SUBMISSION TO

IRISH COUNCIL FOR BIOETHICS

ON THE

STEM CELL RESEARCH

SUBMISSION FROM

MOTHER & CHILD CAMPAIGN

LIFE INSTITUTE

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We are entering a genetic age; an age that holds many confrontations, challenges and tests. At the core of every decision we make must be fundamental medical and scientific ethics and the principle of 'First, do no harm'.

The advance of biotechnology should not be at the expense of our own humanity and of our ability to adhere to basic principals. Many practises which are now possible and permissible are abhorrent and would be rejected by the majority of Irish citizens. It is crucial therefore that *The Irish Council for Bioethics* understand the desire of the majority of Irish people to protect life from fertilisation.

IN-VITRO FERTILISATION

In-vitro fertilisation (IVF) is far from being a simple, efficient and successful procedure as proclaimed by its proponents. Research shows that IVF has serious health implications for the child it produces, and for the woman availing of this technology. We must also consider the human cost of the loss of so many child embryos. Every decent person feels compassion for those who are inexplicably unable to conceive their own children. The end, however, does not justify the means and, with IVF and other assisted reproductive technologies, we can see that some people have very different ends in mind for some embryonic human beings. We have a duty as a society to defend human life, and that responsibility is no less for the tiniest human lives being formed through assisted reproductive technology.

IVF remains a procedure with low success rates. It is a very expensive treatment, and of course patients, or the state, must pay for treatment regardless of success or failure. Strong competition between IVF providers is causing bad practices to develop regarding published success rates and approval of patients for IVF treatments. The most fundamental ethical problem with IVF is that more human embryos are formed in the process than are required for treatment. This loss or destruction of human life is unethical and immoral.

Major studies have found that IVF has negative outcomes for children who are conceived and born through this technology. An Australian study entitled The risk of major birth defects after Intra-Cytoplasmic Sperm Injection and *In-vitro* Fertilisation compared IVF children with children conceived in the conventional manner. It found that IVF children are twice as likely to suffer from birth defects. The birth defects associated with IVF include lower birth weight, babies being born premature, an increased risk of the neurological condition, cerebral palsy, in the child, and a range of urological disorders. IVF has also been associated with congenital heart defects, Down's Syndrome, club foot, and cleft palate.

IVF also has inherent risks for the woman receiving treatment and most of these dangers arise from the abnormal process of extracting ova from the woman's ovaries. Ovarian Hyperstimulation Syndrome (OHSS) is one of the commonest complications of IVF and it arises from the overstimulation of ovaries through superovulation. Some women availing of IVF treatment have died from this syndrome, including 32-year-old Mrs Jacqueline Rushton from Dublin who died from OHSS, on 14 January 2003, while receiving fertility treatment in the Rotunda Hospital, Dublin.

A comprehensive and urgent review of the dangers, for mother and baby, from the IVF procedures, and a commitment to the protection of the human embryo, should be undertaken by the State.

FREEZING HUMAN EMBRYOS

One of the most difficult and controversial topics surrounding the issue of embryonic stem cell research is: what is done with the frozen embryos who are currently in storage and are destined for destruction?

Firstly, the very fact that supernumerary embryos are proposed for destruction should lead us to question the ethics of producing these embryos in the first place. While it may be true that some of the frozen human embryos will eventually die, that is no justification for taking an active role in their premature death. Inmates on Death Row are also destined to die; should we allow scientists to treat them as research subjects, or to conduct experiments on these men and women before they are executed for their crimes? The chance of survival of any human life - at embryonic stage or otherwise - should not be the basis for respect accorded and due to that human life. Deliberately experimenting on these embryos undermines their worth and treats them as research material.

Apart from the right-to-life issue for these embryonic human beings, it would appear that the promise of acquiring stem cells from embryos, currently frozen, is a false one of the would-be genetic engineers. Leading fertility experts agree that frozen embryos would yield a far smaller number of stem cell lines than is often assumed. Dr William Gibbons, of the Jones Institute for Reproductive Medicine in Virginia, says that the Institute has about 200 frozen embryos available for destructive research but “there is no guarantee that we would get any stem cells from those 200 frozen embryos.” Dr Barry Behr of Stanford University notes that “by far the vast majority of embryos that are frozen are not good. If we thawed 10,000 embryos, we would get 100 or so that are viable.” So, behind the seemingly impressive number of frozen embryos that are being proposed for stem cell research, the reality is that the actual number of stem cell lines likely to be produced from them is so small as to be clinically useless. Dr David Prentice of the Do No Harm organisation says that, “in order to treat diseases (which is still a very distant prospect using human embryonic stem cells) hundreds of thousands of more embryos, beyond those currently frozen and available for research would be needed.” Prentice goes on to suggest that this number of embryos could only be achieved by a deliberate effort to produce new embryos for the sole purpose of destroying them - an outcome the use of frozen embryos is supposed to avoid, but would, in fact, most likely encourage.

The increasing lack of respect for life occurs when the profit-driven agenda of the biotech industry is allowed to drive scientific ethics. It is very clear what we must do to prevent this tragedy from getting even worse: we must immediately stop forming “excess” embryos and allow no further freezing of embryos.

EMBRYONIC STEM CELL RESEARCH

Over the last decade or so human embryonic stem cell research has become one of the most controversial developments in the international bioethical debate. The fundamental ethical problem with research on embryos is that this type of research will assure the destruction of many early human lives. It is not possible to extract stem cells from the living human embryo without destroying him/her in the process. International documents such as the Nuremberg Code, the World Medical Association's Declaration of Helsinki, and the United Nations Declaration of Human Rights reject the use of human beings in experimental research without their consent, and permit research only if there is therapeutic benefit for the human subject. Clearly, the child embryo has not given consent to being experimented on, and even the strongest advocates of embryo research agree that it is by no means therapeutically beneficial to the embryo. Therefore an ethic which condones research using human embryos violates the standards set out by these documents. It also undervalues human life, damages the integrity of science and medicine, and degrades society.

Research on human embryos is morally, ethically, scientifically, and medically, wrong, and should be outlawed in every country. This research destroys early human lives and undervalues the embryonic human being to the moral status of penicillin mould. Furthermore this controversial research is unnecessary, as ethically acceptable alternatives to the destruction of these human embryos exist. Moreover, it is, in fact, completely unethical to redirect funds and resources needed to develop the successes of ethical stem cell research towards destructive research that is not yielding any results.

The controversy surrounding embryonic stem cell research boils down to one essential question: does human life have intrinsic value simply because it is human? The authors of our report believe the answer must be “yes”, and that means we must reject all unethical technologies and philosophies that lead to the objectification of human life, including embryonic stem cell research. If our answer is “no”, then we are prepared to sacrifice the inviolability of human life on the altar of biotechnological power, we are willing to discard our belief in the inherent value of human life and we are ready to exclude from the human family, the smallest form of human being: the child embryo.

REPRODUCTIVE AND THERAPEUTIC CLONING

Since Dolly the sheep was born, the topic and practice of human cloning has been gaining much attention. Two types of human cloning are generally discussed:

- Reproductive cloning is human cloning undertaken for the purpose of bringing a cloned baby to birth.
- Therapeutic cloning involves the cloning of human embryos for use in medical research. Therapeutic cloning is sometimes referred to as "regenerative medicine".

The distinction between the two is spurious as the terms do not describe two different types of procedures. The technique used in therapeutic cloning is the very same as the technique used in reproductive cloning, as both result in a cloned human embryo. Therefore, both techniques are, in fact, reproductive.

The only difference is what is done with the embryo after he/she has been formed. Where reproductive cloning is undertaken, the cloned embryo is implanted in the uterus of a woman, where he/she is allowed to grow and be born. With therapeutic cloning, the newly formed human life is only permitted to grow until the embryonic stage, at which point stem cells are extracted, causing the death of the embryo.

Despite assurances that there are limits beyond which we shall not go, we have learned from the past that limits are breached once the first step is taken. And the first step towards actually bringing a cloned child to birth is so-called human therapeutic cloning, which is unethical and immoral in itself. So in order to ensure that cloning to produce children does not take place, must cloning for research purposes be prohibited? The answer is, quite frankly, and absolutely, yes.

GENETIC SCREENING

Pre-Implantation Genetic Diagnosis is a method used to examine the genes of human embryos formed by IVF technology. After being formed by IVF, a biopsy is carried out to remove a cell from the developing embryo. The DNA in this cell is then tested for chromosomal abnormalities or genetic mutations. If such a condition is detected, the embryo is destroyed. If not, the embryo may be implanted in a woman, and allowed to grow and develop and, eventually, be born. PGD is most frequently used for people who have a family history of genetic disabilities, including cystic fibrosis, Huntington's Disease and Down's Syndrome.

Like many other experiments or research techniques that involve human embryos, the greatest concern with PGD is that it will, without doubt, involve the destruction of many early human lives. Humans begin life at the moment of fertilisation. From that point on, human beings are entitled to the respect proper to their human nature, to protection from harm and to rights appropriate to their stage of development. PGD fails to respect the human value of the embryos examined in the laboratory, because the aim of PGD is to destroy those human lives found to have "undesirable" genes.

This procedure is completely incompatible with a respect for the right to life, because it entails destroying those human beings who do not measure up to an arbitrary measure of desirability. It is not possible to have respect for a human individual one is prepared to destroy if that individual does not measure up to a particular specification. No one has the right to excise an imperfect child, as if that child were no more than a tumour.

One of the commonest arguments the proponents of PGD use is that it is better to discard those embryos that have disabling genetic conditions than to allow those children to be born with such a condition. This notion is, in fact, being promoted at an alarming rate, but the suggestion that children with disabling conditions are of bad quality will appal most Irish people, and can only be disturbing for those people who are currently living with a disability.

Some people argue that PGD is preferable to pre-natal screening leading to abortion of an unborn child who has a genetic condition. This argument is fundamentally flawed. Both PGD and pre-natal screening aim to detect disabled individuals so that they can be destroyed. With PGD these individuals are discarded at the embryonic stage, and with pre-natal screening they are killed through abortion at a later stage of pregnancy. The two kinds of diagnosis are essentially the same, the only difference being the age at which the disability is detected and the disabled individual destroyed.

The very act of selecting our children through PGD creates an ethical problem. By choosing the characteristics of our children we change the relationship between us and them: choosing results in treating them as just so many other consumer commodities or objects. The relationship becomes more like one between designer and object than between parent and child. In one sense, even if science can't yet - and may never -

allow the would-be genetic enhancers to select all of the desirable traits that they want, their ideology has already damaged our perception of children, and what it means to be a parent. Childbearing and rearing seems increasingly to be viewed as being primarily about satisfying our desires, working toward our fulfilment through our children's lives. We are deemed by the bioethics elite to have a “procreator's right” to design our own children to achieve these goals. The Council for Responsible Genetics summed it up succinctly when they said: “All people have the right to have been conceived, gestated and born without genetic manipulation.”

ADDITIONAL INFORMATION WHICH THE LIFE INSTITUTE RECOMMEND IS CAREFULLY CONSIDERED BY THE IRISH COUNCIL FOR BIOETHICS.

1. NAPROTECHNOLOGY - AN ETHICAL ALTERNATIVE TO IVF

Infertility is defined in the medical world as the inability to achieve a pregnancy after at least one year of trying. It is a significant problem for many couples around the world. In the United States up to 1 in 5 couples experience difficulty in conceiving, and in Europe infertility affects 1 in 6 couples. The most common causes of infertility are: failure to ovulate, the age of the woman, and a drop in the production of male sperm. These, and other factors, such as Sexually Transmitted Infections, contribute to a couple not being able to have a baby.

Artificial Reproductive Technology (ART) is a term to describe the methods used in helping couples become pregnant. These methods are In Vitro Fertilisation (IVF), Intra-Cytoplasmic Sperm Injection (ICSI), and Gamete Intra Fallopian Transfer (GIFT). However, these are not the only techniques available in helping couples who are having difficulty conceiving.

Natural Procreative Technology, or the abbreviated NaProTechnology (NPT) is a new, safe, and effective means of treating infertility that can avoid the perceived need for ART in many cases. NaProTechnology is a couple-centered, disease-based approach to investigate, diagnose, and treat infertility. This technology is called “natural” because it refers to the method of conception through a natural act of intercourse as opposed to any artificial intervention which replaces intercourse. Studies conducted in the area of NaProTechnology, and the clinical experience of those who practise it, show great promise for this method.

NaProTechnology was created by Consultant Obstetrician Dr Thomas Hilgers in the United States, over a period of 20 years. Training programmes have been offered to doctors since 1991 and this technology has been available to Irish patients since 1998. NaProTechnology allows a closer evaluation of fertility, and frequently leads to the detection of abnormalities that may have been previously overlooked. It offers an approach to the investigation and management of infertility, is considerably more successful than IVF, and is minimally invasive.

NaProTechnology holds a number of significant advantages over other methods of Assisted Procreative Technology, including IVF. Significantly, there is absolutely no loss of human life with this technology. This is not the same for IVF, where, for every single child that is born through the procedure, an average of 19 embryos will die. Because the formation of human life in such an unnatural manner is avoided, there can never be any “excess” or “spare” embryos formed, thus eliminating the unethical practice of embryo storage and future destruction. With NPT, babies are conceived and born in the

natural manner, and so the other complications associated with IVF are also minimised or eliminated.

2. Adult Stem Cells - An Ethical Alternative to Embryo Research

When stem cell research first came to public attention in the late 1990s, most of the non-embryonic research successes had not yet been published. At the time, researchers told people that the best source of cures would be embryonic stem cells, and that nobody should value a tiny embryo above a sick child. The media too played its part in promoting embryonic stem cells as the body's repair kit, and helped to create a belief that these cells could be used to cure a range of diseases such as Parkinson's, Alzheimer's and spinal cord injuries. Now, the growing weight of scientific evidence is beginning to discount this idea that embryonic stem cells are the answer, and former supporters of embryonic stem cell research are now favouring adult stem cells as the method of choice for treating degenerative diseases.

Biotech optimist Michael Fumento, author of the book *BioEvolution*, accurately referred to adult stem cells as "stupendous stem cells". An adult stem cell is an undifferentiated cell found among differentiated cells in a tissue or organ. It can renew itself, and can differentiate to yield the major specialised cell types of the tissue or organ. Adult stem cells have been isolated from numerous tissues, umbilical cord, and other non-embryonic sources, and have demonstrated surprising ability to transform into other tissue and cell types and to repair damaged tissues. Adult stem cells have received intense scrutiny over the past few years due to their previously unknown cures for certain diseases. The key questions regarding adult stem cells are:

(I) their tissue source of origin
(ii) their ability to form other cell or tissue types to treat diseases
(iii) and their effects on other tissues and organs.

Adult stem cells have been successful in treating up to 65 different conditions, while not a single successful treatment has come from the use of embryonic stem cells. For this reason, most biotech companies are not engaging in embryonic stem cell research, and not because of ethical problems, but because adult stem cells seem more likely to provide effective medical treatments to suffering patients.

The term "adult stem cell" is in fact confusing, because these cells are present even in infants, and similar cells exist in the umbilical cord and placenta. Adult stem cells have in fact been discovered in the following tissues: bone marrow, muscle, liver, pancreas, cornea (of the eye), mammary glands, salivary glands, skin, heart, cartilage, teeth, adipose tissue (fat), placenta, and umbilical cord blood. Adult stem cells have been successfully isolated from all of these, and other tissues, and have been shown to have various therapeutic applications to human patients, and animal experiments.

Those who advocate the destruction of the human embryo in order to extract its stem cells for experimentation will often try to downplay the therapeutic successes of adult stem cells. The commonest argument used against adult stem cells is that they are not

pluripotent, meaning that they are unable to transform into every tissue type in the human body, as embryonic stem cells are.

This is not entirely true, however, and as various clinical trials and studies continue, we are realising that the pluripotent nature of adult stem cells is far greater than was previously considered. Our report has already mentioned that scientists have turned skin cells into brain cells, and umbilical cord stem cells into liver cells, and there are many more examples of this type of research. Human stem cells from bone marrow have been shown to differentiate into various cell types including neuronal cells as well as cartilage, bone and fat cells.

An animal experiment using bone marrow cells also revealed that these cells transformed into cardiac and skeletal muscle cells. Bone-marrow-derived stem cells have also been able to form neuronal tissues, and a single adult bone marrow stem cell can contribute to tissues as diverse as liver, skin, and digestive tract. Neuronal stem cells can produce other tissues including blood and muscle, liver stem cells can render pancreatic cells, cord blood cells can render liver cells and brain cells. The list of adult stem cells that have the ability to transform into other cells continues to grow, and it is not possible to discuss every one in our report; again a very in-depth report, which details a lot of studies conducted in this area, is available online. Suffice it to say here that adult stem cells do in fact exhibit pluripotent abilities, and more and more of these abilities are being realised and developed.

This may very well be the reason why many embryonic stem cell researchers are now turning to adult stem cells to develop cures and treatments. In August 2005, *NewScientist* reported that scientists had found umbilical cord blood cells that were extremely versatile, and capable of transforming into other tissues of the human body. The researchers referred to these stem cells as “embryonic-like” and said that they had “found a unique group of cells that bring together the essential qualities of both types of stem cells for the first time.”

Regardless of whether embryonic stem cells are more pluripotent or not, what is important in this debate is to review the evidence. Medically and scientifically, adult stem cells appear to be far more efficient than embryonic stem cells, as their therapeutic applications have been tried and tested, and have been proved to work. One of the main reasons they succeed where embryonic stem cells do not, is that adult stem cells do not have the problem of immune rejection by the patient that embryonic cells do, and that is a far bigger advantage than pluripotency. Adult stem cells generally come from the patient’s own body, and therefore are genetically identical to the patient’s own body cells. This eliminates the danger of immune rejection by the patient.

Ethically, the use of adult stem cells is acceptable; the use of embryonic stem cells isn’t. Treatment using adult stem cells does not necessitate the destruction of human beings. It is entirely and ethically legitimate to use adult stem cells, including those derived from other non-embryonic sources, such as umbilical cord blood, and placenta, for the treatment of diseases and other therapeutic applications. The authors of our report

strongly suggest that resources be directed towards this area, so we can develop and expand the cures and treatments that are currently available. The bank of knowledge regarding adult stem cells has expanded greatly in just a few short years. Evidence from both animal studies and human clinical trials shows that they have significant capabilities for growth, repair, and regeneration of damaged cells and tissues in the body. These are the true "self-repair kit" for the human body. The potential of adult stem cells to impact medicine in this respect is enormous and should be fully developed.

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