SUBMISSION

on the

PROHIBITION OF HUMAN CLONING BILL 2002

and the

RESEARCH INVOLVING EMBRYOS BILL 2002

to the

SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Parliament House, Canberra ACT 2600

Phone: 02 6277 3515 Fax: 02 6277 5829

Email: community.affairs.sen@aph.gov.au

by

FESTIVAL OF LIGHT

4th Floor, 68 Grenfell Street

ADELAIDE SA 5000

Phone: 08 8223 6383 Email: office@fol.org.au

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Introduction

The Research involving embryos and prohibition of human cloning bill 2002 has now been split into two parts.

The **Prohibition of Human Cloning Bill 2002** has been passed unanimously, without amendment, in the House of Representatives on 29 August. It is clear that there is overwhelming support, in parliament and the community, for a complete ban on all forms of human cloning.

However questions have been raised about the wording of this bill, and whether it would stand up in a court of law.

The drafting of the second bill, the **Research Involving Embryos Bill 2002**, has been the subject of much deeper controversy. There are doubts whether its wording is adequate to provide the strict controls on human embryo research which all parliamentarians would want.

However there is a much more serious flaw - the bill would allow destructive experiments on embryonic human beings, thereby breaching a moral line which no Australian parliament should cross.

The Prohibition of Human Cloning Bill

This bill received unanimous endorsement by the House of Representatives on 29 August 2002. We too wholeheartedly endorse the bill's aim of prohibiting all forms of human cloning, including creating or developing a human embryo containing the genetic material provided by more than two persons.

The cloning prohibition is needed in order to uphold the principle of the sanctity of human life and the unique identity of every human person.

However we believe this bill needs some amendment. The focus of public debate has been on the controversial Research Involving Human Embryos Bill, and little attention has been given to the wording of clause 7 - *Definitions*. The definition of terms such as "human embryo" is crucial - inadequate wording could render the entire legislation ineffective.

The Andrews Report released in 2001 [House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human cloning: scientific, ethical and regulatory aspects of human cloning and stem cell research*, August 2001] noted that three Australian states (Victoria, SA and WA) have laws which limit research on human embryos, but definitions vary - so that the *somatic cell nuclear transfer* ("Dolly the sheep") method of cloning humans is prohibited only in South Australia.

The UK parliament approved regulations banning human cloning for reproductive purposes in January 2001. However in November 2001 the English High Court found those regulations to be defective because they defined embryos as being created by the fusion of sperm and eggs, and therefore did not cover embryos cloned by the somatic cell nuclear transfer method.

Clause 7, line 23, defines "human embryo" as a "live embryo that has a human genome or an altered human genome...", but nowhere is the term "embryo" defined, so the definition of "human embryo" is inadequate. Biotechnology firms could attempt to bypass the legislation by arguing that their experiments on human embryos were not really on "embryos". Since "embryo" is not defined in the bill, they could devise their own definition of "embryo" and claim that what they were using was not this definition.

There are similar problems with definitions of "hybrid embryo", which again does not define the term "embryo". Moreover it is not good enough to say, as in clause 7, page 5, line 10: "(e) a thing declared by the regulations to be a hybrid embryo". The legislation itself should broad enough to cover any permutation or combination of human/animal gene manipulation which could constitute an embryo. Implementing regulations at a later stage may be too late.

We are not qualified to suggest the optimum wording for definitions of terms like "embryo",

but recommend that the Committee consult experts such as Melbourne bio-ethicist Dr Nicholas Tonti-Filippini, who has had considerable experience in this field.

The Research Involving Embryos Bill 2002

This bill, like the first, fails to define the term "embryo" in clause 7 - see comments above.

Almost all MPs would support one aim of this legislation - to provide effective controls on human embryo research - but would this aim be achieved?

Senator Boswell has pointed out that there are considerable vested interests in this area. The editorial in *The Australian* (5/8/02, p 12) pointed out that "Dr Trounson's group will get $46.5 million in handouts for research that offers a potential bonanza for him and his peers."

With the possibility of enormous profits from illegal experiments on human embryos, the parliament must make every effort to get the wording right to ensure effective prohibition of research abuse.

The bill relies on ethical guidelines for research developed by the Australian Health Ethics Committee (AHEC). These guidelines are currently under review. There is no certainty about what future AHEC guidelines will contain. The bill itself should include the ethical guidelines under which licences will operate. Moreover the bill does not attempt to prohibit profiteering from patents on human genetic material - it should be amended to prevent what could become a type of human slave market.

The bill wrongly uses the term "excess ART embryo"

Clause 24 of the bill defines "excess ART embryo" to mean "a human embryo that ...(b) is excess to the needs of (i) the woman for whom it was created; and (ii) her spouse (if any) at the time the embryo was created."

Clause 24 also defines "excess" to refer to the situation where each spouse has "given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or (b) each such person has determined in writing that the embryo is in excess to their needs, and the determination is in force at that time."

The bill thereby makes the unwarranted assumption that if an embryo is no longer wanted for implantation by the woman and man for whom it was created, then the embryo would not be wanted for implantation in another, adoptive mother and thus would be available for experiments as if it were a laboratory rat.

The same sorts of arguments were used by Nazi scientists in World War II. Jews and other inmates of concentration camps, they argued, would soon die anyway and using them for experiments would help mankind generally. This "logic" was firmly repudiated by the rest of the horrified world. Have we forgotten?

Human embryos which are no longer wanted by their natural parents may very likely be wanted for adoption by other infertile couples. We do not allow scientists to experiment on born children whose parents no longer want them - rather, we place those children with couples who can give them the care they need. Human embryos deserve the same care.

Mrs Marlene Strege of California, in a letter published in *Festival Focus* (September 2002, p 3) said:

> *I have been reading everything that is going on in Australia regarding embryo stem cell research.*
>
> *We adopted our daughter as a frozen embryo through the Snowflake Embryo Adoption program (www.snowflakes.org). It is one of three adoption programs of Nightlight Christian Adoptions, Fullerton, California.*

I was able to give birth to Hannah, who is now 3 years old. To date 19 children have been born through this program to their adoptive parents and many more are on the way across the US.

Infertility is a medical diagnosis affecting 6.5 to 10 million couples in the US. My family spoke before a congressional subcommittee hearing last year on the option of adoption vs destruction for those embryos who are "in excess of clinical need". Actually there is not an excess when you consider there are more couples suffering from infertility than embryos likely to survive thawing.

I believe there are something like 70,000 children in your country who may be killed for their stem cells. They need to be placed for adoption instead. Any woman can carry any embryo - tissue and blood matching is not necessary. The adoptive family completes all the requirements for adoption in their state, just as they would for any other adoption including a home study. The genetic family then chooses the adoptive family they want to place their children with.

Australia does not have any ART embryos who could be considered "excess" to the needs of both their natural parents and would-be adoptive parents. The bill should therefore prohibit any kind of destructive experiments on these tiny humans.

Human life begins at fertilisation

Some people - and even the Anglican Primate, Archbishop Carnley of Perth - have argued that human embryos are not really "human" until they are 14 days old, and can therefore be considered sub-human (like laboratory rats) before this period in their development. However such an argument does not stand up to scrutiny.

Archbishop Barry Hickey, in a letter published in *The Record*, Perth, on 12/9/02 said (in part):

Archbishop Peter Carnley's attempt (Bulletin, 3/9/02) to justify treating the human embryo as not really human in its first 14 days simply does not stand up scientifically or logically. Nor should his views be taken to be representative of Christian leaders in Australia.

Archbishop Carnley has wanted to establish his thesis for some time, but unfortunately each time he attempts it he leads himself into difficult logical waters.

This is clear from his attack on Deputy PM John Anderson's acceptance of the establishment of a unique DNA structure at the moment of fertilisation as the beginning of a human life which, if all goes well, will follow the pattern of that DNA structure to full human development.

Dr Carnley says: "It seems incontrovertible that at the time of fertilisation of an ovum by a sperm a new and living cell comes into being, with its own unique DNA composition." He then goes on to try to reduce the significance of this by saying, "After all, a unique DNA profile will be found in cells produced by a swab of the inner mouth."

Unfortunately he has missed the point. The cells taken from the mouth or any other part of the body do not have a DNA structure unique to each one. They share a DNA structure which is <u>common</u> to all of them but which is <u>unique</u> to the person whose DNA structure was established at the time of fertilisation.

The DNA structure is unique to each person, not to each cell. The only exception is the very first cell created by fertilisation when the uniqueness of the person is present only in a single cell. From that point on, as cell division occurs, the DNA structure remains unique to the person but is common to all of the cells that will ever be produced by that person whatever his term of life.

It is therefore scientifically and rationally appropriate to say that life begins at the moment of fertilisation. Standard texts on embryology confirm this.

It is not scientifically or rationally appropriate to say that this living organism must carry out a certain amount of its unique development before it can be said to be an individual life.

The reality is that long before implantation in the womb, scientists can tell us whether the embryonic person is male or female, whether it has certain health conditions, and a great variety of other information individual to each embryo.

To say that life does not exist or something other than human development is taking place in the first 14 days is to contradict all that modern science has learned about the earliest stages of our development. Moreover, IVF researchers, such as Dr Trounson, confirm that any point other than fertilisation is totally arbitrary as a "marker" for establishing when human life begins.

If twinning is to occur in a particular case, so be it, but it is not rational to say that because an embryo can divide and create a new human being, it is somehow not human until the division takes place (or does not take place). Only a living, developing human embryo can divide to make twins.

An embryo is human life in its earliest stages of development and it deserves the respect and protection due to all human life.

We as a nation cannot allow ourselves to compound the original error by treating these tiny lives as "surplus" and therefore available for destruction or other forms of experimentation.

If we decide that we as adults are so important that we can use or destroy other human lives on the chance (or even the certainty) that we will benefit from their death, then at the core of our society we have granted ourselves the right to take life for whatever purpose we consider appropriate. The only remaining argument will be whether Parliament at any particular time will approve one particular purpose or another, and respect for life will have become a subjective matter dependent on the numbers at the time.

NHMRC Licensing Committee - ethics and community interests are a low priority

Professor Alan Trounson could be said to be the leading advocate for the Research Involving Embryos Bill. Recent revelations about his misrepresentation of the efficacy of embryonic stem cell research and as well as the extent of his vested interest in this research suggest that his ethics in this area may not be above reproach:

Festival Focus (September 2002, p 2) reported (in part):

The ABC TV 7.30 Report (29/8/02) showed a film clip of Professor Trounson in the office of SA federal MP Mrs Chris Gallus, demonstrating a video of a paralysed rat. Professor Trounson claimed the rat had been cured after being injected with human embryo stem cells.

However this claim was later shown to be false. The rat had been injected with germ cells from a foetus, not stem cells from an embryo. It had not been cured - its condition had merely improved.

Professor Trounson, who has received a $46 million government research grant, also misrepresented his financial interest in ES Cell International, a firm doing embryo stem cell research (The Australian, 31/8/02 p 6; 2/9/02, p 3). Senator Ron Boswell (Nat, Qld) said Trounson had told MPs he had divested himself of all relevant shares, but records showed he still had a considerable financial interest in stem cell research.

Dr David van Gend of Toowoomba said Professor Trounson had also falsely suggested that embryonic stem (ES) cells had cured rats with Parkinson's and mice with diabetes.

Trounson had told MPs that diabetic mice had improved following treatment with ES cells, but omitted the fact that improvement was minimal and all the mice had soon died. He also failed to tell MPs that diabetic mice treated with adult stem cells in June this year

had a magnificent improvement, returning to normal insulin levels.

Trounson failed to tell MPs about a recent study on rats with Parkinson's who were treated with ES cells. The cells gave only partial relief to only some of the rats, and 20% died from brain tumours caused by the ES cells.

Many MPs who supported the embryo bill said they did so because of the great potential for embryo stem cell cures for diseases. They were apparently unaware that ES cells have not cured any illness, whereas adult stem cells, which have no ethical problems, have been highly successful.

These reports of Professor Trounson's behaviour are disturbing, because of Clause 31 of the bill which sets out the attributes of the nine members of the NHMRC Licensing Committee. Most of these positions could be filled by someone like Professor Trounson or an advocate for his research, eg:

(c) a person with expertise in a relevant area of research; or

(d) a person with expertise in assisted reproductive technology; or

(e) a person with expertise in a relevant area of law; or

(g) a person with expertise in consumer issues relating to assisted reproductive technology; or

(h) a person with expertise in embryology.

None of these positions represents the interests of the general community, and this imbalance should be redressed. A representative of the major Australian churches, for example, would be a step in the right direction.

The bill does not give high priority to ethical considerations - which the NHMRC is required only to "have regard to" (clause 36 (4) (c) and (d)). Moreover ethics committees (HRECs) of research institutions are not required to have members with any training in ethics: in at least one institution that we know of, the HREC includes people without any special ethics expertise who have simply volunteered for the job. Yet even Adolf Hitler and Joseph Stalin would have claimed to be ethical!

The Licensing Committee, as it is constituted under the bill, has the potential to become a rubber stamp for human embryo research industry advocates, to the possible detriment of the rest of the community.

The bill does not require parents of embryos to be fully informed

The bill requires that the parents of the so-called "excess" ART embryo give written consent for the embryo to be used for experimentation, but does not require the parents to be fully informed beforehand about the nature of the experiments to be undertaken.

This is a serious omission, especially since stem cells from the couple's so-called "excess" embryos could be exported overseas quite legally under the bill, and once overseas (say in Bangladesh, where there are no controls), anything at all could be done to those stem cells. It is possible they could be ultimately used to produce human clones - even though this research would be illegal in Australia.

Evidence given by NHMRC consultant Andrea Matthews to the Senate Community Affairs Legislation Committee on 29 August 2002 said that under the bill, "yes, the embryonic stem cells could be sent overseas."

Later that afternoon, Dr Clive Morris of the NHMRC told the Senate Committee that licences by the bill's NHMRC Licensing Committee would only apply to research undertaken in Australia - once stem cells from an "excess" embryo were exported to another country, the laws (however inadequate) of that other country would apply.

The natural parents may well refuse consent for their embryos to be used for research if they knew of this possibility. Couples on IVF who have been quoted in the media as being willing for their "excess" embryos to be used for research said they did so because they wanted to help cure

diseases like Alzheimers. However it is far more likely that their embryos, if released, would be used for such things as pharmaceutical testing. The bill should not allow such couples to be misled.

Commercial considerations

There is potentially a lot of money in human embryo research - most of it probably not in the area of ES cell "cures" for disease, but in other areas such as drug screening. Yet as Dr Morris told the Senate Committee on 29 August, "issues of IP (intellectual property; patenting) and commercialisation are not covered in this bill." The drafters were given no instructions to cover this vital area, so that there are no safeguards against human embryos being used for commercial profit, without the knowledge or consent of the parents. This is a glaring omission which should be urgently rectified.

The bill would allow export of human embryonic material to countries without controls

As mentioned earlier, the bill has no restrictions on the export of the products of research of human embryo experimentation such as stem cells and stem cell lines. This loophole should be firmly closed.

The bill should not over-ride state laws which protect the embryo

It is not clear that the Commonwealth Constitution provides the head of power for the Research Involving Human Embryos Bill 2002. There is no international treaty which could be called upon under sec 51 (xxix) (external affairs) of the Constitution, cited in clause 4 of the bill, which would authorise destructive research on human embryos.

On the contrary - the Preamble of the International Convention on the Rights of the Child protects the child both before and after birth. We believe that sovereign states have the right and power to enact and enforce their own legislation to protect the right to life of the human embryo in line with this international treaty which Australia ratified in December1990.

Nevertheless, as Andrea Matthews told the Senate Committee on 29/8/02, "The intent of clause 56 and our advice from the Australian Government Solicitor about the effect of clause 56 is that, yes, to the extent of the Commonwealth constitutional powers, that would override existing state laws that ban uses of excess ART embryos that damage or destroy the embryo."

This advice from the Australian Government Solicitor could be challenged - but even if it is ultimately confirmed, we submit that state governments should be allowed to give their human embryos greater safeguards than those provided by this bill. The South Australian *Reproductive Technology Act 1988* should be allowed to stand - and it provides some excellent starting points for amending of the Commonwealth *Research Involving Embryos Bill 2002*.

Clause 56 of the Research Involving Embryos Bill should be amended so that it does not over-ride state laws which have stricter provisions safeguarding human embryos. Clause 56 should be worded to the effect that: "This Act does not over-ride the operation of any state law which protects the human embryo from destructive experimentation."

The primary concern

Our primary concern, and that of the many people who have contacted us, is that the Research Involving Embryos Bill treats human embryos as less than human, by allowing them to be subject to destructive experimentation. The bill should be amended so that it, like the SA Reproductive Technology Act 1988, safeguards human dignity at all stages of life, including those at which the human is most vulnerable.

We quote here the editorial of *Festival Focus*, September 2002:

Humans are not laboratory rats

The Research Involving Embryos and Human Cloning Bill (see p 1) has created more controversy - and more real debate - than almost any other piece of legislation in federal parliament.

The bill, now split in two, has been referred to the Senate Community Affairs Legislation Committee. The first public hearing was on 29 August and the atmosphere was tense. Three people who had helped draft the bill gave evidence, but they did not have satisfactory answers to all the senators' questions.

The bill to outlaw human cloning passed the House of Representatives unanimously - but the bill does not adequately define a human embryo, so may ultimately prove unworkable in a court of law.

The other bill is supposed to ensure that strict controls will be enforced in the area of human embryo research. However this bill, too, has disturbing loopholes. In addition, allegations of deception by Professor Trounson, one of the bill's strongest supporters, raise serious concerns.

For the bill is not about experiments on laboratory rats. The bill would allow destructive experiments - "tinkering" - with tiny human beings. We are talking about patenting of forms of human life; about profiteering from the results of these human experiments. There is no prohibition on these practices in the embryo research bill.

Historically, scientists and doctors have universally recognised the sanctity of human life. Other animals can be used for research, but not humans. Nazi Germany crossed this moral line with its horrific experiments during World War II on Jews and other concentration camp victims. These people were deemed to be "sub-human" and "about to die anyway". The rest of the world reacted with revulsion. Have we forgotten so soon?

The "surplus" IVF embryos may be unwanted by their natural parents, but they are still real humans. The Prime Minister has claimed that they would "die anyway", but there is another option. The tiny embryos could be made available for adoption by some of Australia's many infertile married couples and be given the chance of a full and normal life.

Federal MPs speaking in support of embryo experiments made emotional claims about embryonic stem cells' potential to cure disease, ignoring the proven success of adult stem cells which have no ethical drawbacks or tumour potential.

The irony is that very few of the so-called "surplus" embryos would be used for stem cells. Most would be used to test the toxicity of drugs, in IVF experiments, and in research on chromosomes and genes. It is possible that human embryos could be used for bio-warfare - testing the effect of poisonous chemicals on different races.

Many Australians are unaware of the more sinister aspects of human embryo research. They have been mesmerised by misleading claims of miracle cures spread by people like Alan Trounson.

The House of Representatives debate is almost over, but Australians should be grateful that we also have a Senate - a house of review. We pray that our senators (12 from each state - see "Commonwealth Parliament Offices" in the White Pages) - will act to prevent any opening of this terrible Pandora's Box.

Conclusion

We strongly support the Prohibition of Human Cloning Bill, provided that it is amended to clearly define the term "embryo" as outlined above.

We strongly recommend major revision of the Research Involving Embryos Bill 2002, so that it provides full protection for human life from its beginning at conception onwards.