of the proposed research, laying down clearly guiding principles and limits for the research.

3. In our opinion, one contentious issue that the consultation paper did not touch on, as far as the derivation of ES cells is concerned, is the intent involved in producing the embryos. It is the intention to create a child that makes the creation of an embryo a morally justifiable act. Deliberately creating embryos that are disconnected from human relationships takes them out of context and demands for stronger justification than the acquisition of potentially important information. To create embryos solely and with the pre-meditated intention for research seems to cheapen the act of procreation and turn embryos into commodities. Some observers in US have also warned that it can put women at risk as sources for ova for projects that provide them with no benefit. A clear distinction can and should therefore be made between

research using ES cells derived from spare embryos in fertility treatment and research using ES cells created specifically for research. In our opinion, the former is permissible and should be allowed, as long as measures reflecting principles of research ethics are in place, including:

a) clear separation exists between the decision to create embryos for fertility treatment and that to donate the human embryos in excess of clinical need for research purposes
b) physician for fertility treatment should have no financial or professional stake in the proposed ES cell research
c) assurance of voluntariness and absence of inducement, monetary or otherwise
d) informed consent is obtained to the extent permissible
e) individuals undergoing fertility treatment should be approached for consent for donation of human embryos only at the time of deciding the disposition of embryos in excess of the clinical need.
f) directed donation of the embryos must be prohibited

The Jones Institute for Reproductive Medicine in Virginia, USA, created uproar in July 2001 when they published a study in the journal *Fertility and Sterility* using ES cells derived from eggs and sperms created and donated specifically for research. To compound the issue, the 12 egg donors were paid US$1500 to 2000 each, and the sperm donors US$50 each. Ironically, as no federal funds were used, no laws or regulations were violated as the US guidelines are restricted only to federally funded research, though privately funded research is urged to voluntarily comply with the safeguards and standards proposed by the US National Bioethics Advisory Committee, which opposes derivation or use of human ES cells from embryos made solely for research purposes. In our opinion, allowing the making embryos for research will lead to embryos being treated as products or as mere objects, risk commercializing procreation, and trivialize the act of procreation. We totally agree with George Annas when he wrote in an article in *New England Journal of Medicine* in 1996 that:

> *" It is society's moral attitude toward procreation and the interests of those whose gametes are involved in making the embryos that provide the moral force behind the restriction or prohibition of the manufacture of embryos for non-procreative uses. A moral framework that reduces the matter to an exclusive focus on the intrinsic properties of embryos, ignoring the interests of those whose gametes make the embryos and the circumstances under which procreation occurs, cannot persuade, or even engage, those to whom the creation of embryos solely for research is morally suspect. Obtaining consent is not enough. A new framework — one that takes relationships seriously — is essential."*

We are not sure if this concern of ours is adequately covered, or at all, by any of our existing regulation or guidelines. If none of the existing local regulations or legislation deal specifically with this, the SMA hopes that this feedback to the BAC would receive due consideration and that explicit and clear directions can be set.

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26 November 2001

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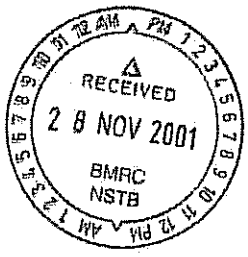
Our Ref:
SMC 14.2
Your Ref:

27 Nov 2001



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Dear Prof Lim Pin,

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

1. I refer to your letter of 8 November 2001.

2. The Singapore Medical Council (SMC) supports in principle the overall approach of the Bioethics Advisory Committee (BAC) as stated in the consultation paper.

3. As Singapore is a multiracial, multicultural and multi-religious society, it is important that social issues in human stem cell research are accorded equal standing with ethical and legal issues.

4. Many religious bodies in Singapore believe that life begins at conception. While we foresee no fundamental ethical objections to research using adult stem cells ('AS cells'), the use of embryonic germ cells derived from aborted foetuses ('EG cells') and especially embryonic stem cells derived from early embryos ('ES cells'), even if they are not more than 14 days old, will require further deliberation by the BAC after the inputs from the various religious bodies in Singapore have been obtained.

5. The SMC supports the UK legislation and controls on embryo research which provides a degree of protection in law while allowing the benefits of any proposed research to be weighed against the respect due to the human embryo.

6. The SMC shares the views of the BAC that reproductive cloning of human beings should not be permitted while human 'therapeutic cloning', should be conducted under strict guidelines and supervision to block any potential of creating a human embryo for reproductive cloning.

7. Although the paper has not commented on experiments on animal reproductive cloning, we feel that such experiments should be permitted for scientific purposes. It is conceivable that in the future, experiments on animal stem cells may throw light on human stem cell behaviour. The BAC is encouraged to address this issue at the outset to avoid any ambiguity in the future.

8. There is a need for Singapore to establish a system to ensure that the guidelines for stem cell research are strictly adhered to by the researchers. This may involve the setting up of a body at a national level as an oversight committee, backed by legislation that provides for stiff penalties for breaching rules governing such research.

9. The public policy balance between the opportunities that biomedical science offers to improve human welfare and the limits set by important ethical obligations will need to be regularly reviewed and redefined, where necessary, to take into account the impact of new scientific discoveries in the area of human stem cell research and changes in societal and religious mores.

10. In conclusion, I would like to thank you for inviting the SMC to share its views with the BAC on this very important issue.

Yours sincerely,

Lee Suan Yew

DR LEE SUAN YEW
PRESIDENT
SINGAPORE MEDICAL COUNCIL

SINGAPORE NURSES ASSOCIATION
新 加 坡 护 士 协 会
PATRON: The First Lady of the Republic of Singapore

27 December 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof Lim

The Singapore Nurses Association is pleased to be invited to give our feedback regarding Human Stem Cell Research in Singapore.

Biomedical research and development thus far has demonstrated immense potential to alleviate suffering and improve the quality of life for many with once incurable conditions. However, the threat of misuse of knowledge is real and it is wise to have in place preventive measures in the first instance. The setting up of Bioethics Advisory Committee (BAC) is indeed timely.

Nurses who have cared for couples in the fertility programmes or nursed severely premature babies in the Neonatal Intensive Care Units can particularly identify with the fragile, yet surprisingly resilient, beginnings of life. It was comforting to note that the BAC had taken much pain to give the relevant information, which addresses very real ethical and social concerns of human research.

Having some understanding of the biological properties of the human stem cells through the nursing curriculum enables nurses to understand their miraculous ability to proliferate and develop into specialised cell types. The discovery of using stem cells for new therapies, pharmaceutical development and human developmental biology holds great treatment possibilities. These new developments are especially attractive when seen in the light of the vast clinical application. The rewarding joy of being able to nurse a terminally ill patient back to health would always be a wonderful experience. It would make all the difference for the many families involved.

The consultative approach adopted by BAC to seek the views of the representative groups in the preparation of final recommendations to the Cabinet is commendable. As nurses are in direct involvement with patients and their significant others, it is very much appreciated that our views be sought in this issue. Many patients are able to confide their fears and apprehension, in the nurses caring for them. Often, we share our patients', and that of their loved ones' eager anticipation of a breakthrough which could bring hope of new cures for their debilitating and fatal illnesses. While we are members of the medical team, it is important we are able to maintain an objective perspective of contentious experimental treatment modalities.

SNA HOUSE, 77 MAUDE ROAD, SINGAPORE 208353. TEL: 3920770 FAX: 3927877
EMAIL: sna@pacific.net.sg WEBSITE: www.sna.org.sg

SINGAPORE NURSES ASSOCIATION
新 加 坡 护 士 协 会
PATRON: The First Lady of the Republic of Singapore

The Singapore Nurses Association is confident that the BAC would continually monitor adherence to the stated recommendations and guidelines. We would appreciate if we could be kept in the loop with publications of independent review of studies, where appropriate.

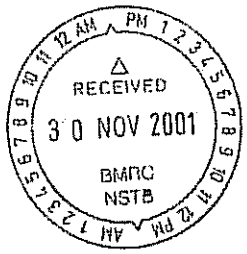
Thank you.

Tan Wee King
Hon Secretary
Singapore Nurses Association

SNA HOUSE, 77 MAUDE ROAD, SINGAPORE 208353. TEL: 3920770 FAX: 3927877
EMAIL: sna@pacific.net.sg WEBSITE: www.sna.org.sg

SINGAPORE NURSING BOARD

29 Nov 2001



Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

Thank you for inviting the Singapore Nursing Board to provide feedback regarding human stem cell research in Singapore.

The Board is of the view that research with AS cells and with EG cells if the decision to abort is taken separately and independently from the decision and consent to extract EG cells, would be ethically acceptable. In Singapore's society where abortions are performed on socio-economic grounds, the issue of using early embryos not more than 14 days old for serious research to benefit others, does not appear to be so ethically contentious.

We agree that reproductive cloning can be exploited and hence should be forbidden

We would like to make a few suggestions to the paper:

(1) Para 1, page 2 – ".... and adult stem cells derive from tissues such as the bone marrow, umbilical cord blood and brain..."

Perhaps placenta could be included.

Level 4, Institute of Health, 3 Second Hospital Avenue, Singapore 168937 Tel: 2361996 Fax: 2361998

(2) Under the heading "Ethical and Social Considerations"

It may be necessary to include a statement specifying that any information that could lead to the identification of donors of foetal tissue must be removed prior to the derivation or use of ES or EG cells.

We would like to commend the BAC for this succinct and well-written paper.

Yours sincerely

ANG BENG CHOO
REGISTRAR

D. SCIENTIST/RESEARCHER GROUPS

1. Biomedical Engineering Society (Singapore)
2. Science Teachers Association of Singapore
3. Singapore National Academy of Science
4. Singapore Society for Biochemical and Molecular Biology

Biomedical Engineering Society (Singapore)
c/o Orthopaedic Diagnostic Centre, National University Hospital
Lower Kent Ridge Road, Singapore 119074
Tel: 772 4424 Fax: 774 4082
Email : secretary@bes.org.sg http://www.bes.org.sg

28 November 2001

Prof. Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Prof. Lim

FEEDBACK ON HUMAN STEM CELL RESEARCH IN SINGAPORE

Thank you very much for your letter dated 8 November 2001 seeking feedback from the Biomedical Engineering Society (BES) on your Committee's current views on human stem cell research in Singapore.

The Executive Committee of BES deliberated on the consultation paper prepared by your Human Stem Cell Research Subcommittee (HSR) recently. We are in full agreement with the views expressed in the paper. We believe that they represent the best compromise between ethical concerns and the advancement of scientific research for the benefits of mankind.

Concerning your view that there must be a well-established and effective framework for the control of research involving embryos in Singapore, we would like to add further that a Registration of Researchers in this area be set up to regulate the practice of research. This can be established along the same line as that for medical doctors, professional engineers and architects, etc.

If your Committee needs further help from BES, we would be most happy to oblige.

Yours Sincerely

Prof. Chew Yong Tian
President
Biomedical Engineering Society (Singapore)

Reply to BAC from Science Teachers Association of Singapore

(STAS)

Catherine
WOON/MOE/SINGOV

12-12-01 06:56 PM

To:
cc:
Subject: Re: Request for Feedback regarding human stem cell research in Singapore -please reply by 27 November 2001

----- Forwarded by Catherine WOON/MOE/SINGOV on 12-12-01 07:02 PM -----

Catherine
WOON/MOE/SINGOV

26-11-01 09:15 PM

To: "Subramaniam s/o RAMANATHAN (STE)" <subrar@nie.edu.sg>@SMTP
cc: <chew@sci-ctr.edu.sg@SMTP,>
Subject: Re: Request for Feedback regarding human stem cell research in Singapore -please reply by 27 November 2001

Dr Subra and Dr Chew

I am pleased to give my views on this :

I strongly agree that there must be strict control of research involving embryos in Singapore and thus "therapeutic cloning" should only be permitted under strict conditions, only for the purpose of controlling diseases. There should be watch-dog for monitoring such research at all times. If strict control is not possible, then such research should not be carried out.

Human embryos of less than 14 days old (ES cells) created through in-vitro fertilisation techniques but not used in assisted reproduction treatments can be used for research under stringent guidelines and monitoring, again for the sole purpose of curing diseases.

I do not agree with the 1990 Act (UK) which allows the creation and use of human embryos up to 14 days old for research purposes as this, to me, goes against the natural law of procreation. Any embryo to be used for research should only come from the consent of the individual donors.

Research using AS cells should not present any ethical objections. For EG cells, I agree that no ethical issues arise from the use of such cells, so long as the decision taken to abort is taken separately and independently from the decision and consent to extract the EG cells from the foetus.

The objectives of human stem cell research must be defined very clearly to protect human life and also to prevent abuse of embryos before such research is allowed. Researchers should also be subject to the law if infringements to the stipulated guidelines drawn up are not followed.

"Subramaniam s/o RAMANATHAN (STE)" <subrar@nie.edu.sg>

"Subramaniam s/o RAMANATHAN (STE)" <subrar@nie.edu.sg>

20-11-01 03:38 PM

To: "Carmee Lim (E-mail)" <carmee@singapore.com>, Catherine WOON/MOE/SINGOV@SINGOV, "Chew Tuan Chiong (E-mail)" <chew@sci-ctr.edu.sg>, "Ohla Woon Kim (E-mail)" <woonkim@cbn.com.sg>, George GOH/MOE/SINGOV@SINGOV, "Heng Chye Kiou (E-mail)" <chyekiou@vicom.com.sg>, "Koh Lip Lin (E-mail)" <liplin@pacific.net.sg>, "LEE Peng Yee (MME)" <pylee@nie.edu.sg>, "TAN Wee Hin Leo (Director - NIE)" <whltan@nie.edu.sg>, Chye Tin LIM/MOE/SINGOV@SINGOV, "Ng Kok Lip (E-mail)" <nkl@pacific.net.sg>, Yap Kwang TAN/MOE/SINGOV@SINGOV, "Tham Seong Chee (E-mail)" <sctham@pacific.net.sg>
cc:
Subject: Request for Feedback regarding human stem cell research in Singapore -please reply by 27 November 2001

Dear Members,

Our Association has been approached by Prof Lim Pin, Chairman of the Bioethics Advisory Committee, for comments on "Human stem cell research in Singapore". A postion paper on this is enclosed for information.

We need to reply by the end of this month. Thus, we would appreciate it if you could scrutinise the enclosed paper and let us have your feedback by 27 November 2001. This would allow us some time to consolidate your inputs before reverting to the Bioethics Advisory Committee.

Responses can be sent to Dr Chew.

Thank you for your assistance.

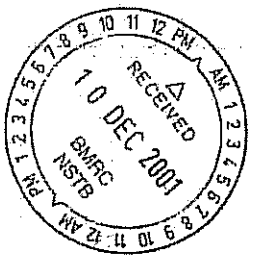
Best wishes.
Subra

BAC.HSR. ConsultationPaper.Nov

SINGAPORE NATIONAL ACADEMY OF SCIENCE
c/o Singapore Science Centre
15 Science Centre Road
Singapore 609081
Tel : (65) 425 2500
Fax : (65) 565 9533

3 Dec 2001

Professor Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101



Dear Professor Lim

REQUEST FOR FEEDBACK REGARDING HUMAN STEM CELL RESEARCH IN SINGAPORE

Thank you for your letter of 12 Nov.

We have solicited feedback on the contents of the consultation paper in relation to the above from our members, and summarize herewith the comments received.

We feel that the Bioethical Advisory Committee (BAC) has taken a moderate stand with regards to the control and supervision of research on stem cells. This is a good move since any additional unnecessary imposition of restrictions compared to the existing standards elsewhere will dampen the research interest in this potential field in Singapore. As existing standards already cover the ethical issues on both adult stem (AS) cells and embryonic germ (EG) and embryonic stem (ES) cells, the committee has correctly decided not to impose special restrictions nor ethical objections to such research, provided the use of embryos is less than 14 days old as stipulated in the UK guidelines. We should also support the need for the additional mechanisms in which the BAC can review existing guidelines and policies on stem cell research on a regular basis.

Notwithstanding the foregoing, it is necessary that there be strict control of research involving embryos in Singapore, and thus "therapeutic cloning" should only be permitted under strict conditions, only for the purpose of controlling diseases. There should be a watchdog for monitoring such research at all times. If strict control is not possible, then such research should not be carried out as ethical issues will then need to be addressed.

to abort is taken separately and independently from the decision and consent to extract the EG cells from the foetus.

The objectives of human stem cell research must be defined very clearly to protect human life and also to prevent abuse of embryos before such research is allowed. Researchers should also be subject to the law if infringements to the stipulated guidelines drawn up are not followed.

Thank you and best wishes.

Yours sincerely

Professor Leo Tan Wee Hin
President

SINGAPORE SOCIETY FOR BIOCHEMISTRY
AND MOLECULAR BIOLOGY
C/O DEPARTMENT OF BIOCHEMISTRY, NATIONAL UNIVERSITY OF SINGAPORE
10 KENT RIDGE CRESCENT, SINGAPORE ~~0511~~ 119260
FAX: (65) 7791453

December 3, 2001

Professor Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101.

Dear Professor Lim,

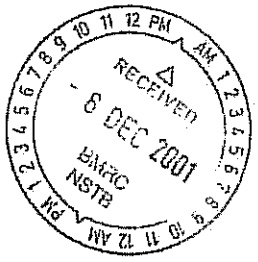
Thank you for your invitation to give our views on the BAC's consultation paper on human stem cell research. I am sorry that this reply is late.

The Council members of the Singapore Society for Biochemistry and Molecular Biology considered the document carefully. We agree with all the views expressed and believe strongly that there should be control of research involving embryos. We are concerned that the mechanisms that are put in place should be rigorous and seen to be rigorous. Because the scientific community in Singapore is very small, care must be taken such that there should not be any conflict of interests arising from membership of the appropriate governmental oversight committees which will be tasked to monitor that such research is adhering to ethical guidelines and standards.

Yours sincerely,

Hoon Eng

Dr. Khoo Hoon Eng
President
Singapore Society for Biochemistry and Molecular Biology
C/o Department of Biochemistry, Faculty of Medicine
National University of Singapore
10 Kent Ridge Crescent
Singapore 119260.



E. OTHER

1. Personal View from a Member, Inter-Religious Organisation (IRO)

INTER-RELIGIOUS ORGANISATION, SINGAPORE
(Established 1949)
Registered Address: 132 A Changi Road, Singapore 419719
Mailing Address: Raffles City P O Box 712, Singapore 911724

HINDU JEWISH ZOROASTRIAN BUDDHIST TAOIST CHRISTIAN MUSLIM SIKH BAHA'I

Tel: 383 3752, Fax 383 3753 HP 9697 9625

30 Nov 2001

Prof Lim Pin
Chairman
Bioethics Advisory Committee
250 North Bridge Road
#15-01/02 Raffles City Tower
Singapore 179101

Dear Sir

I am to refer to your letter of 8 November 2001 addressed to our President requesting feedback regarding human stem cell research in Singapore.

Attached hereto is the personal view of [redacted] an IRO Council Member, Address: [redacted] on the subject for your Committee's consideration.

Yours sincerely

HARBANS SINGH PS
Secretary

IRO2001.BACReturn

To: P Harbans Singh

Council Feedback (BAC Request)

This is my individual view not my faith's view.

(1) The problem arises with one of the 10 commandments. "Thou shalt not kill." To Christians this means human beings although an exception is made for war.

(2) A woman should not kill an unborn child since it is a separate human individual.

(3) When does a separate individual arrive? At conception or much later. I would say much later.

(4) Early embryos have no neural streak or presumably no sensation. It is therefore allowable to use the stem cells for research especially to alleviate human suffering.

(5) Such cells must be disposed of before 14 days old.

(sd) [redacted] 21/11/2001

CSGB2001.BAC(2)[redacted]

Please note that the identity of the writer has been removed in the interest of privacy.