Human Embryonic Stem Cell Research

On the Path to an Investment Framework

April 2003
Second Edition
Executive Summary

- The Ethical Investment Advisory Group is in the process of researching the impact of human embryonic stem (ES) cell research on the Church of England’s ethical investment policy, with a view to developing an investment framework encompassing companies involved in this type of research. A paper has been produced that endeavours to introduce the subject of embryonic stem cell research using human stem cells, the regulatory regime, and the ethical and theological arguments surrounding this research. Copies are available from the SRI Unit at CCLA and can also be found on the Church of England’s website. Investing in a sector that does, or may in future, carry out ES cell research will need to be considered carefully. The few companies in the UK currently involved in this research are small, and usually listed, if at all, on the Alternative Investment Market. Following contact, it does not appear that any of the major UK pharmaceutical companies are currently involved in human ES cell research, although stem cells derived from foetal tissue and adult stem cells are being used in research. However, the development of this research will undoubtedly bring more companies onto the stock market, and a greater interest from the larger pharmaceutical and biotech companies.

- Human stem cell research is said to promise new life changing treatments and possible cures for many debilitating diseases and injuries, including Parkinson’s disease, diabetes, heart disease, multiple sclerosis, burns and spinal cord injuries. A stem cell is a type of cell that has the ability to divide or multiply indefinitely in culture and become any one of more than 200 different types of tissue cells in the body, such as muscle cells, blood cells, nerve cells and even new teeth. Scientists hope to use these cells to develop new tissues, treatments and potentially even organs for transplanting into a patient.

- The main area of controversy surrounding this research arises from the harvesting of cells for research. The most flexible stem cells are obtained from embryos owing to their ability to become any type of tissue cell in the body (although adult stem cells are showing the same possibility). A fertilised egg forms a blastocyst 4 days after conception. This blastocyst has two types of cells; an outer layer (which becomes the placenta and other supporting tissues needed for foetal development) and an inner cell mass (the stem cells). In order to harvest these cells, they are removed from the blastocyst, a process that destroys the embryo. As well as foetal tissue, stem cells can also be obtained from adults but these are already differentiated. Research into the process of “dedifferentiation” and “redifferentiation” into another type of cell is ongoing and showing signs of success.

- Human stem cells can be obtained from a number of sources. The first is IVF (In Vitro Fertilisation) treatment, where surplus embryos (and unfertilised eggs for creating embryos) are donated for research with the consent of the donor rather than being destroyed following treatment. The second source is aborted tissue where stem cells are taken from the aborted foetus. Another is umbilical cord blood, rich in stem cells. These cells are harvested following the baby’s birth. The most controversial is perhaps therapeutic cloning, where cells are created for research that are genetically identical to the donor (patient). This is done by removing the nucleus of an egg and fusing this egg with any enucleated cell from the donor. This will create an embryo genetically identical to the donor. Cells can then be harvested from this embryo for treatment. Being an exact replica, there is potentially less chance of rejection following transplantation. There has been talk of taking stem cells, rather than an egg, and using the same process to create genetically identical stem cells. Should this
be viable, cloning embryos for research would be unnecessary. Finally stem cells can be created from adult cells.

- Despite highly publicised promises, such as recent animal research showing stem cell treatment reversing symptoms of Parkinson’s disease, stem cell research has had problems. Animal research has also shown ES cell unsuitability, shown by the growth of tumours following the injection of ES cells into mice. The other problem is cell and tissue rejection owing to ES cells being genetically different from the patient if they have not been obtained through therapeutic cloning.

- Ethical dilemmas include the status and ensoultment of the embryo, the respect for human life and the possible abuse of the cloning technique should it be perfected for research purposes, which is not illegal in the UK. Future cloning techniques could be used to create human life in countries lacking regulation on human cloning, as has been claimed by Clonaid, although there remains no proof of these claims. Cloning is often considered to be morally unacceptable. In addition ES cell research requires the destruction of the embryo through extraction of cells from the cloned embryo, also a consideration with IVF embryos. Ethical considerations surrounding aborted foetuses focus on the moral concern of the practice of abortion and the respect for human life.

- Approximately 35 countries have formally banned human reproductive cloning (cloning embryos with the purpose of creating a human being) including Germany and Switzerland. This did not necessarily include therapeutic cloning (cloning embryos for research purposes), which is allowed in some jurisdictions such as China, Israel and the UK. The framework for human ES cell research and use in the UK is based on the Human Fertilisation and Embryology (HFE) Act 1990 (relating to fertility treatment), and The HFE Regulations 2001 (for research). It is a criminal offence to carry out any treatment using human embryos outside the body without a license granted by the HFE Authority (HFEA). Research is allowed on embryos up to 14 days of development, after which the embryos have to be destroyed. Cloning embryos is legal, however it is illegal to transfer any cloned embryos into the uterus of a woman and to mix human adult cells with live eggs of any animal species. Licenses are granted by the HFEA if research is “necessary or desirable” and the use of embryos deemed essential. However, once stem cells are extracted from the embryos, there is no legislation in the UK to regulate the research.

- The US is more conservative, limiting Federal funding for stem cell research to cell lines already created. Developing new ES cell lines will not receive any Federal funding. The US House of Representatives has passed a bill that would ban human cloning and sentence violators to prison and fines as high as $1m, although this still has to be considered by the Senate. The EU will not fund research into cell lines developed from cloned embryos, or the creation of embryos specifically for research purposes. In April 2003, MEPs voted for an Europe-wide ban on ES cell research, and MEPs will have to vote on the proposed new law again before it comes into effect.

- The Church of England combines strong opposition to abortion with a recognition that there can be, strictly limited, conditions under which it may be morally preferable to any available alternative. Children are seen as a gift from God and the welfare of any child created by third party donation of eggs or sperm is deemed as of overriding importance. The Church’s former Board for Social Responsibility recognises that there is a spectrum of views
surrounding human ES cell research, however it has stated that any proposals for using embryos must be deemed “absolutely necessary” and ideally, take place only after all other avenues have been explored. The Bishop of Oxford chaired the House of Lords Select Committee on this subject, which remained convinced that research on embryonic stem cells needs to be done at this stage if the benefits of both adult stem cell research and other types of research were to be realised.

- To conclude, the three main contentious areas surrounding human stem cell research are the use of stem cells from aborted foetuses, embryonic stem cells obtained from excess IVF embryos and therapeutic cloning. Much of this mirrors past debates the Church of England has had on the status of the embryo and ensoulement. The most contentious issue is probably cloning for two reasons; creating life as a means to an end (research) and developing a technique, that when perfected, could be used to clone human life. “Playing God” is a concept that many scientists, whatever their religious convictions, find unacceptable. Currently, none of the large pharmaceutical or biotech companies are involved in ES cell research (although stem cells derived from foetal tissue are used in research), however this area could grow in significance for the sector, should findings and applications prove more conclusive.

- The EIAG has now completed its preliminary work and discussions on the subject of human ES cell research, although research and thinking is still progressing. The Group hopes that, following the process of consultation with a range of stakeholders, an investment policy on human ES cells can be formulated in keeping with the views of the wider church, as and when these develop, hopefully in the coming year. However, this is a fast moving field with a continuous stream of research being published, which will need to be taken into consideration in any ultimate formulation of an investment framework.

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Introduction

1. This paper has been compiled by the Socially Responsible Investment (SRI) Unit at CCLA Investment Management, which provides research services for the Ethical Investment Advisory Group (EIAG) of the Church of England. The purpose of this paper is to examine the ethical investment implications of human embryonic stem (ES) cell research. The paper attempts to introduce this subject, the regulations surrounding this research, and the ethical and theological arguments and implications this may have for the ethical investment policy of the Church of England.

2. Human stem cell research promises new treatments and possible cures for many debilitating diseases and injuries, including Parkinson's disease, diabetes, heart disease, multiple sclerosis, burns and spinal cord injuries. However, in order to understand the ethical dilemmas it is essential that one has an understanding of what stem cells are, their differing form, how they arise and their potential medical uses and applications.

3. Investing in a sector that does, or may in future, carry out ES cell research on any created embryo will need to be considered carefully. One of the main reasons is that this type of research is extremely expensive with very little near future reward. Additionally, legal consequences may arise for the industry should major problems occur in any future patient treatment. The tobacco industry is a good example of this.

4. Most companies involved in this new technology and research are currently small and, if listed at all, tend, in the UK, to be on the Alternative Investment Market (AIM), the London Stock Exchange’s global market for smaller, growing companies. However, should this research develop rapidly (which is quite likely), more companies will list, and grow and the larger pharmaceutical, biotech and health companies may become interested in the uses of ES cell research for their businesses.

5. The ethical questions surrounding this type of research focus on the source of ES cells. The EIAG will attempt to develop an investment policy to encompass those companies whose business activities may participate in, or benefit from, the different types of stem cell research.

6. All stem cells and research discussed in this paper relate to humans rather than animals, unless otherwise stated. The paper has not considered the implications of stem cell research and cloning in relation to animals.

What is a stem cell?

7. A stem cell is a type of cell that has the ability to divide or multiply in culture for indefinite periods, giving rise to specialised cells, first isolated by scientists in 1998. Recent research has suggested that stem cells can give rise to many different types of cells, such as muscle cells, blood cells, nerve cells and even new teeth. With this ability to replicate new stem cells, as well as give rise to more specialised daughter cells, banks of tissues and cells could be created for use in medical treatments. The main source of these cells is from foetal tissue, umbilical cord blood and bone marrow and they are found in two main forms; pluripotent and multipotent. Stem cell versatility and abundance reduces with age.
The development and differentiation of stem cells

8. Development begins in the human body when an egg is fertilised and it is this single cell that has the potential to form an entire organism. The single fertilised egg is known as totipotent. The first few hours see the cell divide rapidly into other identical totipotent cells. After 4 days of division, cells begin to specialise and form a blastocyst. Within the first 14 days following conception embryos have the ability to divide into 2 blastocysts, forming identical twins.

9. A blastocyst has two layers of cells, the outer layer, which becomes the placenta and other supporting tissues needed for the development of the foetus in the womb, and the inner cell mass. It is the inner cell mass that we are most concerned with as these stem cells have the ability to give rise to over 200 different kinds of tissue cells in the body. However these inner cells are not totipotent, lacking the ability to form an organism on their own, and are known as pluripotent stem cells, their potential is not total and they are not embryos. These cells have the greatest potential, having the ability for enormous versatility. Pluripotent stem cells are obtained from IVF surplus embryos, nuclear cell transfer and foetal tissue from terminations (first trimester). When these pluripotent stem cells are derived from an embryo, they are known as embryonic stem (ES) cells. As these cells divide they become more specialised giving rise to cells which perform a particular function, such as skin stem cells which in turn give rise to different types of skin cells. These stem cells are called multipotent stem cells. These stem cells are present in children and adults. They can be obtained from some adult tissues, such as bone marrow, and from mature adult tissue cells programmed to behave like stem cells, as well as from later abortions and umbilical cord blood. Although research continues to provide a better understanding into this type of cell, there is no conclusive evidence that these cells can be manipulated to turn into all other types of cells in the body.

The process of stem cell cultivation

Stem cell injection
The source of stem cells

10. As already mentioned, human stem cells can be derived from a number of sources. These are early embryos (blastocysts) from IVF, embryos created through cloning, germ cells or organs of aborted foetuses, umbilical cord blood, some adult tissue (e.g. bone marrow) and mature adult tissue cells reprogrammed to behave like stem cells.1

Advantages and disadvantages of the different types of stem cells

<table>
<thead>
<tr>
<th>Stem Cells</th>
<th>Totipotent</th>
<th>Pluripotent</th>
<th>Multipotent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage of Development</td>
<td>Approx 0-4 days</td>
<td>To form an entire organism</td>
<td>To create any type of over 200 tissue cells</td>
</tr>
<tr>
<td>Potential</td>
<td>To create specific tissue cells</td>
<td>To create specific tissue cells</td>
<td></td>
</tr>
<tr>
<td>Advantages in Research</td>
<td>N/A</td>
<td>• Versatile</td>
<td>• Later foetuses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Easy to isolate</td>
<td>• Children</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Divide in culture indefinitely</td>
<td>• Adults</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cloning issues</td>
<td>• Umbilical cord blood</td>
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<td>• Pro-life ethical debate</td>
<td>• Umbilical cord blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hard to control</td>
<td></td>
</tr>
<tr>
<td>Disadvantages in Research</td>
<td>N/A</td>
<td>• No ethical dilemmas</td>
<td>• Limited use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cloning issues</td>
<td>• Limited availability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pro-life ethical debate</td>
<td>• No evidence yet for creation of other cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hard to control</td>
<td></td>
</tr>
</tbody>
</table>

Mature and adult stem cells

11. Adult stem cells have the fewest ethical problems, as they can be obtained from adults who can give proper consent. These stem cells are not as versatile as ES cells, however this may prove advantageous as they may be easier to control owing to their defined function. Although these cells are already specialised stem cells, current research has shown they may have the potential to differentiate into other types of cells, showing more flexibility than first thought. So one may ask the question, why not just use multipotent stem cells? Whilst holding promise, these cells still have their limitations and research has yet to prove their ability to differentiate.

12. Adult stem cells are not currently available in large quantities and grow slowly, so it is not certain that it will be possible to create sufficient tissue for transplantation. In addition, with age, the numbers decrease and wear and tear increases. Another disadvantage is that these cells have not yet been found for all types of tissue, although research findings are increasing all the time. This makes them difficult to isolate and purify. Obtaining some types of stem cells (such as brain stem cells) from a patient would require major surgical procedures. With these limitations there may not be sufficient time to cultivate enough cells for treatment and expanding these cells in the laboratory has proved problematic.
13. Despite numerous limitations, these types of cells should not be ruled out as they have potential to produce one type of cell from another. If adult stem cell technology could be used, all the ethical problems arising from destructive use of embryos could be avoided.

**Umbilical cord blood**
14. This is the blood that remains in the umbilical cord after a baby is born. It is a substance, which, like bone marrow, is rich in stem cells and provides a readily available source of stem cells for transplantation in many situations where bone marrow might be considered. These cells are harvested after the baby is born and is a relatively uncontroversial source of stem cells. The cells are more useful than adult stem cells, being pluripotent.

**Tissue from aborted foetuses**
15. Another source of stem cells is from foetal material following abortion. Abortion is legal in the UK up to 24 weeks into pregnancy, by agreement of two doctors, who must certify that a woman's mental or physical health (or that of her child) is at greater risk if she continues with the pregnancy. In rare cases when the mother’s life is in danger, or foetal abnormalities are present, abortion may be allowed after this time. Cells are taken from the foetal tissue or organs of an aborted foetus, usually around the area destined to become the testes/ovaries. Cells obtained from the later foetus may be more limited in their application. Ethical issues arise from obtaining stem cells from aborted foetuses.

**IVF treatment**
16. The pluripotent stem cells, as already described, arise from the inner cell mass of a blastocyst and are the most useful stem cells, consequently these have more complex ethical issues attached. These blastocysts (containing ES stem cells) can be obtained from a number of sources. One such is from excess embryos following IVF treatment. During treatment oocytes (eggs) will be inseminated with sperm (outside the womb) to create embryos. Up to 3 of these will be planted into the womb of the woman receiving treatment. The remaining embryos may be frozen for future use. The embryos to be discarded may be used for research purposes. Surplus eggs may also be fertilised with sperm to create embryos specifically for research. The Human Fertilisation and Embryology Authority (HFEA) states that IVF embryos are not created for the purpose of research but for the end purpose of creating a child, however surplus embryos and eggs can be used for research, with informed consent. The statutory storage period for frozen embryos is 5 years, which can be increased in special circumstances. The parents are also allowed to specify the length of storage up to 5 years. These frozen embryos can also be used for research if consent is received.
Cloning

17. One of the most controversial areas of ES cell research is that of Somatic Cell Nuclear Transfer (SCNT), or non-reproductive cloning in humans. The nucleus (cell structure containing chromosomes) is removed from an egg. What are left are the nutrients in the cell. A somatic cell (any cell other than a sperm or egg cell) is placed next to this egg and the two fuse. The resulting fused cell is genetically identical to the donor of the genetic material and has the full potential to develop into an entire animal i.e. it is totipotent. The egg containing the transferred nucleus then develops outside of the body until it forms a blastocyst, the inner cells could be used to develop cell lines. The ES cells from the blastocyst can be induced to develop into all types of genetically identical cells found in the body of the donor (patient). The stem cells created from the patient’s somatic cell would overcome the problem of compatibility and rejection, and could be potentially transplanted to treat diseases and other medical conditions.

18. Two other methods worth noting where embryos would not need to be considered are Ooplasmic Transfer and Parthenogenesis (discussed later in paragraphs 51 & 52).

Medical applications & problems for stem cells

19. Applications for pluripotent ES cells are fairly extensive and can aid our understanding into human development. Areas for application include identifying factors involved in the cell decision making process that results in cell specialisation and providing new insight into diseases such as cancer. In addition, pluripotent ES cells could improve drug development and safety testing procedures. Research using stem cells has also found promising results in treating many diseases. Stem cells could be used to generate replacement cells and tissues to treat conditions such as Parkinson’s disease, Alzheimer’s disease, leukaemia, strokes, heart disease, diabetes, multiple sclerosis, rheumatoid arthritis, spinal cord injury and skin conditions, including burns. The suffering from these illnesses is acute and treatment using stem cells could be life changing, allowing those who are no longer able to lead a normal life some hope of recovery.

20. The treatment of diseased and damaged tissue would involve transplanting new cells or tissue of the type affected by the particular disease, such as cardiac cells in the case of heart disease, into the patient. Recent animal research has shown that stem cells injected into the heart were incorporated into the heart muscle and were found to beat in synchrony with the host heart. Examples include US scientists having reversed the symptoms of Parkinson's disease in rats using stem cells from mouse embryos and evidence that stem cells from adult human bone marrow have the potential to produce all the tissue types in the body, from blood to muscle to nerve.

21. This research however is still in its infancy and much is unknown about the exact process and reasons behind the differentiation of cells and methods of controlling the process of division. In order to provide effective treatment, the cell population transplanted into the patient requires being 100% pure of the cell type being treated, e.g. nerve cells. This is virtually impossible to achieve which has created problems when transplanted. If the cells have not differentiated into the required type of cell, the stem cells still present can grow into tumours through abnormal cell behaviour. Examples of animal research have shown ES cells unsuitability owing to the growth of tumours when ES cells were injected into mice. “Culture of embryonic stem cells affects their totipotency and may give rise to foetal abnormalities.” Other studies have shown the lack of achieving a single uniform
differentiation of cells. Most embryonic mouse stem cells have only achieved a purity of around 80%.

22. Another problem is that of rejection. If the cells are not derived from the patient, either through cloning (which has yet to be fully explored) or adult human stem cells (which have limitations in their own right), then the body may reject stem cells genetically different to its own, as with any other transplant procedure. As of April 2002, human ES cells had not been successfully used in clinical trials on patients, although current research may eventually prove otherwise.

Cloning and the differences between “therapeutic” and “reproductive” cloning
23. The difference between “therapeutic” cloning and “reproductive” cloning needs to be outlined. The cloning process is the same for both (see above), however the end result of the manufactured cells is where the difference lies. Therapeutic cloning uses the cloned embryo for the purpose of research. Reproductive cloning aims to create life by planting the cloned embryo into the female animal or human womb to grow, such as with Dolly the sheep.

Government views, legal and regulatory framework
24. As of March 2002 approximately 33 countries have formally banned human reproductive cloning. This represents 16% of all countries and less than one-third of the world's population.

UK
25. The Nuffield Council on Bioethics set up a working party to anticipate and respond to public concern about human ES cell research, by identifying and defining ethical questions raised following recent advances in biological and medical research. The Nuffield Council’s paper in 2000 examined the ethical issues raised by the potential of stem cells derived from donated embryos, embryos created specifically for research purposes, cadaveric foetal tissue and somatic cell nuclear transfer (SCNT). Their view is that the removal and cultivation of cells from donated embryos does not indicate a lack of respect for the embryo, and recommended that research be permitted for the purpose of developing tissues to treat diseases from derived embryonic stem cells. They took the view that donated embryos from IVF treatment were sufficient, thereby providing no compelling reasons to allow additional embryos to be created for research. This, however, ought to be kept under review. Consent has to be obtained from the donor for research and any subsequent use of the cell line.

26. The UK’s framework for human ES cell research and use is based on the Human Fertilisation and Embryology (HFE) Act 1990 (legislation permitting the creation and use of embryos outside the womb for the purpose of treating infertility), and The Human Fertilisation and Embryology Regulations, 2001(for research purposes). Under the HFE Act, it is a criminal offence to carry out any treatment using human embryos outside the body, to use donated gametes, to store any oocytes, sperm or embryos, or to undertake any research on human embryos without a licence granted by the Human Fertilisation and Embryology Authority (HFEA). The HFEA was set up in 1991 to ensure that high standards of medical research and care are met; it also licenses and monitors all human embryo research.

27. The establishment of ES cell lines is governed by the HFEA, which permits licensed research on human embryos up to 14 days of development. All embryos used for research are to be destroyed after 14 days. It is against the law to keep or use an embryo after the
appearance of the primitive streak (a thickening in surface of embryos) or after 14 days, whichever is earlier. It is also against the law to transfer embryos created by cloning into the uterus of a woman, mix human adult cells with live eggs of any animal species, replace the nucleus of a cell of an embryo with another nucleus taken from another person or embryo and altering the genetic structure of any cell while it forms part of an embryo and using embryos for any other purpose except under the terms of a license. Research involving cloning (cell nuclear replacement) is not prohibited under the 1990 act if it is for the purpose of research mentioned in the Act.

28. To grant a research licence, the HFEA must be satisfied that research is “necessary or desirable”. Also the use of embryos must be deemed essential. Embryo research is permitted under the HFE Act for any of five specified purposes. These are: (1) to promote advances in the treatment of infertility; (2) to increase knowledge about the cases of congenital disease; (3) to increase knowledge about the causes of miscarriage; (4) to develop more effective contraceptive techniques, and (5) to develop methods for detecting gene or chromosome abnormalities in pre-implantation embryos. These regulations were extended in 2001 for further purposes to: (1) increase knowledge about the development of embryos; (2) increase knowledge about serious disease; and (3) to enable such knowledge to be applied in developing treatments for serious disease.

29. However, once stem cells are extracted from the embryos, there is no legislation in the UK to regulate the research. Nor is there specific regulation in place that covers research derived from aborted foetuses or adult cells. Embryonic stem cells are not considered to be embryos and do not fall within the remit of the HFEA.

30. In February 2002, the HFEA approved two applications for clinics to carry out research on human embryos to produce stem cell lines - the first to be issued under the new HFE (Research Purposes) Regulations 2001. The licenses were granted to the Centre for Genome Research at Edinburgh University, and to Guy's Hospital in London, to develop techniques to handle embryonic material under strictly controlled conditions. The two clinics will produce only stem cell "lines" from "spare" embryos created by IVF. However, researchers eventually may clone human embryos.

31. Around 48,000 embryos which were no longer needed for IVF treatment, were used in research between August 1991 and March 1998 and 118 embryos were created in the course of research in the same period. There are currently four main stem cell research centres in the UK; Edinburgh, Cambridge, Sheffield and King’s College London.

USA
32. The US regime is much more conservative than that of its UK counterpart. President Bush has limited federal funding of stem cell research to those types of cell groups known as cell lines, of which approximately 65 exist. These were developed when human embryos were destroyed during the process of harvesting stem cells. Federal money will not be made available for developing new lines, and the creation of embryos for research purposes is prohibited. President Bush has urged further research into the feasibility of utilising adult stem cells to achieve the same therapeutic ends envisioned for ES cells.

33. This ban does not stretch to private foundations and corporations. However researchers argue that private funding will not match government funding. There is a general
view that the USA will suffer a “brain drain” as prominent scientists move to other countries where legislation allows new stem cell lines to be formed.

**European Union**

34. The EU will not fund research into cell lines developed from cloned embryos, or the creation of embryos specifically for research purposes. As of April 2002 the EU had financed fifteen research projects involving stem cells, for around 24m euros. This money goes to adult stem cells and cells from umbilical cord blood or aborted foetuses. It does not provide support for research using foetuses derived through IVF treatment. Currently, the EU policy on stem cell research extends only to the projects it finances. In April 2003, MEPs voted to ban research on stem cells taken from embryos across the European Union. MEPs will have to vote on the proposed new law again before it can come into effect. Otherwise, regulations are set by each member state and vary widely from Italy and Greece, which have no legislation on embryo research, to the UK, which allows research on human embryos. Embryo research is banned in Germany, where the horrible shadow of Nazi experiments on human beings still lingers. However in January the German government agreed to allow imports of embryonic stem cells for research under strict conditions. Denmark allows the creation of embryos for research, however this can only be carried out on embryos less than 14 days old.

35. However, laws in the EU may change. In April 2003, Members of the European Parliament voted for a European-wide ban on ES cell research, and MEPs will have to vote on the proposed new law again before it comes into effect.

**The Non-Governmental Organisations’ views**

36. The SRI Unit met with David King from Human Genetics Alert on 8th August, 2002. This non-governmental organisation (NGO) is concerned with the genetics of cloning human embryos. The organisation is not a religious or pro-life group but concerned with the ethical basis of British life. It sees the embryo as a morally significant entity and deserving of respect, not to be “used” lightly or trivially. It does not oppose research on embryos obtained from abortion or excess IVF treatment and supports a woman’s right to choose. In its view, if there were no alternatives to cloning embryos for research, then the arguments against stem cell research would be greatly diminished but adult stem cells are an option, as are obtaining foetuses from the aforementioned methods. The ethical argument is that once genetic engineering of human embryos for research purposes starts, human cloning will become inevitable. Therapeutic cloning should not be allowed until there is an international ban on reproductive cloning. The NGO has no ethical view on IVF treatment for infertility as the embryos created are for life, not research.

37. There are other NGOs concerned with genetics such as GeneWatch, with a remit more extensive, covering GMOs etc. GeneWatch does not take an anti-abortion position but is concerned that the UK’s very liberal policy on therapeutic cloning may fuel the desire to further reproductive cloning technology. Additionally, the NGO has concerns over the commercialisation of human life such as establishing a trade in human eggs which has the potential to harm poorer women, who may feel compelled to donate eggs for financial reasons. Should the medical case be proven, implications for global health inequalities in the trade and accessibility of ES cells, eggs and embryos are also a concern as it is likely that only the very rich would be able to afford treatments derived from this research. In common
with many others, the NGO believes there is an urgent need for an international ban on human reproductive cloning.

**Moral and ethical implications**

**Embryonic stem cell research**

38. The main ethical argument surrounding ES cell research is over the status of the embryo. The embryo is an amazing entity with the power to direct its own development and growth, albeit not always 100% successfully. This tiny cluster of cells has the power to create a complex biological being and the ability to distinguish each and every part of the body.

39. If one is of the view that life begins at conception, the moral implication for embryos is that they have an inherent right not to be killed or harmed in any way. ES cell research requires the extraction of the inner cell mass of the blastocyst, which destroys the embryo and is therefore not morally acceptable.

40. It has been argued that, in light of recent research on adult stem cells and those taken from post natal umbilical cord blood, there is no need to use embryos. There is also a belief that there is at least ten years of fundamental research and development needed before treatments and techniques, such as a cure for Parkinson’s, are clinically applied. Current hype surrounding non-reproductive cloning has led patients to believe that cures are just around the corner, and this may not necessarily be the case.

**Adult stem cells**

41. If adult stem cells can be manipulated effectively and to the same extent as ES cells, the problems of rejection would be overcome. The cells could be obtained directly from the patient and would therefore be genetically identical. This may, however, not be possible for all treatments. Using adult stem cells for research is not controversial.

**Abortion**

42. Abortion arguments once again focus on the status of the embryo. However aborted foetuses used in this form of research are not destroyed through the research process, or for the specific purpose of research. However, some argue that human life is sacred even after death and that performing research on dead foetuses shows little regard for their life and status. There would also be serious ethical dilemmas should the primary intention be to conceive and destroy human life to harvest the cells as a means to an end. However, if abortions are performed for legal and moral reasons, using the foetal tissue following the abortion could at least bring something good out of a sad event.

**IVF**

43. The ethical implications for the creation of embryos through IVF are the same as for abortion. However, as the procedure for creating embryos is an invasive one, there are implications surrounding the donor of the egg. Although IVF treatment will inevitably lead to surplus embryos, this surplus should decrease as treatment develops and technology improves. However, IVF clinics may realise that there is a profit to be made from making more embryos than is entirely necessary, especially if the mother is prepared to consent to donating leftover embryos for research. This may lead to unnecessary discomfort to the donor, who has to take high levels of hormones in order to “farm” her eggs. Research using
left over IVF embryos or eggs might therefore be linked to the exploitation of women. There is also a supply and demand issue. Eggs are hard to come by, therefore expensive, adding to the attractiveness in exploiting IVF treatment for monetary gain. Many hold the view that creating embryos as a means to an end (i.e. research) crosses ethical boundaries.

44. Those promoting ES cell research believe there is great potential to end the suffering of those living by the use of embryos that would otherwise be destroyed. As embryos can divide for at least 14 days after conception (around the time the primitive streak appears) to form twins, or even fuse, many argue that life does not truly begin before this point. This is also around the time the primitive streak first appears.

Cloning

45. As already discussed, there are two types of cloning, therapeutic and reproductive. Therapeutic cloning has two ethical considerations. First, that cloning itself is often considered morally unacceptable; secondly (as for ES cell research) the research requires destruction of the embryo through the extraction of cells. There is also a problem with terminology such as “therapeutic cloning”, as this term silences legitimate concerns about ethical and social issues. Another term “cell nuclear replacement” avoids the use of the word cloning which most people associate with this technology, giving the subject an air, rightly or wrongly, of a legitimate, ethically free therapy.

46. The attractiveness behind cloning is that it would eliminate the risk of rejection if tissue and even organs could be grown with an identical genetic make up to the patient. However, the idea of cloning embryos in order to extract tissues for transplantation is extremely controversial, fearing it is a step towards cloned or so called “designer babies” and representing a moral degradation of human life. Many, including scientists, argue that the process of cloning turns the human persona into a commodity. Some even argue that a cloned embryo is “not real” because it is not fertilised. Cloning is still very much in its infancy. Much is unknown and medical science is experiencing problems such as animals produced by cloning having abnormalities or dying very shortly after birth. It took 277 attempts just to create Dolly the sheep. She was put to sleep at the early age of six and a half years old, following problems with arthritis and a progressive lung disease. Even the Roslin Institute, which cloned Dolly, has urged scientists not to attempt human cloning owing to massive problems encountered with animal cloning.

47. Another problem is doubt as to the suitability of ES cells for transplantation from cloned cells, owing to their genetic instability. Most cloned animals die before birth and of those born, less than half survive for 3 weeks. Success rates may be as low as 3 to 4%. Cloning is also an inefficient process requiring many eggs just to clone one embryo (an example from China’s Ziangya Medical College claimed that about 5% of cloned embryos develop into blastocysts).

48. However, the main ethical issue arises if therapeutic cloning is perfected in the UK, where it is legal. This technology may be utilised elsewhere in the world for human reproductive cloning (illegal in the UK). There are already organisations who are willing to make use of any technology discovered, such as Clonaid, founded by the Raelian movement, a scientific religious cult whose aim is to be the first to clone a human, believing humans were created by extraterrestrials through cloning. They are offering services to those who wish to have a child, pet or even themselves cloned. They are also offering $5,000 to buy
eggs, leading potentially to the exploitation of women. Since
the first edition of this report, the Raelian movement has
announced, although proof remains elusive, that it has been
successful in producing half a dozen or so cloned babies, the
first being “Eve” in Florida. Many view “playing God” by
genetically designing babies according to the latest fashion or
style in human make-up, could prove irreversibly disastrous.

49. Recent findings suggest however that cloning primates
(which includes humans) may currently be impossible, as
primate cells do not divide properly owing to the
chromosomes being too abnormal for a pregnancy to begin.
Findings by the University of Pittsburgh, reported in the
journal Science, found that from the very start, the cloned
primate cells did not divide properly. Attempting to clone a
rhesus monkey, 724 eggs were used, yielding only 33 embryos and not a single pregnancy.12

50. Some Scientists argue that procedures to clone a human being are well known in
scientific literature and therapeutic cloning would not significantly increase the likelihood of
human reproductive cloning success. Some say the only method needed to prevent
reproductive cloning would be to introduce a law to ban it. However many countries have no
laws governing either therapeutic or reproductive cloning.

Cloning: An ethical solution?
51. There may be an ethical solution to cloning. The New Scientist has reported13 that
companies in the US and Britain have been working on ways to harvest human ES cells
without destroying viable embryos. This is done via Parthenogenesis, also known as “virgin
birth”. The process aims to trick human eggs into believing they have been fertilised, without
the addition of any genetic material from a sperm cell. By using chemicals and electric
shocks, eggs begin to grow like embryos from which stem cells can be isolated. As these
cells only contain one set of maternal chromosomes, the cells are prevented from becoming a
normal foetus, thus preventing life from being created from parthenogenesis.

52. Another method, ooplasmic transfer, which may yield human ES cells without using
viable embryos is the transfer of cytoplasm from an egg (oocytes) into an ordinary adult cell
taken from a patient. The egg cytoplasm seems to turn the specialised adult cell back into an
undifferentiated state or primitive stem cell. This method has been used to create children in
the USA, where cytoplasm from a normal donor egg is injected into the infertile egg of a
mother which is then fertilised using IVF by the father’s sperm.14 Another company using
ooplasmic transfer reported that cow eggs differentiated into cells that looked like ES cells
and by adding certain growth factors could turn them into beating heart cells. This was
reported in the press (not a scientific journal where work is reviewed by peers) and added
value to the company’s share price instantly. As at January this year, there had been no
scientific publication of their findings.15 In the race to be at the forefront of this technology,
companies have rushed out information through press releases or esoteric publications that
have less stringent criteria than do scientific journals subject to peer review, leaving some
doubt as to how advanced this research actually is.
The Christian view

53. A basic belief of the Christian church is in the sanctity of human life. The question of the status of the human embryo is related to the mystery of creation. So many of the Christian views and arguments surrounding ES cell research will be the same as that for abortion, as the life of an embryo and foetus are the main ethical focal point surrounding human ES cell research. However, the newer and possibly more controversial side to this debate is that of cloning, and what the consequences would be if the process of cloning is perfected.

Cloning

54. The Right Rev Michael Marshall, Assistant Bishop of London’s article in The Church of England Newspaper in August 2002 discussed how 30 years ago, Dr Bronowski, in his television series, The Ascent of Man, showed that evolution is founded in variety and creates diversity. Of all animals, man is the most creative, as he expresses the largest store of variety. Every attempt to make man uniform, biologically, emotionally or intellectually, is a betrayal of the evolutionary thrust that has put man at the head of this evolutionary scale. Difference and diversity in human make-up are possibly what keep us healthy, as well as essentially human. Centuries ago, the Table of Affinity proscribed inbreeding, and therefore lack of diversity, as the cause of terrible distortions, physical, biological and psychological.

55. John Habgood, former Archbishop of York, stated that “to treat the genetic core of a person as a manipulable object, is to compromise individual otherness at its very root”.

56. There would be little doubt that many Christians find the process of “playing God” disturbing, believing that God created the earth in a balanced and purposeful way. By manipulating animals and humans via genetic engineering, the human race could upset God’s creation. Are we the masters or stewards of creation? In addition, hand in hand with marriage is God’s gift of sex, which was given to us to create life. Some Christian faiths argue that creating life outside of this is against the will of God. With this in mind, some Christian groups, such as Catholics, feel strongly about the moral implication of IVF “on the grounds that to separate the marital act from the begetting of a child is an unlawful violation of a divinely established single act of procreation”\(^{16}\). However, IVF is also seen as the process by which a woman who has difficulty in conceiving has the chance to experience the joy of having her own baby.

57. God knows us by our fruits as Matthew 7: 16-17 says “Do men gather grapes of thorns, or figs of thistles? Even so every good tree bringeth forth good fruit; but a corrupt tree bringeth forth evil fruit.”

58. As the Bishop of Rochester very aptly put it “once the genie is out of the bottle, it will be impossible to restrict the technique to those experiencing infertility problems”.\(^{17}\) The Bishop is against human cloning, seeing it as potentially creating a child simply as a means to someone else’s end, rather than as an end in himself or herself. Paul in Romans 3: 8 damned those who do evil so that good may come.

Status of the embryo

59. Professor Gilbert Meilaender of Valparaiso University in his testimony on stem cell research before the USA’s National Bioethics Advisory Committee, puts stem cell research into perspective. He says, “The embryo is, I believe, the weakest and least advantaged of our
fellow human beings, and no community is really strong if it will not carry its weakest members.” Against the background of such a question, we reflect upon the significance of stem cell research as it relates to caring for the weakest members of the body of Christ, the human embryo.

60. For Christians who believe that the embryo, regardless of its stage of development, is a human being, body and rational soul, any research that results in its death is forbidden because it results in murdering a human being that is created in the image of God. “My frame was not hidden from you when I was made in the secret place. When I was woven together in the depths of the earth, your eyes saw my unformed body” Psalm 139: 15-16. God commanded “Thou shalt not murder”. This is not based on pious opinion but the very word of God who gives us technology to sustain and care for human life, not to kill it as a means to an end. God created all “that is seen, and unseen”. One might also consider the question whether even those embryos destined for destruction (IVF embryos) should be spared experimentation. Quantifying the difference between allowing someone to die and exploiting their bodies for commercial purposes through their demise, provides much food for thought.

61. Another view to which many Christian schools have subscribed is the philosophic tradition which relates the “ensoulment” of the growing embryo to its development, the more the body develops the more the soul comes into existence. This view is endorsed by many leading figures in the Church of England, such as the Bishop of Oxford. In fact, this is not a new concept but one believed by the Bishop to be a Western tradition until the 19th Century. St Gregory of Nyssa (c. 330 – c. 395) maintained “so long as it is in this unformed state, it is something other than a human being”. The developmental argument can be supported in Exodus 21: 22, where a man is commanded to pay a financial penalty if a fight between two men results in a pregnant woman losing her child in the early stages of pregnancy but receives the penalty of death if the child is lost during the later stages. St Augustine also held the view that homicide would not apply in the loss of an unformed “sort of living, shapeless thing”. The embryo however is a gift from God and therefore does have a special status, needing to be protected by law, even if that status is not absolute at the initial stages of conception.

62. Many view the 14-day mark of an embryo, or the appearance of the primitive streak (whichever comes first), as a key stage in human development and also in ensoulment. This is seen as particularly relevant as before this point, an embryo has the ability to divide into twins, creating two individuals and therefore two souls.

63. Despite the disagreement surrounding the humanity of the embryo within the Church, the embryo is recognised as a significant entity and has the potential to become a fully-grown and living body.

The Church of England and Board for Social Responsibility
64. The Church of England’s Synod stated in 1983 “All human life, including life developing in the womb, is created by God in his own image and is, therefore, to be nurtured, supported and protected”. The BSR sees abortion, “the termination of life by the act of man, as a great moral evil”, however the moral legitimacy of abortion under some circumstances is recognised, such as if carrying the baby may put the life of the mother in danger. The Church believes the demand for abortions is unacceptably high and urges that abortion should be carried out as early in the pregnancy as possible and only after serious
moral reflection. Its view on late terminations (after 24 weeks) of handicapped foetuses is that they should only be given if the baby is likely to die from its deformities soon after birth.

65. With regard to embryology, the Church of England sees children as a gift from God. The welfare of any child created by third party donation of eggs or sperm is of overriding importance, including the need of the child for a father, affirming marriage as the ideal context of procreation and raising children. Women should only be given treatment within their normal childbearing years.

66. The Church of England and BSR recognise the spectrum of views, however the BSR has stated that any proposals for using embryos for research must be deemed absolutely necessary and ideally only take place once all other avenues have been explored. It is still hard to define however whether using embryos is “absolutely necessary”, as the potential of human adult stem cells has not been fully explored. Wanton creation of human embryos should not be permitted.

The House of Lords Select Committee

67. The Bishop of Oxford asked the Government, during the debate in the House of Lords, whether it would refuse to authorise research on ES cells if it was found that adult stem cells were as effective? As Chairman of the House of Lords Select Committee (established in January 2001 and reported on 27 February 2002) on this subject, the Bishop outlined two overriding issues in the committee’s report, the relative potential of stem cells derived from adults compared with those taken from early embryos and the moral status of the early embryo. The committee concluded that, in the first instance, it was essential to carry out research using ES cells, as well as adult stem cells. Some scientists focused entirely on working with adult stem cells supported this, as research in embryonic stem cells will play a key role in realising the potential of adult stem cells. The report strongly supports work on adult stem cells and urged more money be put into this kind of research. With regard to the second issue in the report, the committee recognised the differing views surrounding the moral status of the early embryo, however it took the view that there are morally weighty reasons for doing research that may lead to therapies for many serious and common diseases. With this in mind, the committee viewed it wrong to put a stop to all research on embryos at this stage. The Bishop supported one of the two amendments before the House of Lords, believing research should only be done on ES cells if absolutely necessary, and that it cannot be done any other way, asking the Government to reconsider the regulation if a Select Committee concluded that research on stem cells derived from embryos is not strictly necessary.

Conclusion

68. In conclusion, the three areas of human stem cell research that are the main focus for consideration by the EIAG are the use of (1) aborted foetuses; (2) excess IVF embryos and (3) the creation of cloned embryos to obtain stem cells for research purposes (therapeutic cloning). Much of this will mirror past debates the Church of England has already had over the sanctity of human life and the ensoulment of the unborn foetus. With regard to the use of adult stem cells, there are no major ethical issues that need to be considered, other than the usual ones, such as the care of the patient during treatment.

69. The most contentious of these areas is probably cloning. As with IVF embryos, the usual concerns about creating embryos as a means to an end (i.e. research) in therapeutic
cloning exist. However another unique concern exists. Allowing the advancement of therapeutic cloning technology for research will undoubtedly lead to attempts to clone a human being by organisations intent on this. This is an issue that leaves many, including scientists, with a sense that using knowledge of therapeutic cloning technology to “play God” is moving outside most recognised ethical boundaries.

70. The EIAG hopes that, following the process of consultation and engagement, and the Synod debate on embryo research scheduled to take place in July 2003, an investment policy that represents the main values and beliefs of the Church of England may be formulated. The group would welcome any further feedback from the wider Church and stakeholders. Thoughts and comments may be sent to the SRI Unit at CCLA Investment Management, detailed below.

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<table>
<thead>
<tr>
<th>Word</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Blastocyst</td>
<td>Ball of cells formed 4 days after conception, with an outer layer of cells that will make up tissues required for foetal development and an inner cell mass which is the embryo proper</td>
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<tr>
<td>Cloning</td>
<td>This is the creation of multiple copies of a single molecule, cell or virus</td>
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<td>Cytoplasm</td>
<td>Protoplasmic (translucent colourless substance) content of the cell other than the nucleus</td>
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<tr>
<td>Embryo</td>
<td>The developing baby from conception to about the end of the second month. After that point, the baby is called a foetus</td>
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<td>Foetus</td>
<td>The baby from the end of the eighth week until birth</td>
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<tr>
<td>Gametes</td>
<td>Specialised cells used in reproduction, in a male these are sperm and in a female, oocytes</td>
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<td>Germ Cells</td>
<td>Cells comprising actual reproductive components of an organism</td>
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<td>Immortal cell</td>
<td>A cell that can be grown continuously in laboratory culture</td>
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<td>IVF</td>
<td>In Vitro Fertilisation</td>
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<td>Multipotent stem cells</td>
<td>Found in children and adults these cells can be multiplied and maintained in culture but do not have an unlimited capacity for renewal, can be derived from foetuses and are present throughout life but in progressively decreasing numbers in adults</td>
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<tr>
<td>Nuclear transfer</td>
<td>Cloning</td>
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<td>Oocytes</td>
<td>A developing egg cell</td>
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<td>Ooplasmic transfer</td>
<td>An artificial reproductive technique combining the eggs of two different women, one egg with the nucleus, injected with the cytoplasm of another egg</td>
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<td>Parthenogenesis</td>
<td>A form of reproduction in which the ovum develops into a new individual without fertilisation</td>
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<td>Pluripotent stem cells</td>
<td>These cells are found in embryos and have the potential to give rise to any cells of an adult animal with a particular function, such as blood stem cells, skin cells; these cells can not form an embryo</td>
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<td>Primitive streak</td>
<td>Thickening in surface of embryos resulting in the first recognisable stage in embryonic development</td>
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<td>Recombinant protein</td>
<td>A protein with a non-parental combination of genes from the processes of genetic recombination</td>
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<tr>
<td>Reproductive cloning</td>
<td>Cloning an embryo to be implanted into a womb with the intention of creating a fully-grown human being</td>
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<tr>
<td>Stem cells</td>
<td>Cells that are able to divide for an indefinite period in culture to give rise to specialised cells</td>
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<tr>
<td>Stem cell line</td>
<td>Created when stem cells, properly nurtured, are able to replicate or divide, theoretically forever, creating what is called a stem cell line</td>
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<tr>
<td>Somatic cell</td>
<td>Any cell other than egg/sperm cell eg skin, heart, nerve</td>
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<td>Somatic cell nuclear transfer</td>
<td>SCNT aims to create stem cells for advancing medical research into intractable and often deadly human diseases. It involves removing the nucleus of an unfertilized egg cell, replacing it with the material from the nucleus of a “somatic cell” (a skin, heart, or nerve cell, for example), and stimulating this cell to begin dividing</td>
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<tr>
<td>Therapeutic cloning</td>
<td>Cloning an embryo for medical research, not for implanting into a womb</td>
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<td>Totipotent cells</td>
<td>These cells have unlimited capabilities and can differentiate into every kind of cell line found in a developing embryo, and hence could develop into an embryo. From conception to approximately 4 days old, until blastocyst begins to form</td>
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