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Mr. E. Humphrey
Community Affairs Committee
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Dear Mr. Humphrey

Re Inquiry into legislative responses to the Lockhart Review

This submission consists of two parts;

1. A response to the Lockhart Review as released on December 19, 2005
2. A Response to the Patterson Bill on Human Cloning and Research involving Human Embryos.

SECTION I

THE LOCKHART REVIEW

Pursuant to their Terms of Reference, the Lockhart Committee tabled its report on December 19, 2005.

There was great community interest in the Review and the community was invited to participate. From the very beginning, there was concern that the terms of reference did not contain a section on the moral status of the embryo which in fact is the critical issue. The chairman quickly reassured the public that the committee was interested in this issue and it would be addressed.

The Report was released to the public on the deadline date and theoretically the Lockhart Committee ceased to exist. The report resulted in a public outburst against its contents and its recommendations. During the following year, a deep divide occurred in the community. The Lockhart

Committee did not mention the breakdown of the submissions other than in vague terms, but an independent analysis of the submissions by the organization **DO NO HARM** found that over 80% of them were against any change to the 2002 laws.

The Federal government, through its cabinet meeting, decided not to act on the report and the PM commissioned a second report from **mpconsulting** which can be downloaded from the website of the Prime Minister's Department.

This latter report commented repeatedly that many of the contentious recommendations of the Lockhart Committee were unsupported by evidence. To quote the mp consulting report: "The (Lockhart) Committee's considerations appeared to be based around the potential of SCNT for the treatment of illness and the Committee's own resolutions of the ethical issues.

There were considerable problems with the Lockhart Committee and its Report. On such a contentious issue as the use of ESCs for experimentation and possible clinical trials in humans, the structure of its membership was unbalanced and compromised. Three of its members were on the record of having been advocates of so-called therapeutic cloning well before their appointment to the committee. One, the deputy chair and spokesperson for the committee, had declared her support for creating embryos for therapeutic cloning when she addressed a Parliamentary Inquiry on the subject in 2000. Moreover she is an adviser and advocate for the leading cloning lobby group of the International Society for Stem Cell Research. She is a member of its Ethics Committee. Prof. Alan Trounson is a member of its Board and a signatory of a letter to the Australian Parliament, supporting the implementation of the Lockhart recommendations (August 15, 2006). See the ISSCR website. Two others, Scofield and Kerridge, both ethicists, were on the public record before being appointed to the Lockhart Committee for their support of research using cloned embryos. (Website of DO NO HARM)

Moreover some of its recommendations were based on inaccurate and dishonest data from the discredited South Korean scientist, Hwang Woo Suk. It is more than eight months since this fraud was made public but the surviving members of the Lockhart Committee have not acknowledged the significance of this fact.

Despite the reassurances given by the late chairman of the Review Committee, there is nothing in the report about their deliberations on the moral status of the embryo. There is merely a gratuitous statement about its non-value before the 14th day.

When it comes to Community Standards, the report is incoherent. There were 1035 submissions and the greater majority were against so called therapeutic cloning. There were nine petitions and only one supported therapeutic cloning. There were 378 signatories to this petition that drew heavily on the scientific community. The largest petition contained 624 signatories, all

against therapeutic cloning, based on their belief in the moral status of the embryo from the moment of formation of the zygote.

Moreover the Report did not mention the key survey on Australian attitudes conducted by researchers from Swinburne University of Technology in 2004 which revealed that the majority (63%) were not comfortable with scientists using cells created by cloning.

How these were all dismissed as inconsequential in measuring community standards is bewildering.

It is interesting that the Prime Minister commissioned another report from *mpconsulting*. This firm is a consultancy organization in Canberra that specialises in various fields of policy development, programme evaluation, regulatory measures and stakeholder consultation. They are consultants to many government and statutory bodies, including the NH&MRC. According to the report of Michelle Gratten and Annabel Stafford, *mpconsulting* stated ***“there is no scientific basis for watering down the law to allow therapeutic cloning.”*** There is plenty of evidence to support that advice but there is also a lot of misinformation about which stem cells are achieving the best and most promising results. Senator Patterson’s reported comment that the second report was unnecessary and Washer’s remark that it “almost smacked of cash for comment” were both disingenuous and almost libellous.

My impression of the Lockhart Report is that it has done our system of honest inquiry a grave disservice and it has added a new dimension to the issues that now confront our bioethicists – the power and behaviour of the lobby with a vested interest and the distortion of the virtue of compassion.

In the fields of Reproductive Technology and Biotechnology generally, the underlying ethical position of the scientists around the world is based on Utilitarianism.

A very successful tactic of the scientific community is to appeal through the media, to present victims with severe physical disabilities who plead for such research to continue as their last chance of any hope of recovery from their crippling handicaps, even though there is no scientific evidence that embryonic stem cells can achieve such an outcome. *Compassion* becomes the key to ethical behaviour and opposition to embryo experimentation becomes a mark of insensitivity to human suffering.

James V. Schall (a political analyst) has remarked that today’s ethical appeal to compassion as the focus of decision making is a feature of the modern corruption of the word *Justice*. This new concept is an extension of the demands for “social rights” that have penetrated into virtually all fields of human society so that if embryonic stem cells may improve my state of health, I have a right to have my wishes fulfilled by the justice system acting out of compassion for my

suffering. But surely the *virtue of justice* would extend to the human embryo, to a more fundamental right for it to exist and to grow and not to be treated as a material commodity for the good of others. This modern clamour for a host of human rights lends itself to a vague use of language, with no hierarchy of values that serve both the good of the individual and the common good of the community.

Science can add a great deal to our store of knowledge but it is not within the scope of its methodology to resolve ethical dilemmas, to determine or to assume how we should act ethically or morally. Moreover scientists can mislead the community by asserting as fact what are essentially “scientific myths” as set out in the paper of Dianne Irving in 1999.ⁱ

In commenting on scientific findings, scientists often make judgements and reach conclusions or recommendations that can be validly contested by non-scientists, especially when they reflect on issues such as human rights, the moral status of members of the human species, the manipulation of public opinion and the distribution of public funds for the dubious promise of an advancement in clinical medicine.

Value judgements reflect the basic beliefs and creed of an individual and these are not derived solely from empirical studies. They are influenced by upbringing, philosophical reflection, behavioural preferences, career pathways, vested interests, and social mores. This applies to theists and atheists alike. They cannot be tested for validity by scientific experiments or methodology. The conclusions drawn from scientific studies are often based on philosophical principles that provide an independent avenue to the acquisition of knowledge. However this aspect of scientific publications is open to distortion and sophistry as data can be used selectively or misleadingly to support an underlying ideology or vested interest of the scientist.

It is highly doubtful if embryonic stem cells can ever be used in clinical medicine when cloning is done using somatic cells of the patient (somatic cell nuclear transfer).ⁱⁱ All its claims for the treatment of any disease process are purely speculative. It is highly doubtful if such cloning can be done without a large bank of donor human ova, which would then complicate the substantial problem of tissue rejection. The procurement of human ova lends itself to the exploitation of women and the problem of informed consent. There is no doubt that the treatment of a patient will be at a prohibitive cost. It is known that cell lines established from such embryonic stem cells tend to undergo genetic drift or changes as successive populations are generated from the original cloned cell. It is known that such cells are prone to serious tumour formation. In the clinical situation, whether it be in clinical trials or treatment procedures, no such activities can be undertaken without the fully informed consent of the patient and institutional ethics committees would be hard put to approve their use.

It is a distortion to suggest that those who oppose experimentation on human embryos are insensitive to the suffering of those with chronic disabilities who may show some response to stem cell therapy. The evidence is overwhelmingly in favour of the use of adult stem cells in such cases but such information is obscured by the scientific lobbies for the use of ESCs.

The diversion of enormous amounts of public funds into research on human embryos is being justified on a clinical premise that is unfounded and a claim that the technology and its products will generate economic wealth for our nation. ***This is otherwise accurately known as the “commodification” of the human embryo and its cell lines*** and there is nothing to suggest that human cloning will not become the standard method of creating human embryos for commercial exploitation.

The review committee has summarily dismissed the ethical questions that have been sharply highlighted in the majority of the submissions that they have received. Whether the submissions have arisen from an intuitive concept of human dignity or a clear understanding of the scientific evidence, the human embryo, however formed, is a member of the human species, the earliest stage of our human existence. It deserves the protection of the law and of international declarations.

SECTION 2

THE PATTERSON BILL

1. Central to the provisions of this Bill is the unfounded assumption that, in its earliest stages, the human embryo has no moral status.

An essential component of the Bill is the proposed definition of the human embryo: ***human embryo means a discrete entity that has arisen from either:***

- a. the first mitotic division when fertilisation of a human oocyte by a human sperm is complete: or***
- b. any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;***

and has not yet reached 8 weeks of development since the first mitotic division

Accompanying the Bill are explanatory notes. Under Item 3 (Definition of the Human Embryo), the following explanation is given:

This item amends the definition of the human embryo to replace the existing definition with a new definition developed by the NHMRC. The NHMRC arrived at this definition by forming the Biological Definition of Embryo Working Party, comprising 3 NHMRC Embryo Research Licensing Committee members and 3 other Australian experts. Their Draft Report of the Biological Definition of the Embryo Working Party was peer reviewed by Australian and international experts.

To begin with, this definition of the human embryo appears in a document released by the NHMRC in December 2005 as **a discussion paper**. It bears no resemblance to any definition of the human embryo found in the standard textbooks on Human Embryology.ⁱⁱⁱ It is in line with the consistent ploy of the Fertility Societies in Australia, the USA and Britain who invented the terms - pre-embryo, pre-embryonic period and the pre-implantation embryo which no longer appear in the standard embryology texts and which are excluded from the literature of the human embryologists.

In human embryology, there are no proven instances of a human embryo being formed by parthenogenesis, as may occur in lower order species. There is no evidence of the formation of human embryos from somatic cell nuclear transfer. These phenomena are peculiar to laboratory experimentation and do not belong to natural events.

Who then are the experts on the NH&MRC Working Party and who were the experts who provided a peer review and who were the advisers to Senator Patterson on her definition of the human embryo?

2. THE MORAL STATUS OF THE HUMAN EMBRYO

This question is the most important one that we have to consider. And it is the one that the scientists have tried to evade by clever tactics. It has bedevilled their ambitions for over 20 years, despite the many successes they have had over the years. It has raised tangential arguments about the separation of religion from politics and has exposed fundamental weaknesses in the way we reach decisions in bioethics. It has aroused many old memories about human experimentation in the mid 20th century and it led to the formulation of universal declarations that rest upon the concept of the sanctity of human life.

It has also led to an expansion of the scope of our reflections on medical ethics generally and to attempts to clarify the meaning of many words as used in the major documents that articulate professional codes of ethics.

I have adopted an approach that has been outlined in part in a previous publication^{iv} and I have attempted to avoid the phrase “the dignity of the human person” for the simple reason that the words *dignity* and *person* are generally used in an imprecise way. I shall commence with an historical introduction.

Historical Perspective

From the very beginning, the pro-life movement has challenged the scientists about the moral status of the human embryo, claiming that human life begins at conception (the fertilisation of the ovum). That marks the beginning of human life that runs on a ***continuum*** until the death of the human body. Whether

the new human being is inside the womb or the fallopian tube, or outside in a petri dish or in the arms of its mother is of no moral relevance.

The scientists have countered by “shifting the goal posts,” by introducing a new term, “the **pre-embryo**.” They first did this in the early 1980s when they changed the meaning of the word **syngamy**. In embryology, syngamy had always meant, and still does, the fusion of the sperm head into the cytoplasm of the ovum. The scientists moved the word to a point about 20 hours later, when the chromosomes of the decondensed zygotic nucleus had lined up in pairs to fire off the first cell division. The pre-embryo was identified as the stage of pre-syngamy.

Later the term pre-embryo became associated with the form of the pre-implanted blastocyst, about 14 days after fertilisation of the ovum.

Today, the World Book Dictionary defines Syngamy as follows : (noun – biology) the union of two cells, as of gametes in fertilisation.

Moreover, as far back as 1986, the majority report (5 to 2) of the Senate Select Committee on Embryo Experimentation made the following statement: *Fertilisation is the process that begins with the penetration of the secondary oocyte by the spermatozoon and is completed by the fusion of the male and female pronuclei.* In the Oxford Biology Dictionary 2001: syngamy is defined as *the fusion of the gametes to form a zygote.*

All this may be subtle description but it is essential to get the facts right. The life history of a new human being begins with the formation of the single celled ZYGOTE, not with a later activity of the entity when it prepares to undergo cell division and certainly not when it becomes implanted into the uterus.

We are concerned with the nature of the human zygote once formed in any way, what the philosophers call the **ontology of the fertilised ovum**, once it comes into existence.

The editor of the scientific journal NATURE (Vol. 436, July 2006) has commented on the Playing the Name Game used by the scientists to deflect the general public and particularly the politicians from the truth about the human embryo, however formed. The scientists are trying to disguise the fact that they are creating and destroying human lives and therefore are desperate to avoid the term human embryo, because it has a negative impact.

The term *pre-embryo* is not a biological description but a term used to strip the zygote of any moral significance and it can be used up to whatever point the scientists wish to set. The language may change as is apparent in the minority report of the Senate Select Committee in 1986. They described marker events and asserted that the embryo could not continue to develop unless it had successfully implanted in the womb of a woman and the embryonic disc appeared. They claimed that these were *significant events* that established the moral status of the embryo. Apparently it had some moral standing up to the point that a decision was made by someone not to proceed with embryo transfer.

Moving forward in time, we find new developments in the field of reproductive technology. The cloning of Dolly the sheep made headlines in

February 2003. This was achieved by the process of **somatic cell nuclear transfer (SCNT)**. The research team was headed by Ian Wilmut at the Roslyn Institute in Scotland. The original work had appeared in the journal Nature in 1996 when Wilmut revealed that two previous sheep clones had been produced – Megan and Morag. Dolly was a Finn Dorset lamb, created from a fully specialised adult mammary cell. Her creation was reported in Nature in 1997 and Dolly was the first mammalian clone produced from the fusion of an enucleated sheep ovum with the nucleus of an adult somatic cell from the same animal. The process of SCNT was introduced into veterinary science so that other mammals have now been created by SCNT. In other words, the first cell in the process constitutes an embryo of the species from which the two cells – the enucleated ovum and the somatic cell – were obtained and the clone is a twin of the person who supplied the somatic cell with its nucleus. So Dolly was a twin of her mother.

It has since been shown that an embryo can be formed by three processes. The normal fusing of a male sperm with a female ovum of the same species; the process of SCNT again using cells of the same species; and the phenomenon of PARTHENOGENESIS a modified ovum, a stimulated single cell. In all three cases, the zygote formed is totipotent for that species.

This series of events set off another round of announcements about human cloning. Professor Robert Williamson is a geneticist who wrote the submission to the Lockhart Committee for the Australian Academy of Science. He maintains that the zygote formed by SCNT is not a human embryo because no human spermatozoon is involved. However Williamson makes a serious error for in determining the moral status of the embryo, we work back from the adult form of the human being and ask *when did it begin?* When was it programmed and empowered to become the kind of being that it is? And it always comes back to the first totipotent cell – the human zygote, however formed.

These attempts by the scientists have achieved considerable success. Whilst they have not altered the terminology used in textbooks on embryology, they have muddied the waters in the popular press and in the media generally. The general public tends to rely on these latter sources to be informed and consequently the true nature of the human embryo has been distorted. There are numerous ways in which this dissembling of the facts is achieved and it becomes an additional subject for discussion in the field of bioethics.

The moral status of the human embryo is determined by its true nature – its ontology – and the implications of that status fall within the fields of bioethics and the law. The word embryo is not divisible into parts and this is best demonstrated in talking about the **life cycle of a human being** and the establishment of an **identity** that belongs specifically to each member of the human species, what we call **self-identity**.

Life Cycle (History) and Self Identity.

When did Louise Brown begin? For that matter when did any of us begin? What we need to know is what is the **life history** of any member of the species *Homo sapiens*? At this point, we are not discussing personhood but the biological evidence of human development. But at the same time, we need to be aware that other disciplines of knowledge are interested in human beings, the disciplines of law, psychology, philosophy, theology, sociology and even politics. However their starting point is scientific knowledge. At the moment, in the present debate over the ethics of embryo experimentation, we have fragmented a human being into stages of development, as if there is no continuing entity across the spectrum of the life of a human being. It is important to resolve this dilemma for our next question will be *how should we as a society treat one another?*

In the field of biology, we are concerned with “living beings” and we have described certain features or attributes that identify that the object of our study is a living thing. The basic level of life is **the cell** and for it to reproduce itself it requires the presence of the DNA found in the nucleus of the cell (as well as the cytoplasm that interacts with it). In the human being, there are several hundred cell types and most of them have a limited existence, even though the human being as such long outlives its constituent cellular components which fortunately keep renewing themselves.. These cells are called **unipotent** – they can reproduce themselves (in fact produce a clone of itself) but its progeny follows the line of specialised functional activity found in that organ or tissue. So that a skin cell will only produce another skin cell. These cells can be grown in culture media and form **a cell line of skin cells**.

There are other cells (we are talking about human beings) at the other end of the scale that are unique. These are **the germ cells**. They are cells that are concerned with the reproduction of **a whole human being**, a multicellular organism. There are two types of them – ova and sperm – ova in the female and sperm in the male. For a new human being to form (in the natural order), it requires an ovum and a sperm to fuse together. In ordinary circumstances, this process is achieved by human intercourse between a male and a female but it has been shown that this can occur by in vitro fertilisation with the assistance of scientific technologists.

However fertilisation is achieved, the new cell or **zygote** is even more unique. It is a **totipotent cell**. It is the first cell in the life cycle of a new human being. Even if identical twins are formed, it is this zygote that is the original cell of origin. *It is when Louise Brown began her life history.*

It has also been shown that when the zygote divides into two cells and then four cells that those cells may be totipotent, that is may separately be the starter cell of a new human being. It seems however that beyond the 4-cell stage – the 8-cell stage – that the totipotency of each of those cells (blastomeres) disappears. But the direction of development of the embryo remains intact.

This means that when one of my youngest grandchildren wants to present a pictorial display of his life cycle, he can present his ultrasound pictures

beginning in very early pregnancy and his digital photographs after birth. He can go further than that; he can present a PowerPoint display of the Carnegie spiral of early embryonic development and proudly say: *this is where I began*.

What exactly would he be doing? He would be showing that his personal identity (just plain him) remains no matter what his morphological appearances may be. When my grandchildren hold up my photograph taken when I was less than one year old, there is no way that I can say *that's not me*. What it does is to reveal that I have a unique personal identity that I will have throughout my life cycle to the day that I die. It establishes the fact that my personal identity remains with me over time and space and that I live in a human community with kinship relationships.

Therefore I find it difficult to accept the statement of an American politician, when he said:

"I just cannot equate a child living in the womb, with moving toes and fingers and a beating heart, with a frozen embryo sitting in a lab somewhere."
(Hatch – NBC Meet the Press).

An interesting article appeared in the Daily Mining Gazette in the USA for September 2, 2006. It concludes as follows:

Why can't Americans give at least as much protection to our offspring as we give to the bald eagle, the living symbol of our national spirit. The Bald Eagle Protection Act, passed in 1940, protects not only the national bird, but the bird's eggs. If one were to destroy that bird's eggs, he would suffer the same sanctions as if he shot the adult bird out of the air. By force of law, we acknowledge that the embryonic eagle inside the egg is the same creature as the beautiful bird high in the sky. Even an atheist can see why a bald eagle's eggs need to be protected - it's not a religious question at all.

None of this discussion has anything to do with theology or the concept of ensoulment. But it does raise the issue of the intervention of other disciplines – the law, ethics, sociology, psychology, philosophy and politics about what are the legal and social implications of this being from the first moment of its existence. It will impact on several International Instruments on human rights and profoundly on the codes of professional conduct, many of which arose over the issue of human experimentation.

The Patterson Bill is a travesty of the truth of human existence and our hard won recognition of what it means to be human.

Dr. Joe Santamaria

ⁱ Dianne N. Irving. International J. of Sociology and Social Policy 1999, 19:3/4: 22-47. When do Human beings Begin? "Scientific" Myths and Scientific Facts.

ⁱⁱ David van Gend. Cloning a new horror. Herald-Sun. Sept. 28, 2006. p.21.

ⁱⁱⁱ Such textbooks as those of O'Rahilly & Muller, Larsen, More & Persaud, Sadler, Carlson and Patten.

^{iv} J.N.Santamaria Embryos, Ethics and Politics. Gabriel Communications 2002